109. The sensor system of claim 106, wherein the information tag comprises a memory.

110. The sensor system of claim 109, wherein the information tag transmits information using at least one connection selected from the group consisting of a serial connection, a radio frequency connection, an acoustic frequency connection, an infrared frequency connection, and a magnetic induction connection.

111. The sensor assembly of claim 106, wherein the sensor information is embedded within the electronics unit.

112. The sensor assembly of claim 95, further comprising packaging configured to contain the sensor assembly during transport, wherein the information tag is provided in or on the packaging.

113. The sensor assembly of claim 112, further comprising a receiver, wherein the receiver is configured to read the sensor information from the information tag.

114. The sensor assembly of claim 95, wherein the sensor information comprises information configured to trigger initialization of the sensor.

115. A transcutaneous glucose sensor system, the sensor system comprising:

a mounting unit adapted for mounting on a skin of a host;

a sensor configured to measure an analyte concentration in the host;

sensor electronics operably connected to the sensor, wherein the sensor is configured to provide data representative of an analyte concentration in the host;

a receiver remote from the mounting unit and configured to receive sensor data from the electronics unit representative of a measured analyte concentration; and

an information tag configured to provide sensor information selected from the group consisting of manufacturing information, calibration information, identification information, expiration information, sensor duration information, archived data, license code information, and combinations thereof.

116. The sensor system of claim 115, wherein the receiver is configured to read sensor information from the information tag.

117. The sensor system of claim 116, wherein the electronics unit is configured to releasably mate with the mounting unit, and wherein the electronics unit is operably connected to the sensor when the electronics unit is mated to the mounting unit.

118. A device configured for placement on a skin surface of a host, the device comprising:

a sensor configured for transcutaneous insertion into a host and operatively connected to sensor electronics for processing data obtained from the sensor; and

a housing adapted for placement on a skin surface of the host and coupled to the sensor electronics, wherein at least one of the housing and the sensor electronics comprises a user interface configured to communicate information responsive to processed sensor data.

119. The device of claim 118, wherein the user interface comprises a screen configured to display at least one numerical value.

120. The device of claim 118, wherein the user interface comprises a screen configured to display trend information.

121. The device of claim 118, wherein the user interface comprises a screen configured to display graphical information.

122. The device of claim 118, wherein the user interface is configured to communicate information audibly.

123. The device of claim 118, wherein the user interface is configured to communicate information tactilely.

124. The device of claim 118, wherein the user interface is configured to provide information to the host in response to activation of a button.

125. The device of claim 118, wherein the sensor electronics are configured to alert the host when the sensor data is outside a predetermined boundary.

126. The device of claim 118, wherein the sensor electronics are configured to filter the sensor data.

127. The device of claim 118, wherein the sensor electronics are configured to calibrate the sensor data.

128. The device of claim 118, further comprising a receiver, wherein the receiver is configured to communicate with the sensor electronics.

129. The device of claim 128, wherein the receiver is configured to request information from the sensor electronics.

130. The device of claim 128, wherein the sensor electronics are configured to transmit sensor data responsive to a request by the receiver.

131. The device of claim 128, wherein the receiver and the sensor electronics are operatively connected by at least one connection selected from the group consisting of a cable, a radio frequency connection, an optical connection, an inductive coupling connection, an infrared connection, and a microwave connection.

132. The device of claim 118, wherein the sensor electronics are releasably attachable to the housing.

133. A transcutaneous glucose sensing device, the device comprising:

a glucose sensor configured for transcutaneous insertion through a skin of a host; and

an on-skin housing coupled to the sensor, wherein the on-skin housing is adhered to the skin, and wherein the on-skin housing comprises sensor electronics configured to process sensor data and to provide sensor data to the host via a user interface.

134. The transcutaneous glucose sensing device of claim 133, wherein the user interface is configured to provide sensor data by at least method selected from the group consisting of visually, audibly, and tactilely.

135. The transcutaneous glucose sensing device of claim 133, wherein the user interface is housed on or in the on-skin housing.

136. The transcutaneous glucose sensing device of claim 133, wherein the user interface is operatively connected to the on-skin housing via at least one wire.

137. The transcutaneous glucose sensing device of claim 136, wherein the user interface is configured to be worn on the host at a location remote from the on-skin housing.

138. The transcutaneous glucose sensing device of claim 133, wherein the user interface is configured to be worn on clothing of the host, and wherein the on-skin housing in configured to be worn on the skin of the host.

139. The transcutaneous glucose sensing device of claim 138, wherein the user interface is directly wired to the on-skin housing.

140. The transcutaneous glucose sensing device of claim 133, wherein the sensor electronics are releasably attachable to the on-skin housing.

141. A transcutaneous glucose sensor system, the system comprising:

a glucose sensor configured for transcutaneous insertion through skin of a host;

an on-skin device coupled to the sensor and comprising electronics configured to process data obtained from the sensor; and

a receiver remote from the on-skin device configured to request information from the on-skin device.

142. The system of claim 141, wherein the on-skin device is configured to provide sensor information indicative of a glucose value of the host by at least one method selected from the group consisting of visual, audible, and tactile.

143. The system of claim 141, wherein the on-skin device is configured to provide filtered sensor data by at least one method selected from the group consisting of visual, audible, and tactile.

144. The system of claim 141, wherein the on-skin device is configured to provide calibrated sensor data by at least one method selected from the group consisting of visual, audible, and tactile.

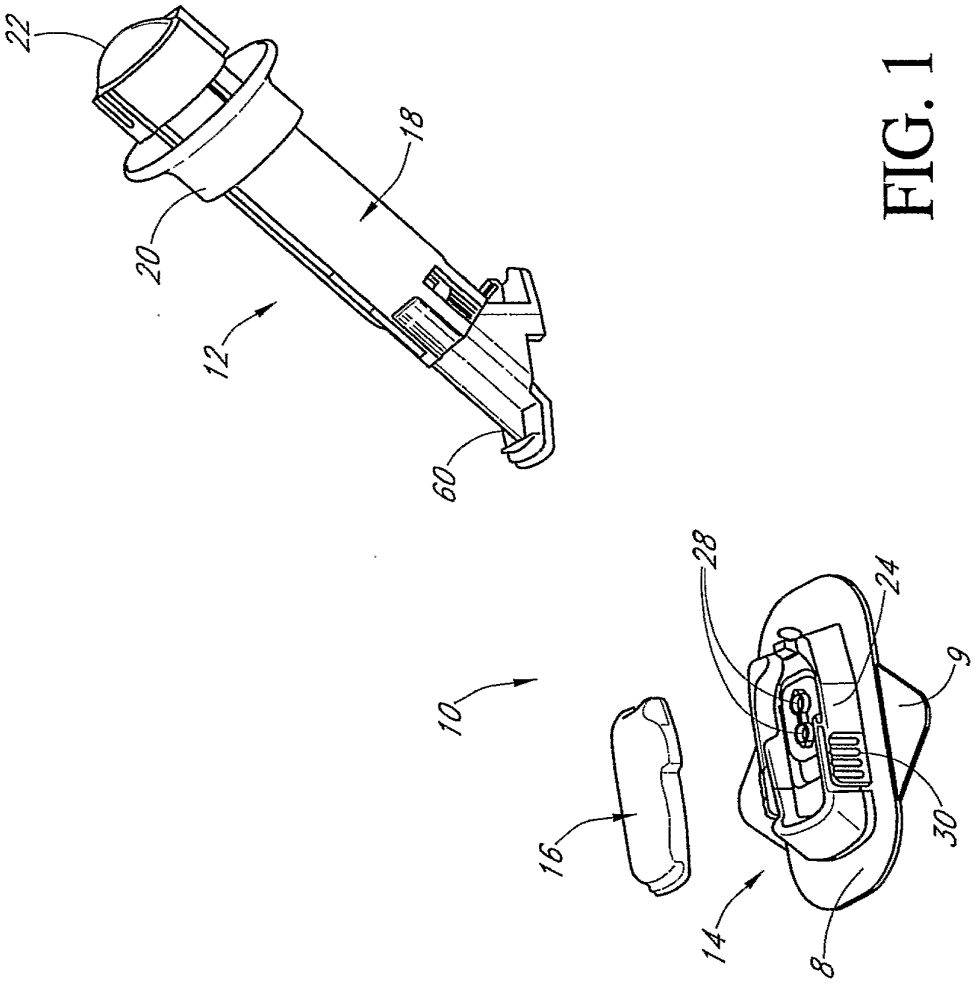


FIG. 1

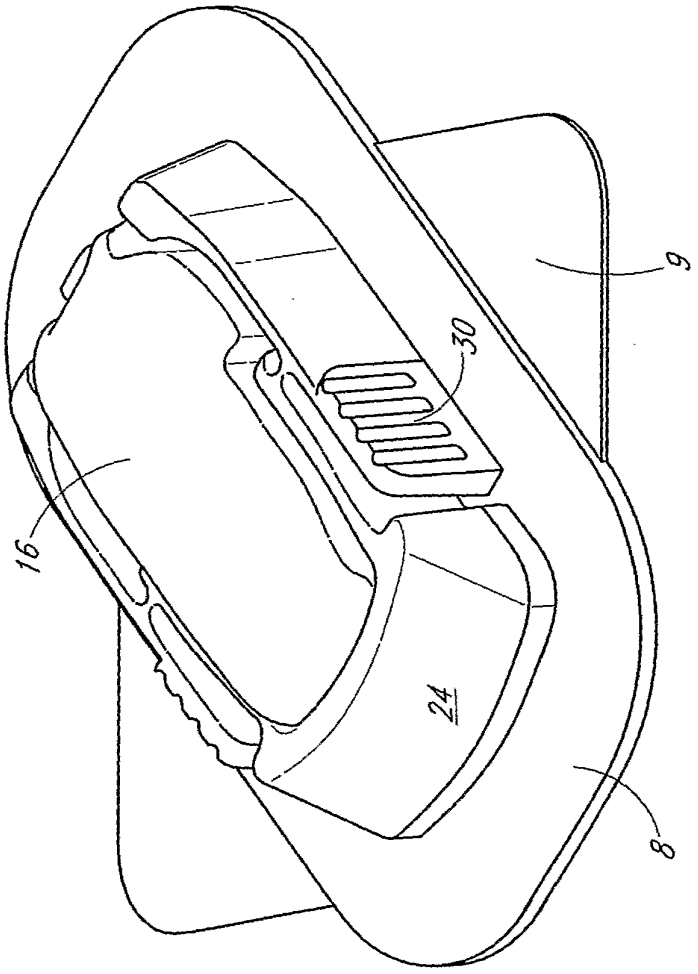


FIG. 2

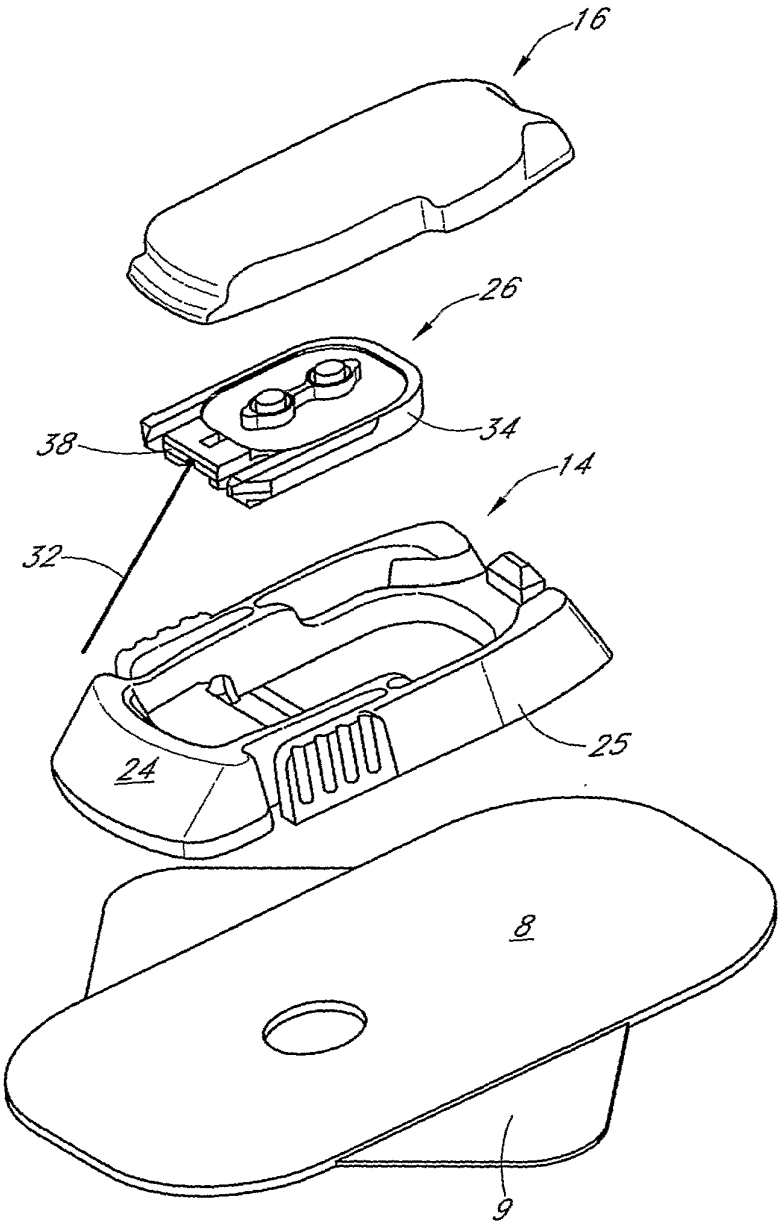


FIG. 3

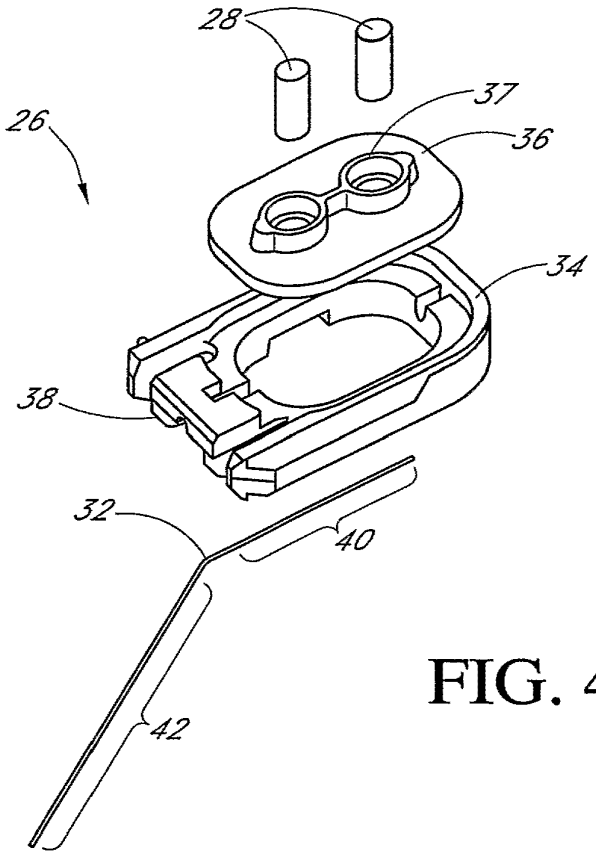


FIG. 4A

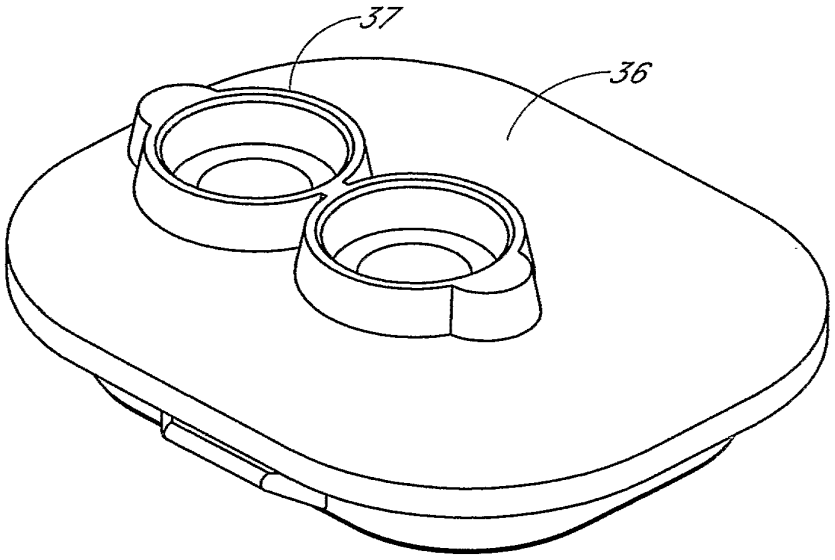


FIG. 4B

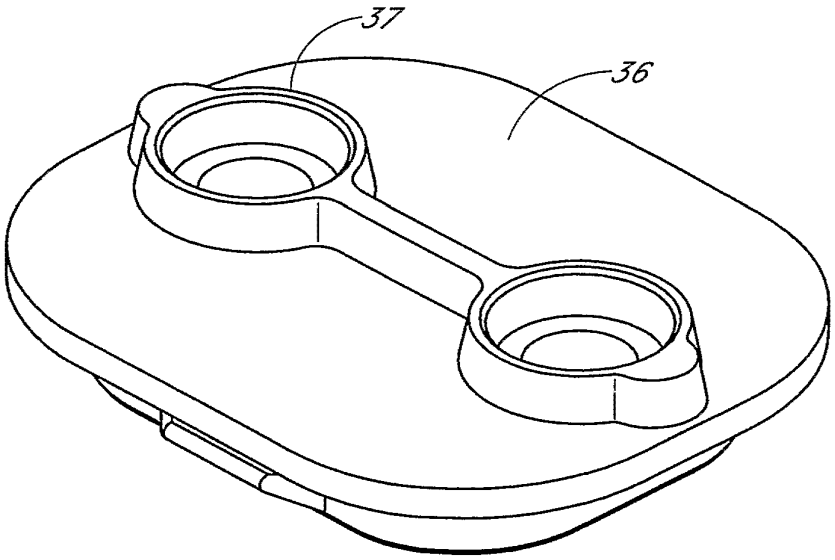


FIG. 4C

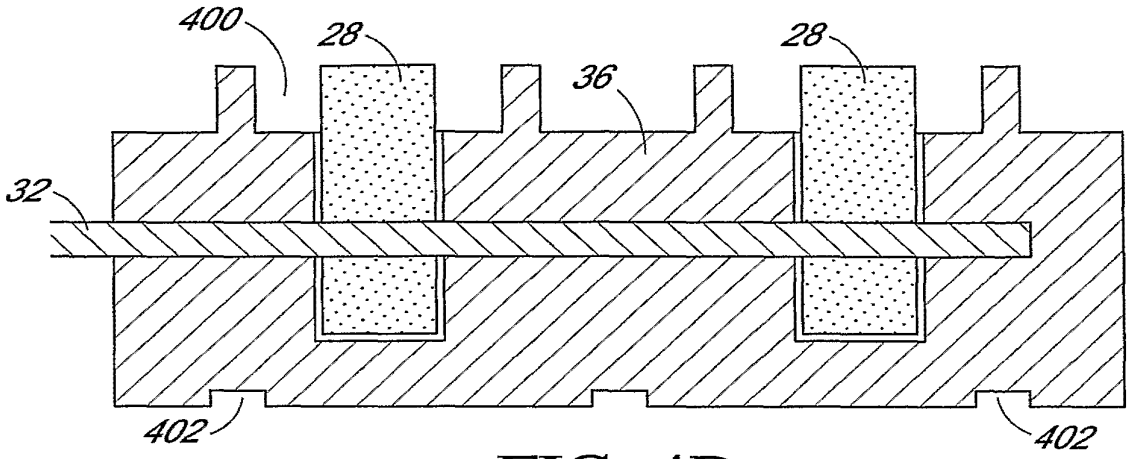


FIG. 4D

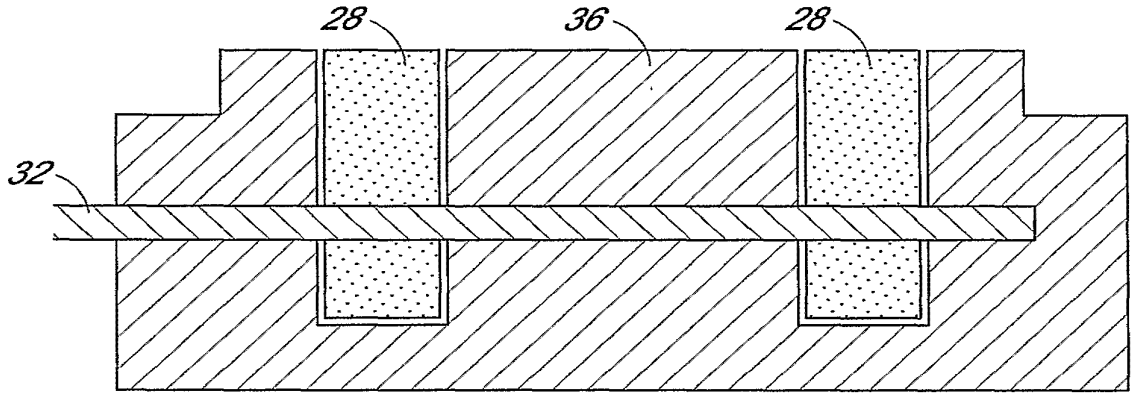


FIG. 4E

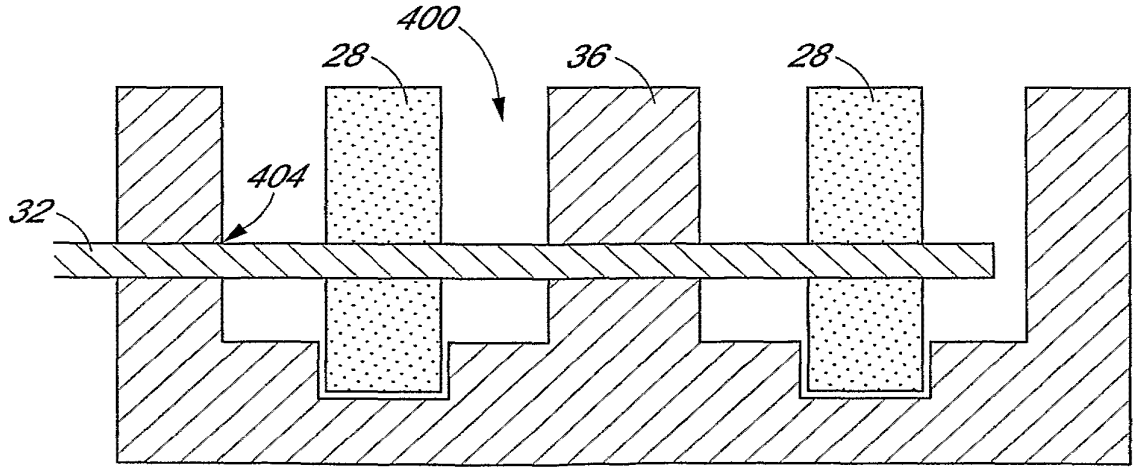


FIG. 4F

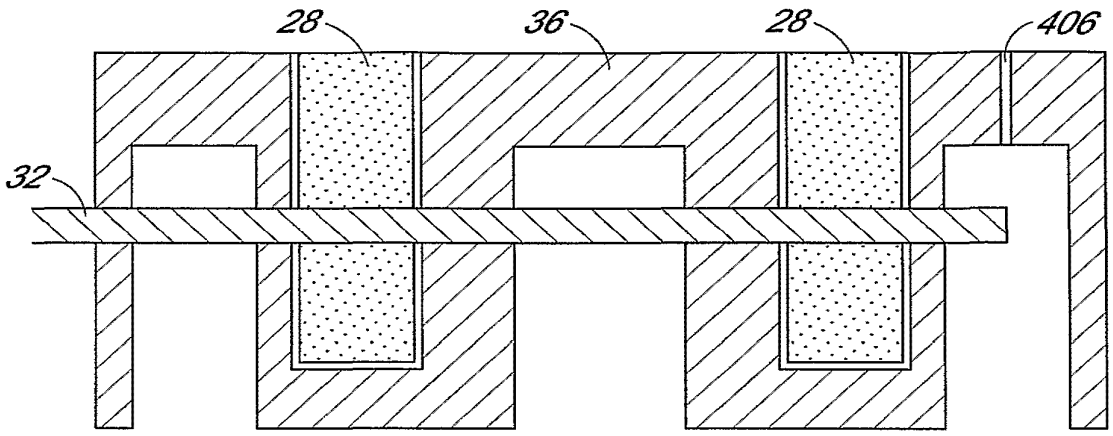


FIG. 4G

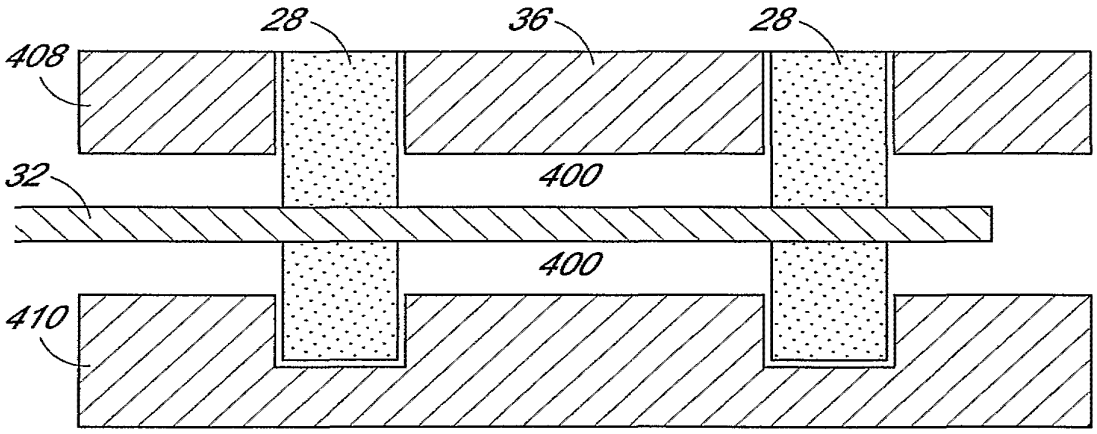


FIG. 4H

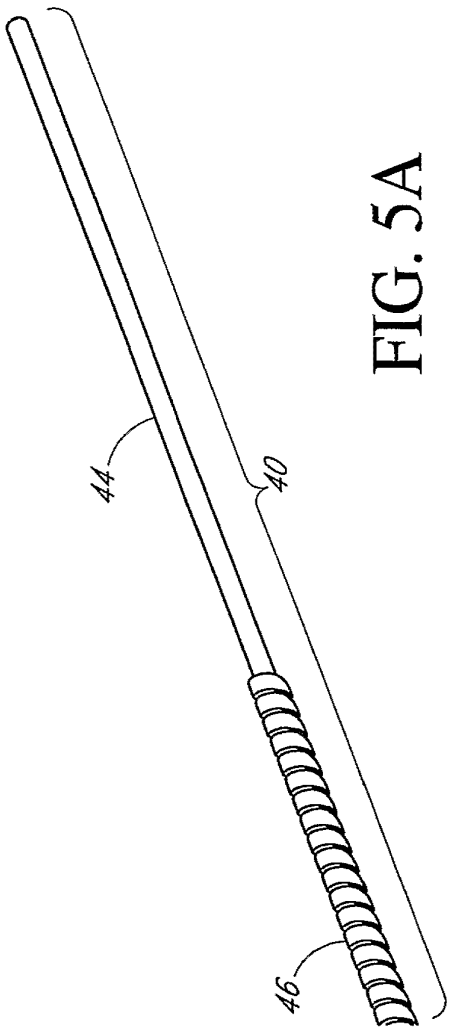


FIG. 5A

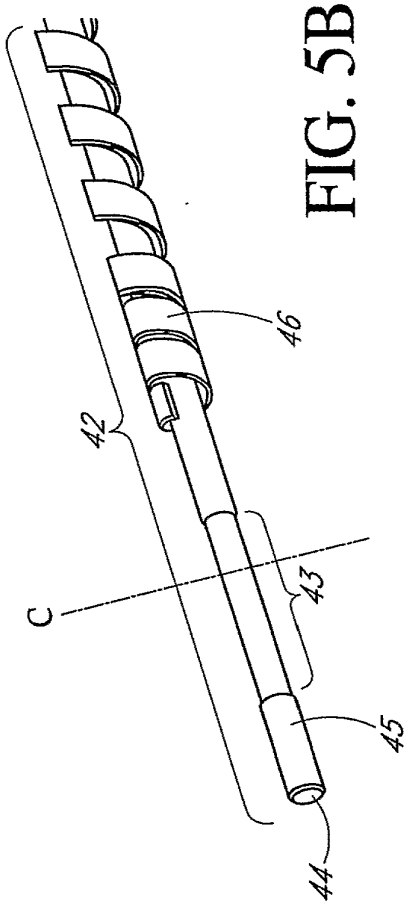


FIG. 5B

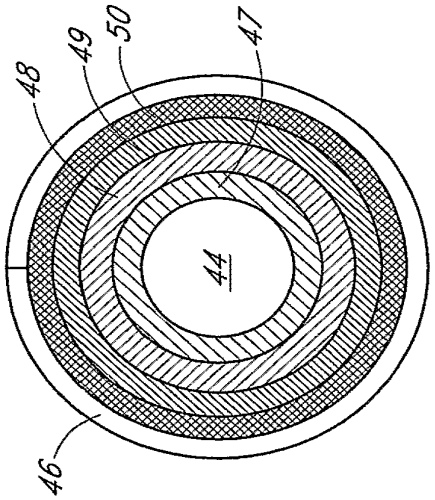


FIG. 5C

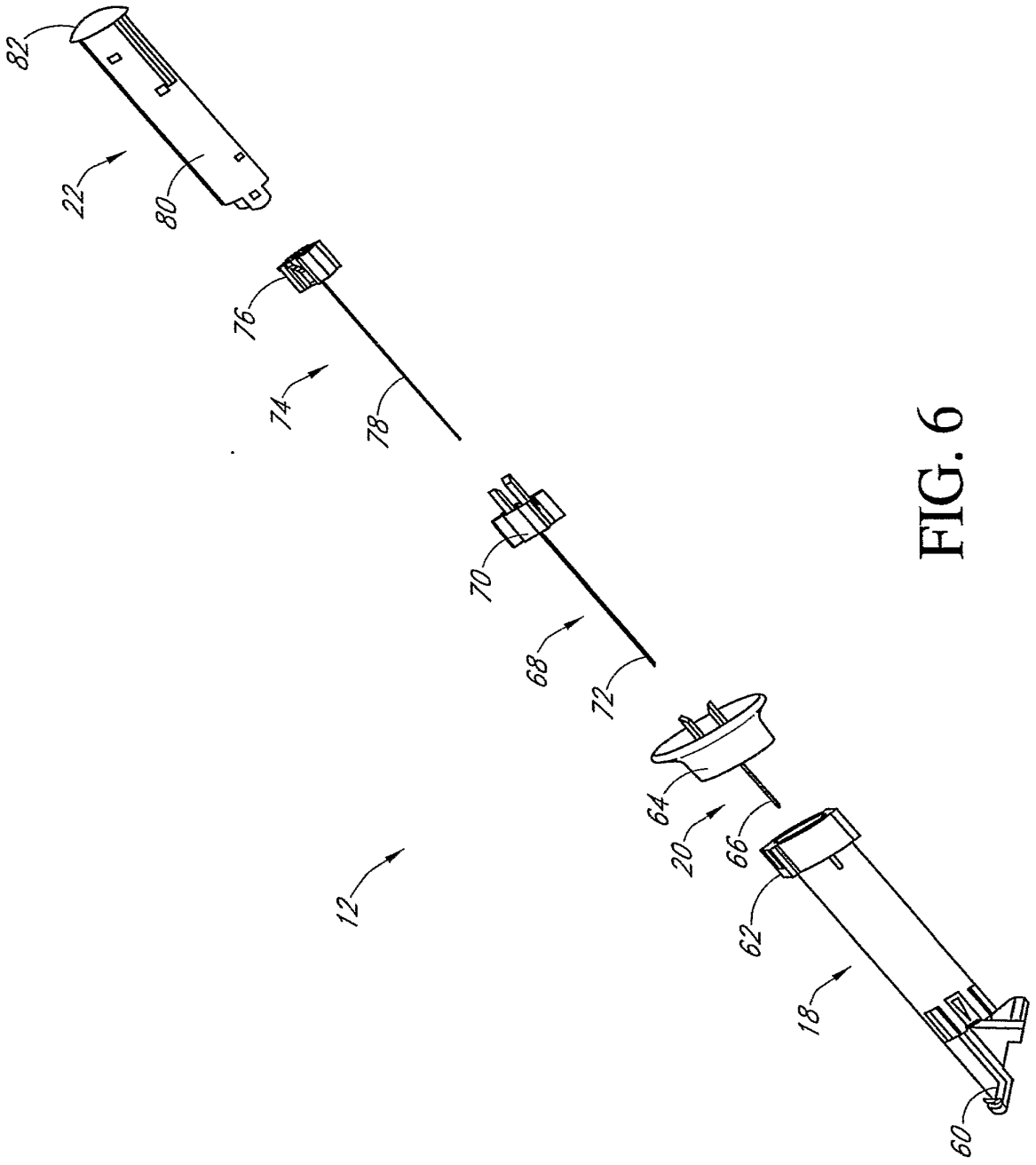


FIG. 6

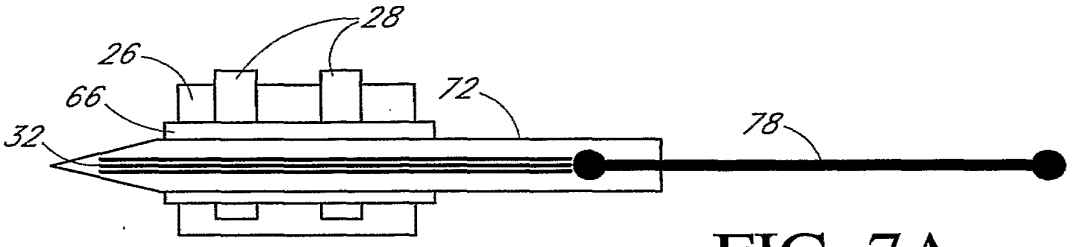


FIG. 7A

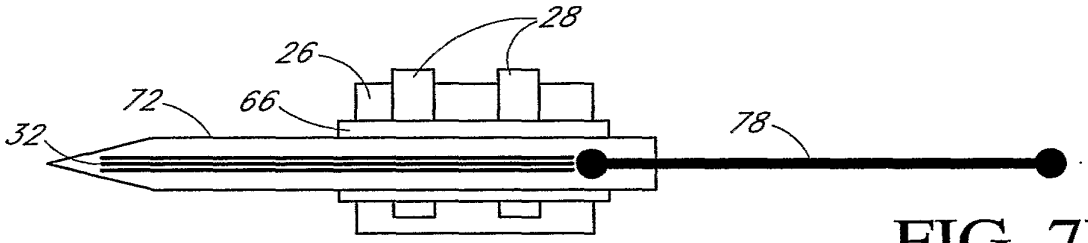


FIG. 7B

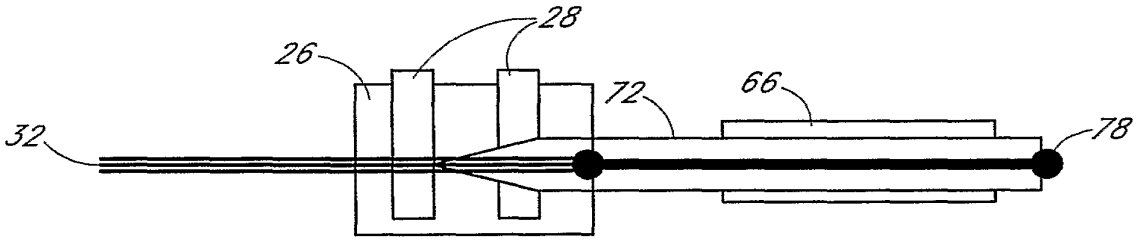


FIG. 7C

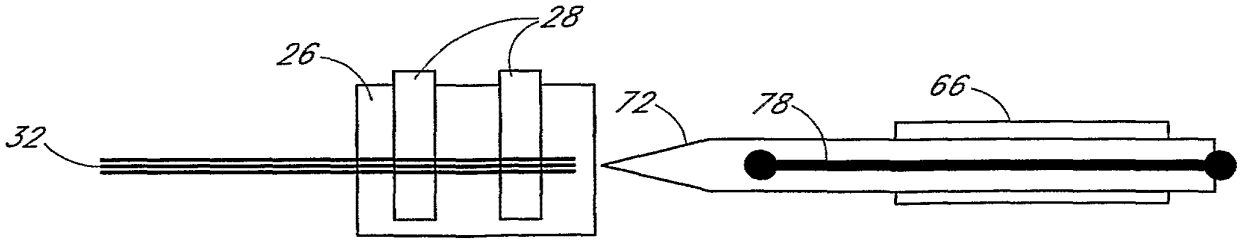


FIG. 7D

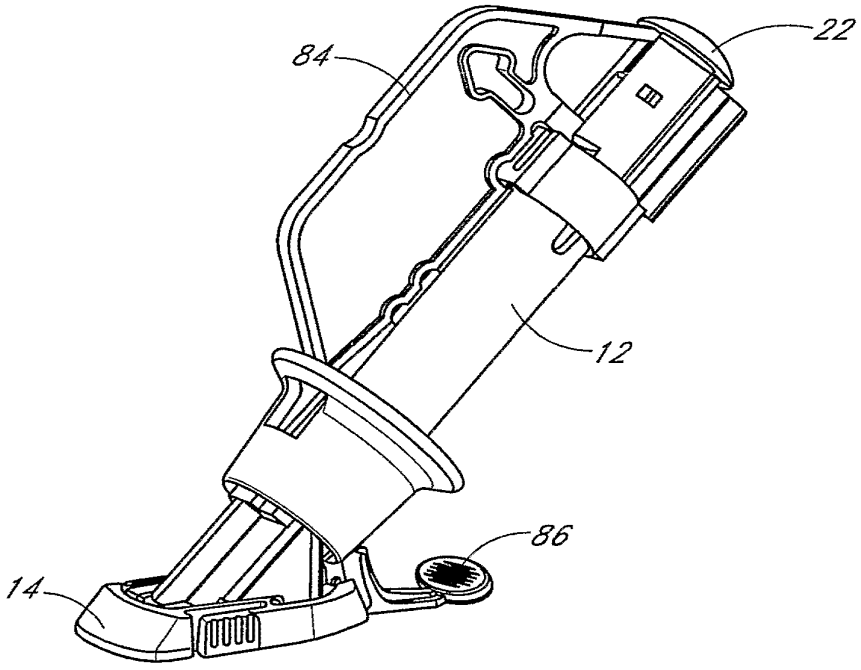


FIG. 8A

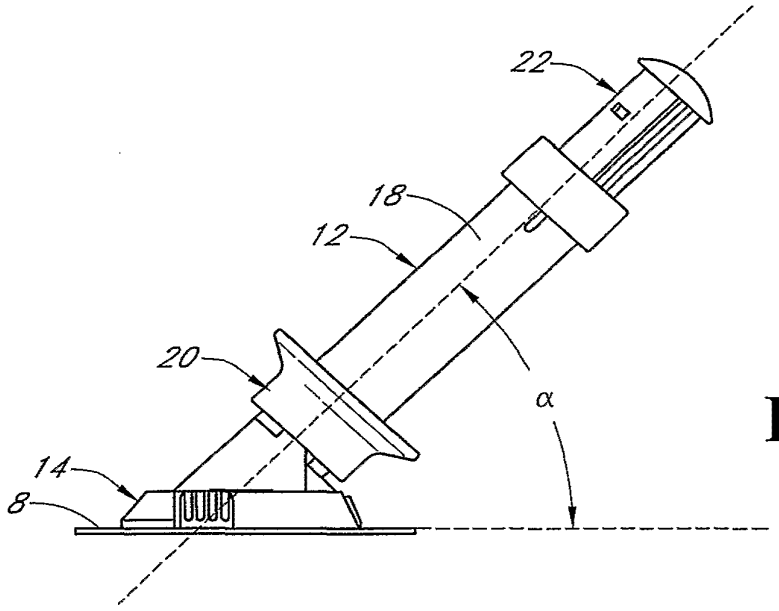


FIG. 8B

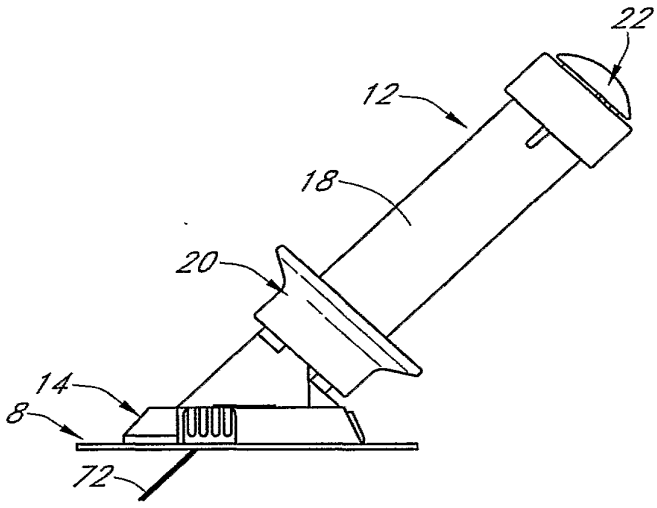


FIG. 8C

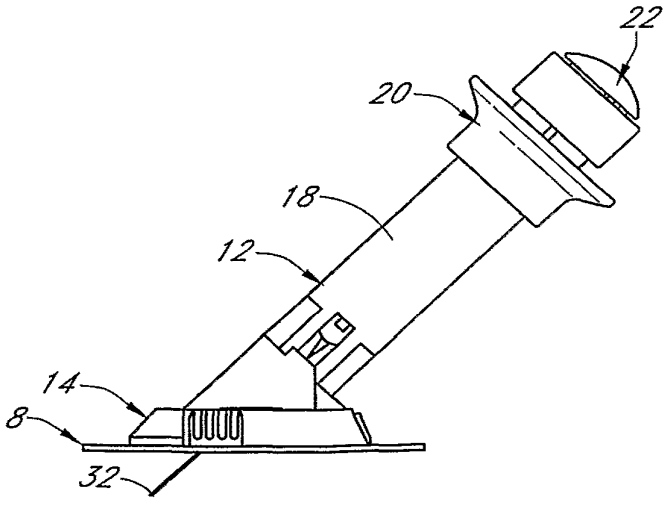


FIG. 8D

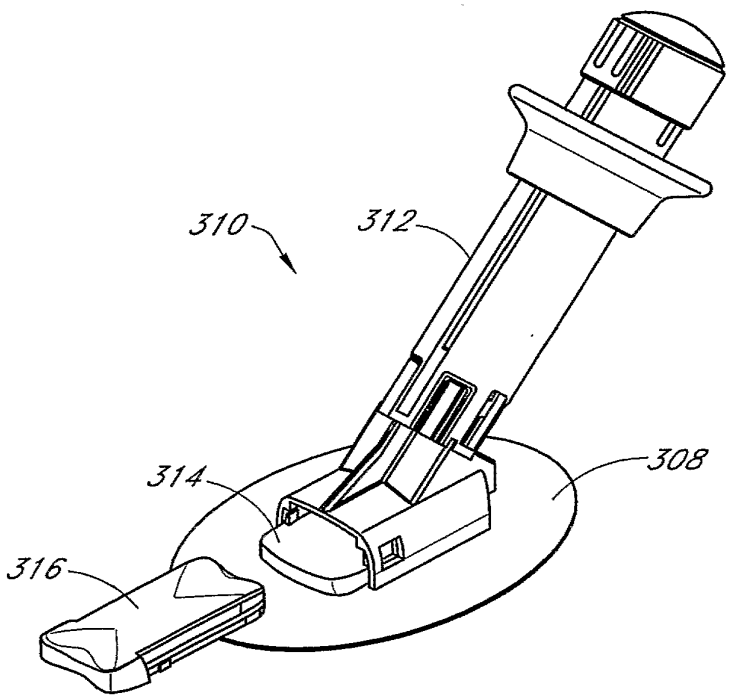


FIG. 8E

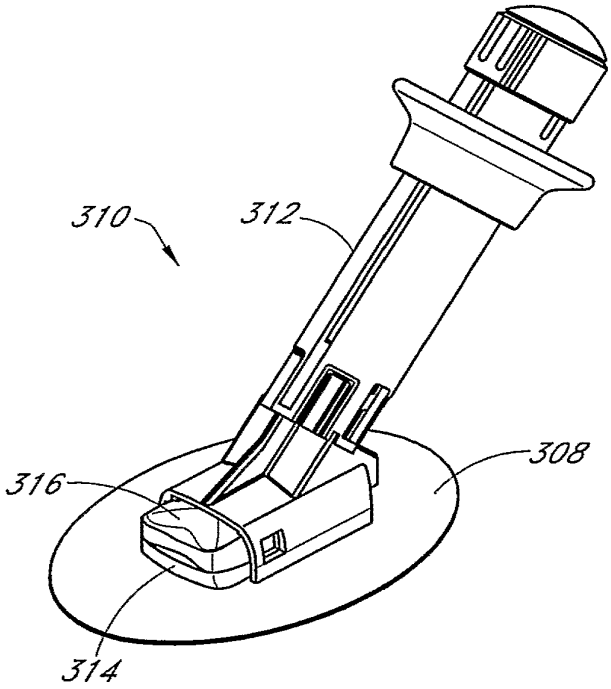


FIG. 8F

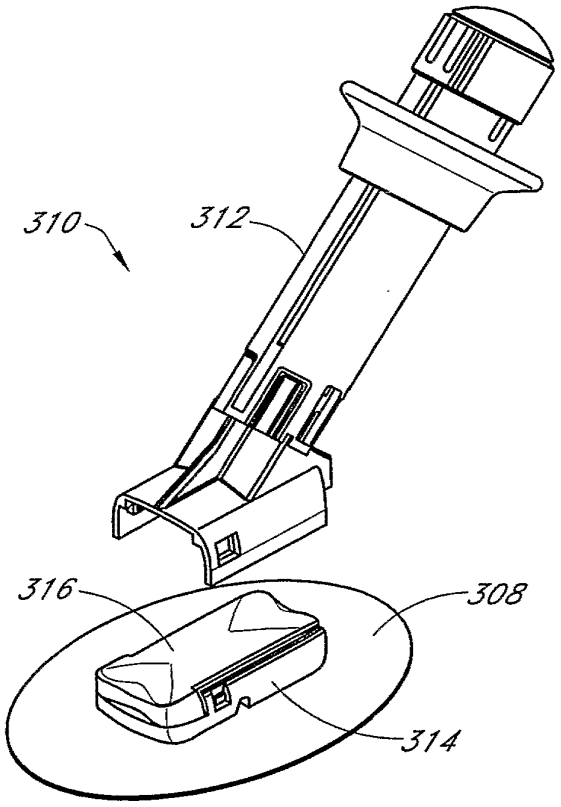


FIG. 8G

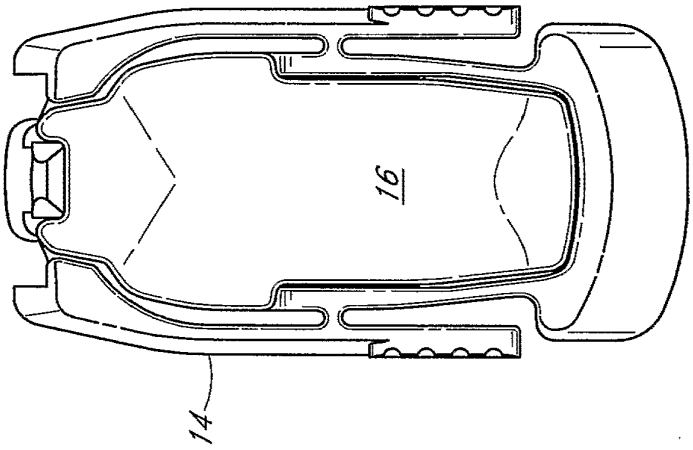


FIG. 8I

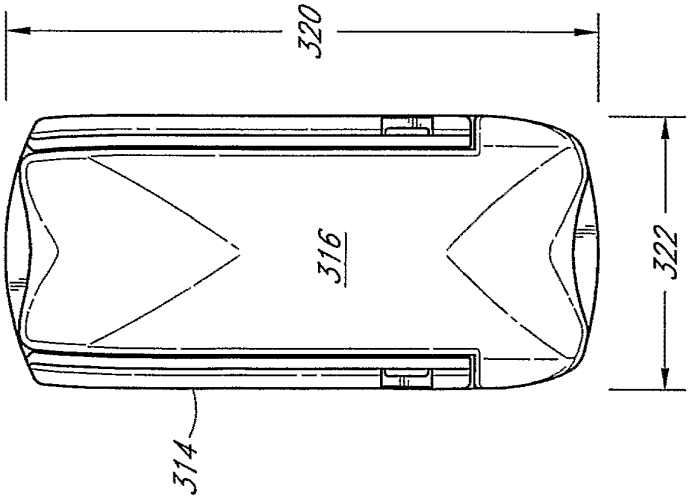


FIG. 8H

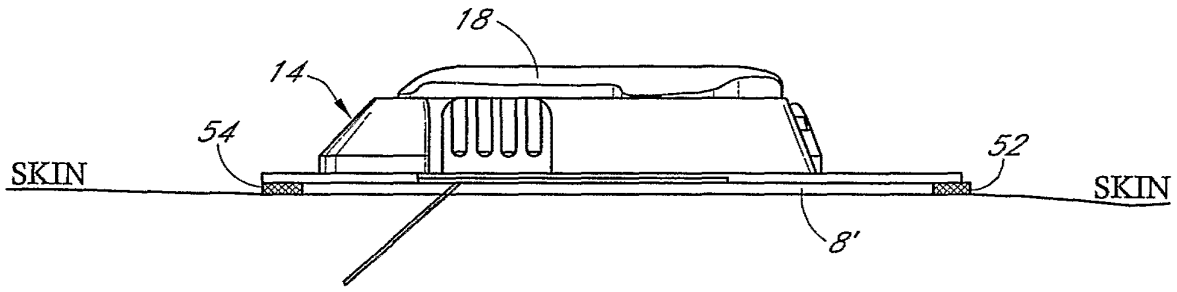


FIG. 9A

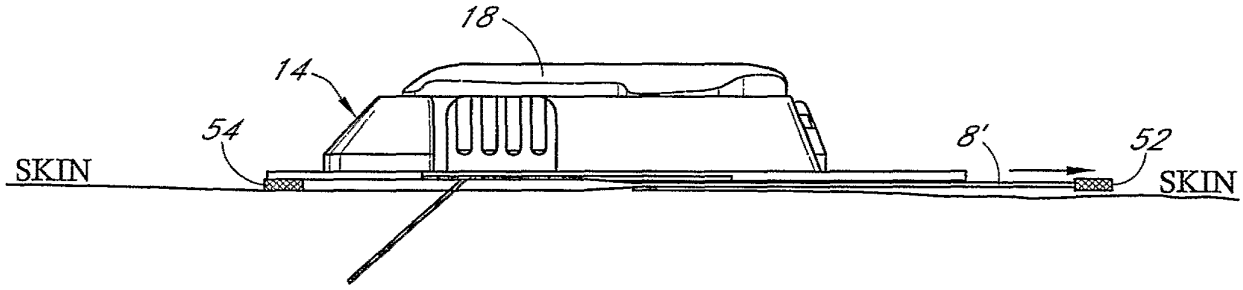


FIG. 9B

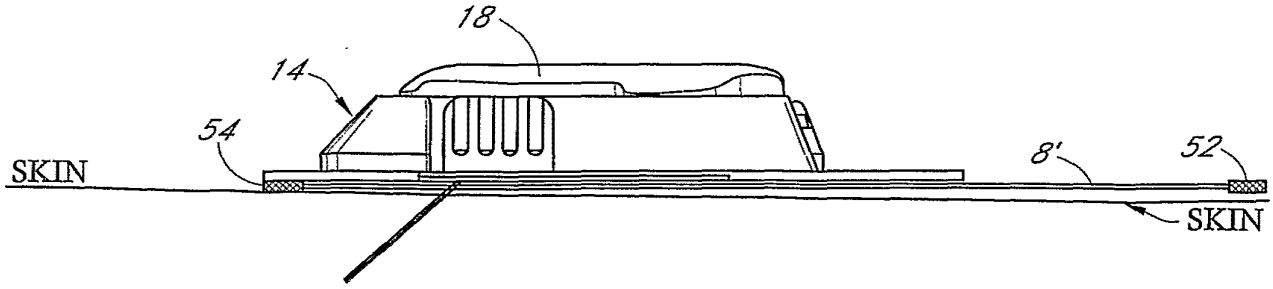


FIG. 9C

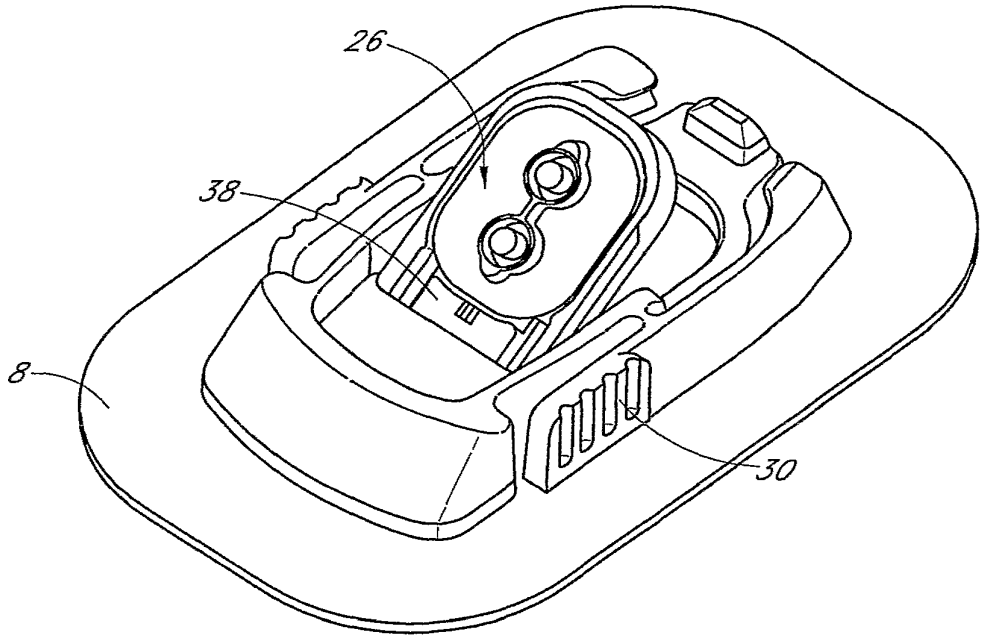


FIG. 10A

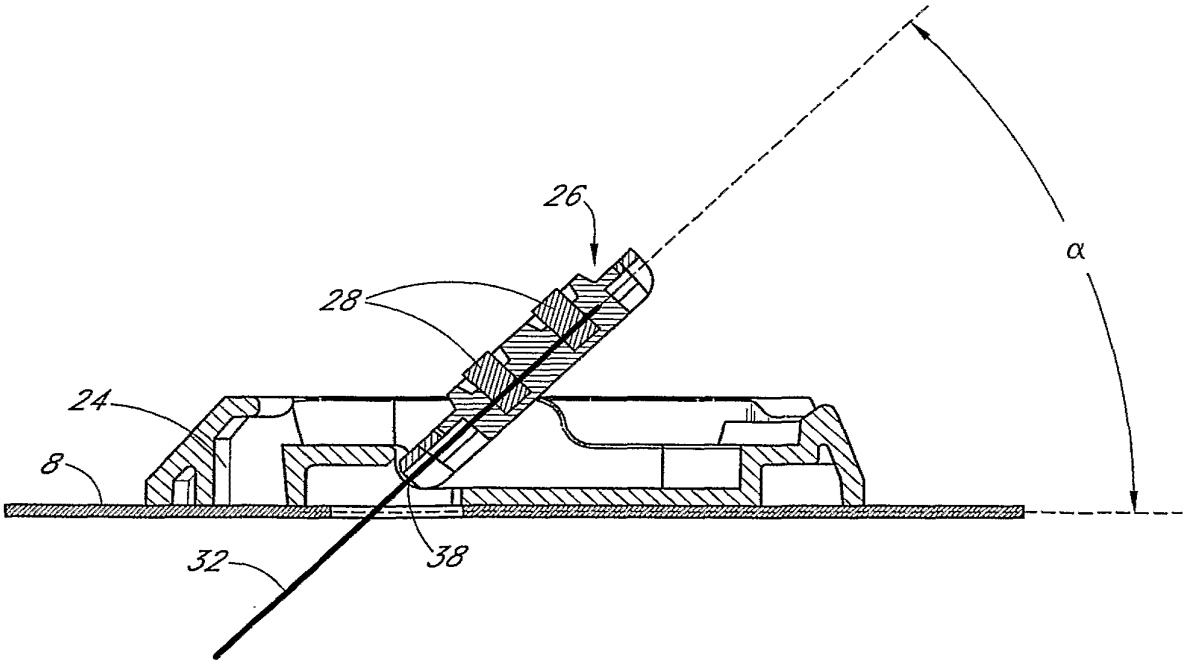


FIG. 10B

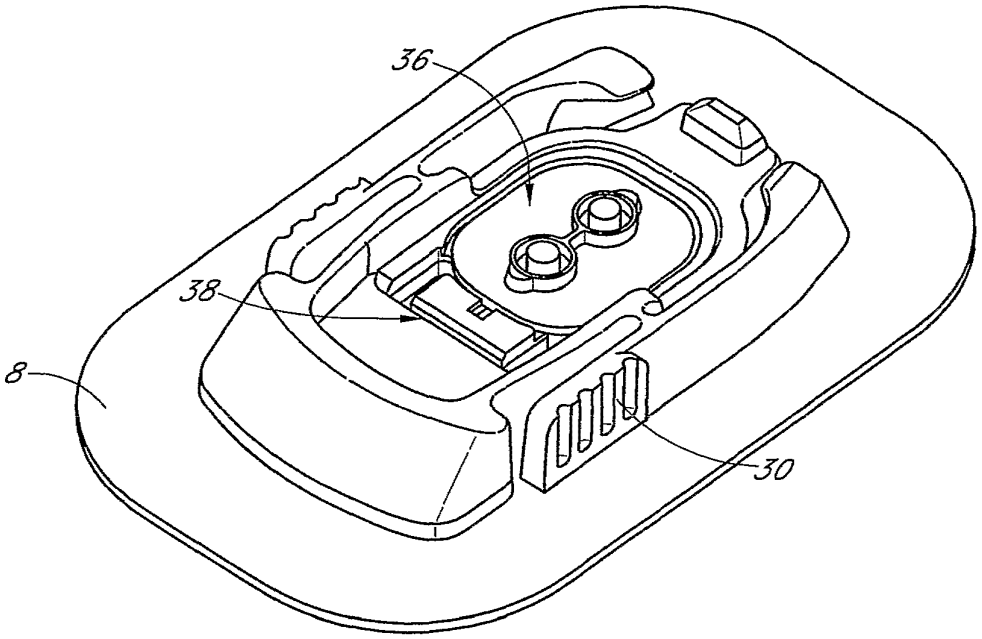


FIG. 11A

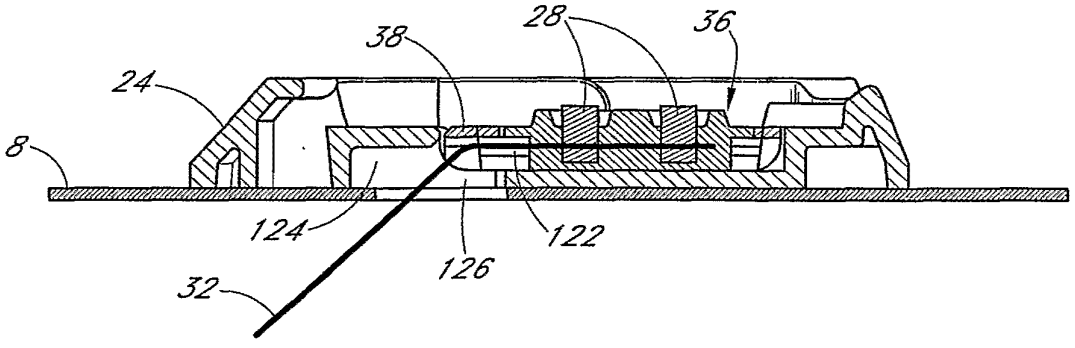


FIG. 11B

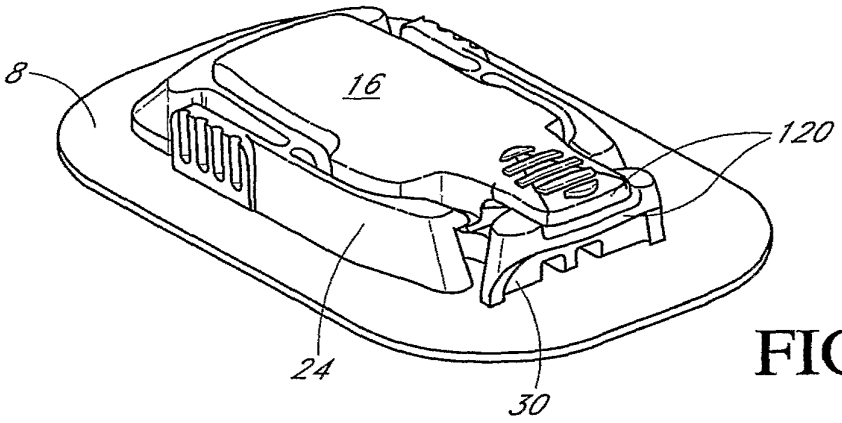


FIG. 12A

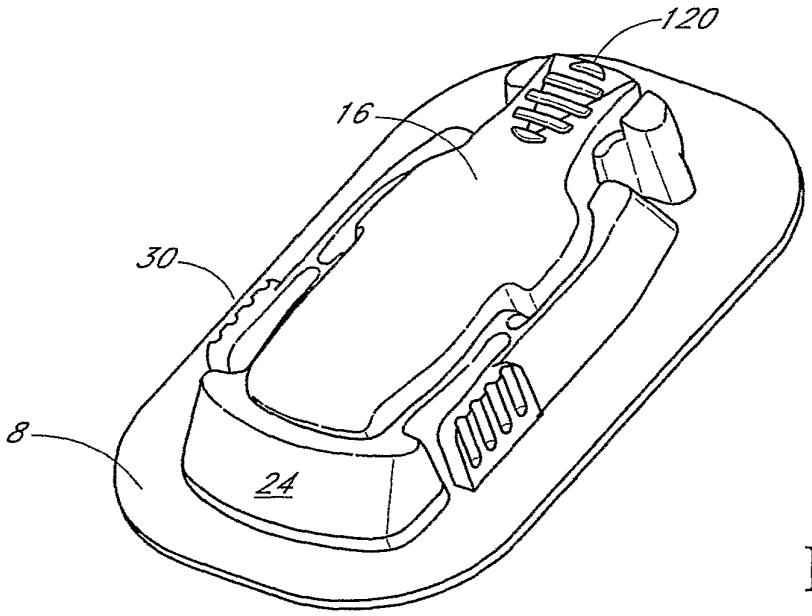


FIG. 12B

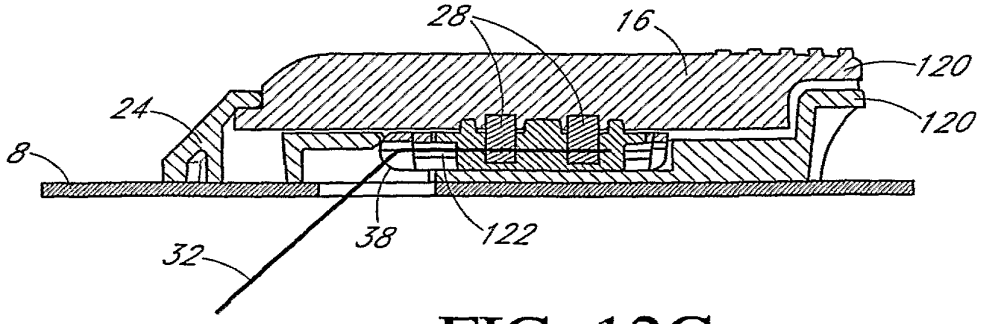


FIG. 12C

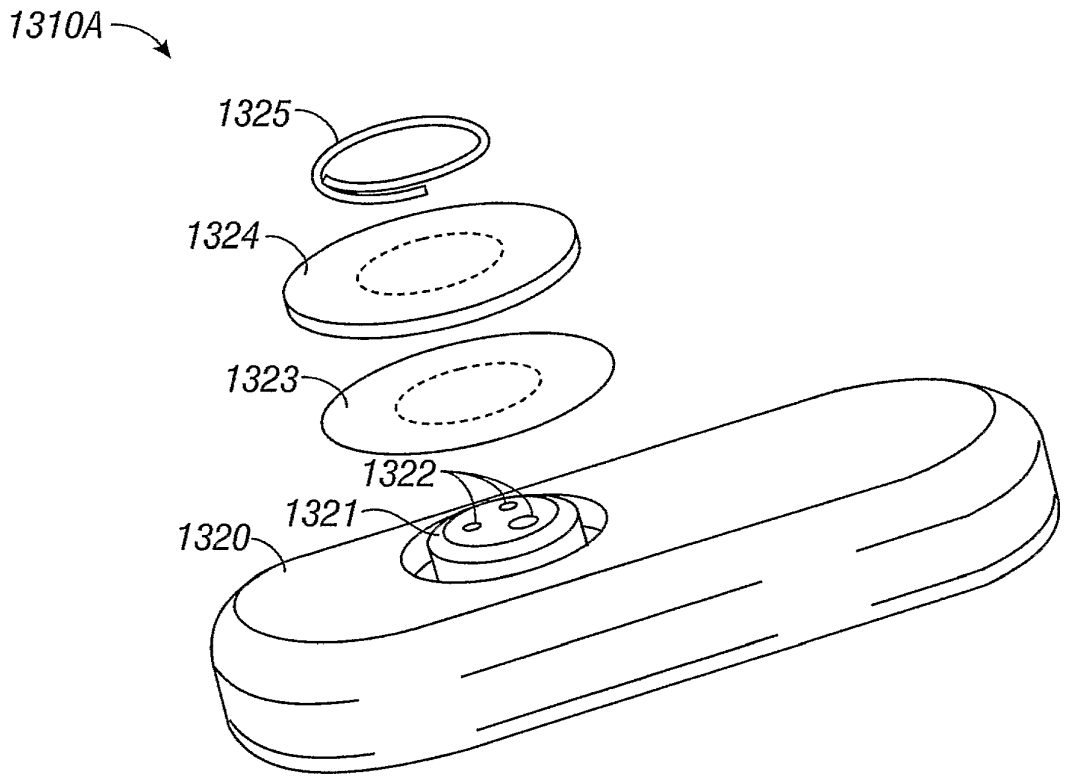


FIG. 13

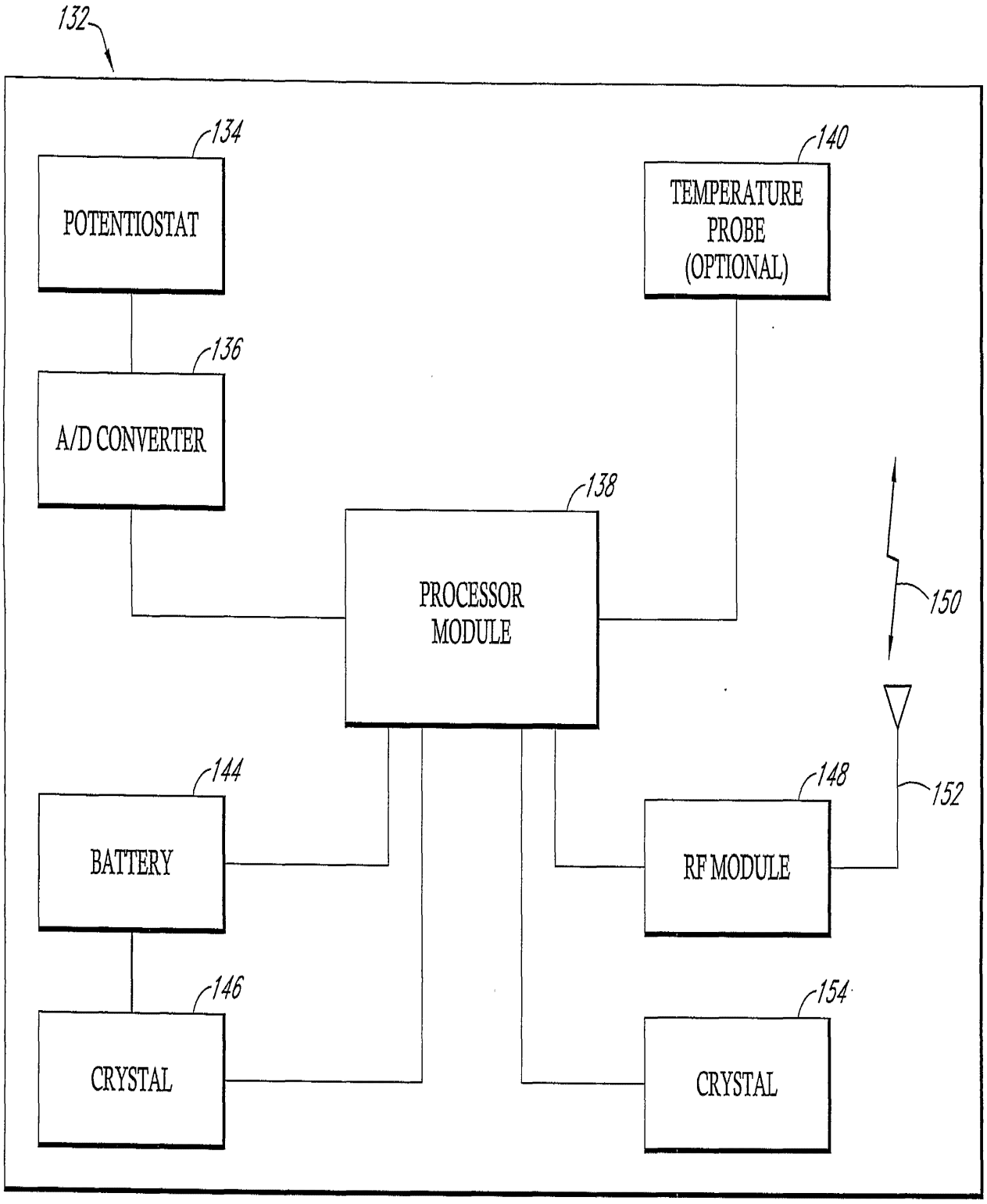

132
134
POTENTIOSTAT
140
TEMPERATURE PROBE (OPTIONAL)
136
A/D CONVERTER
138
PROCESSOR MODULE
150
144
BATTERY
148
RF MODULE
152
146
CRYSTAL
154
CRYSTAL

FIG. 14A

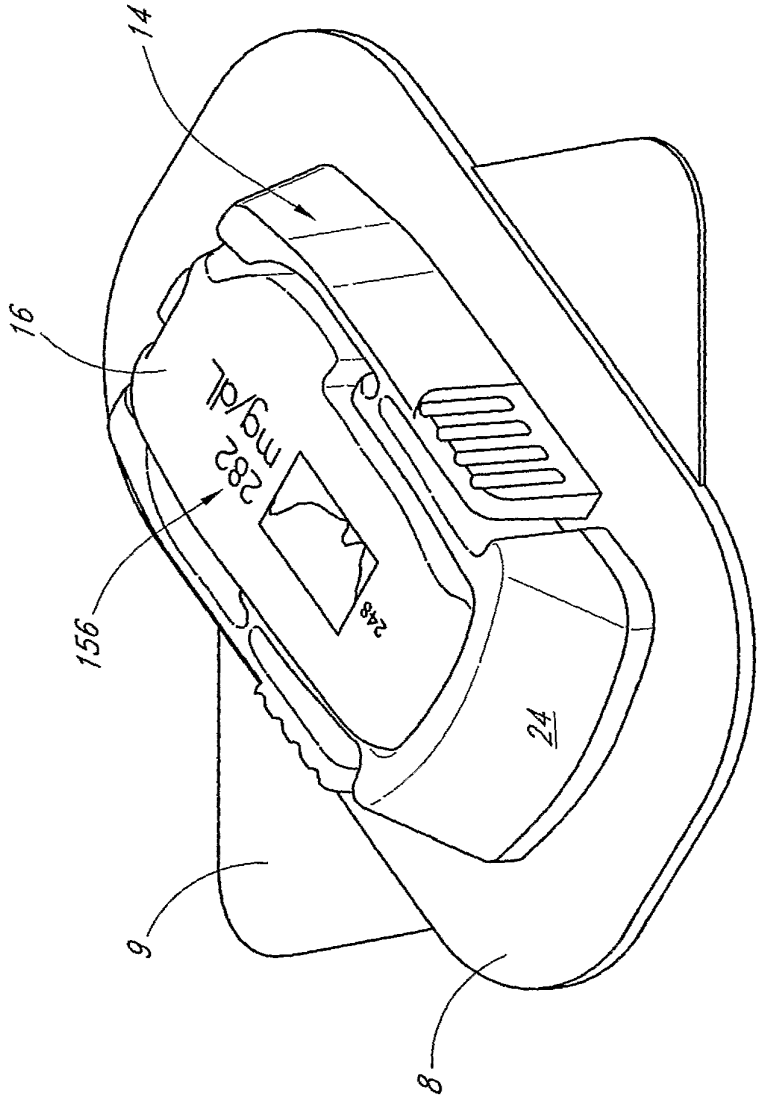


FIG. 14B

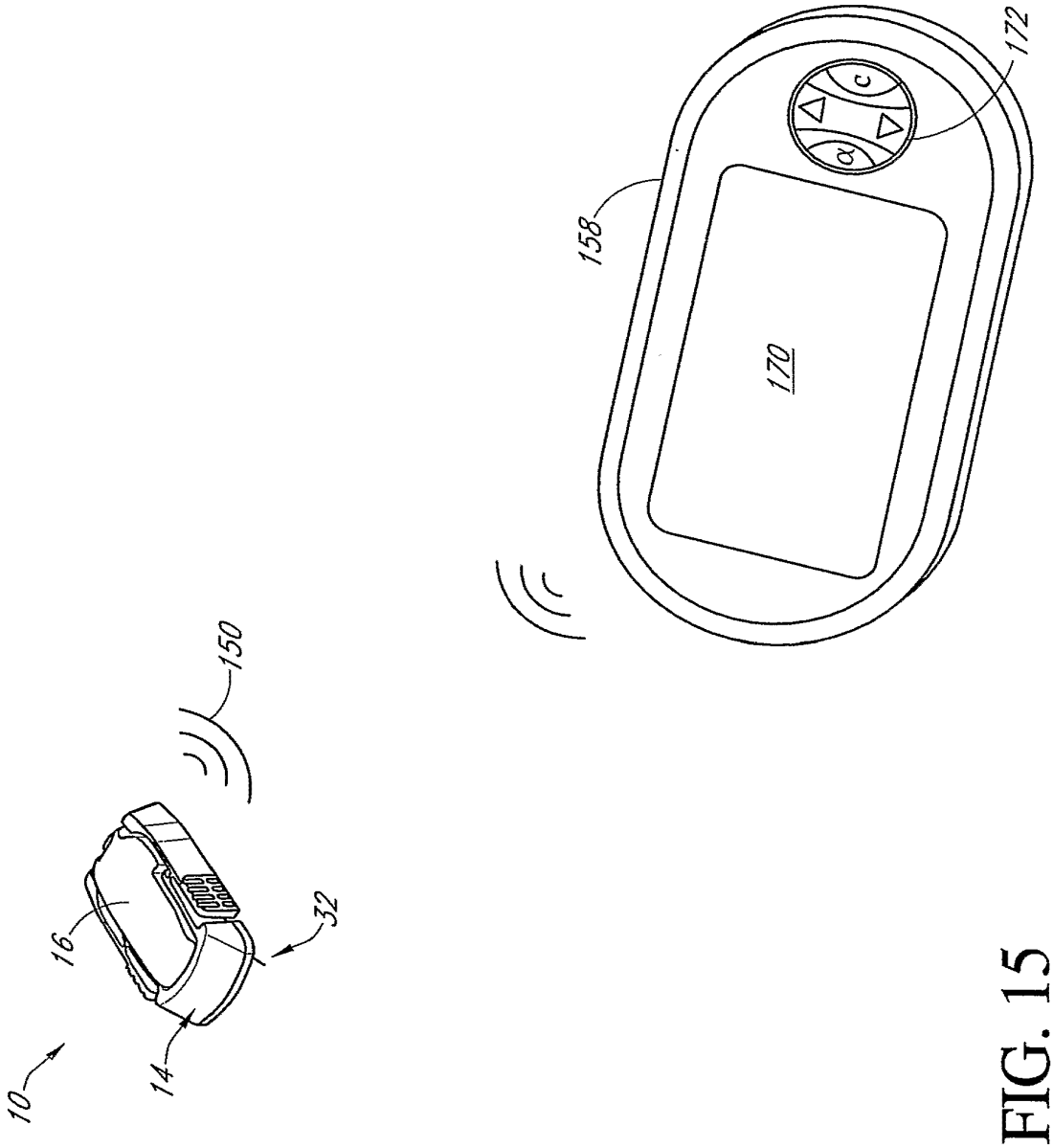


FIG. 15

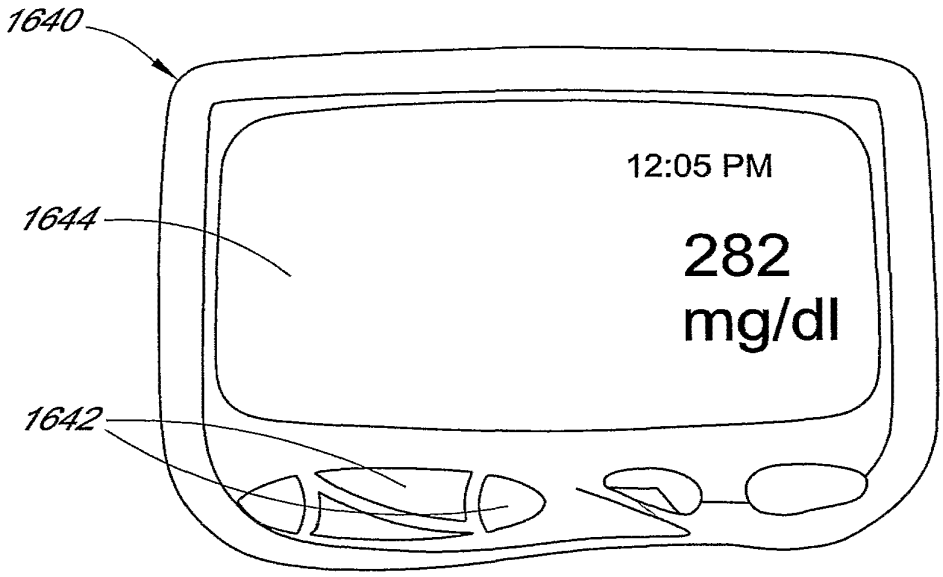


FIG. 16A

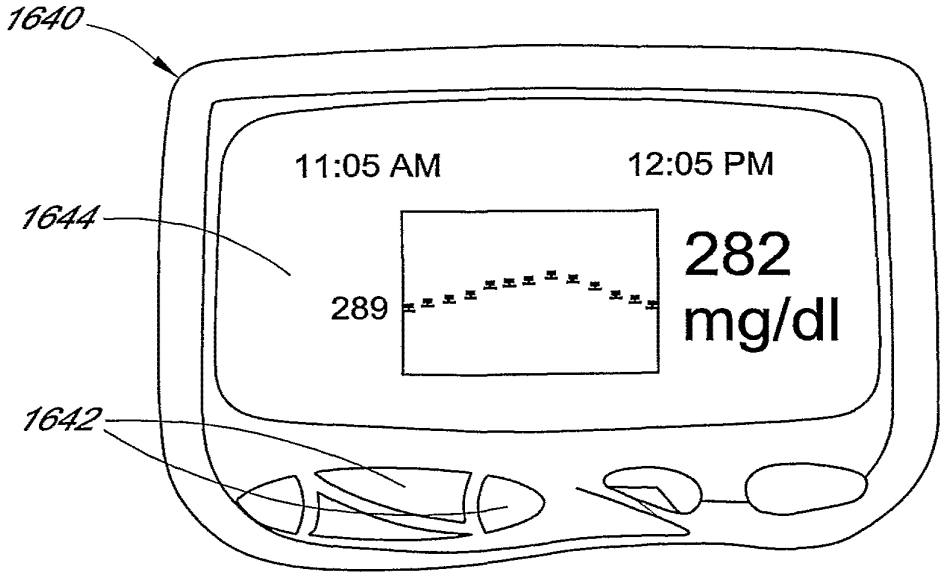


FIG. 16B

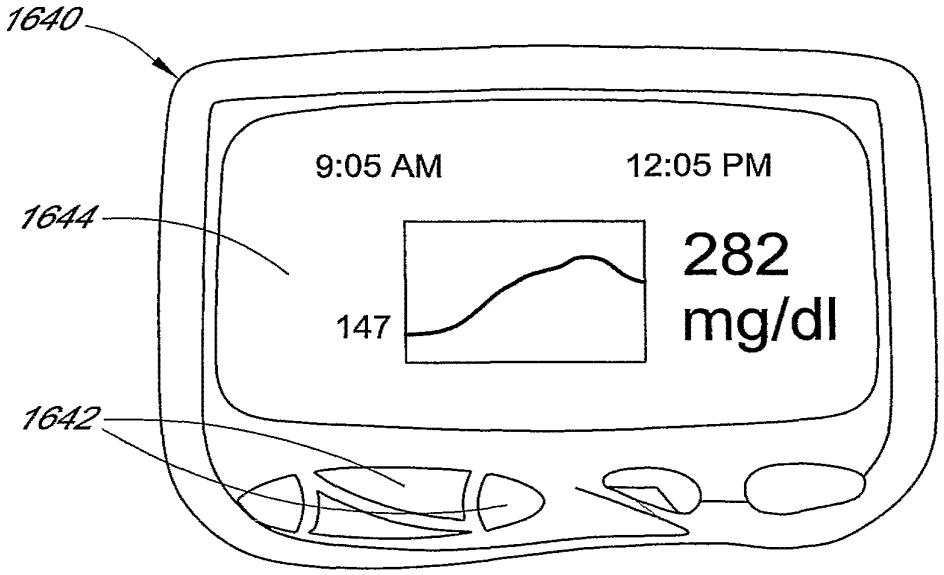


FIG. 16C

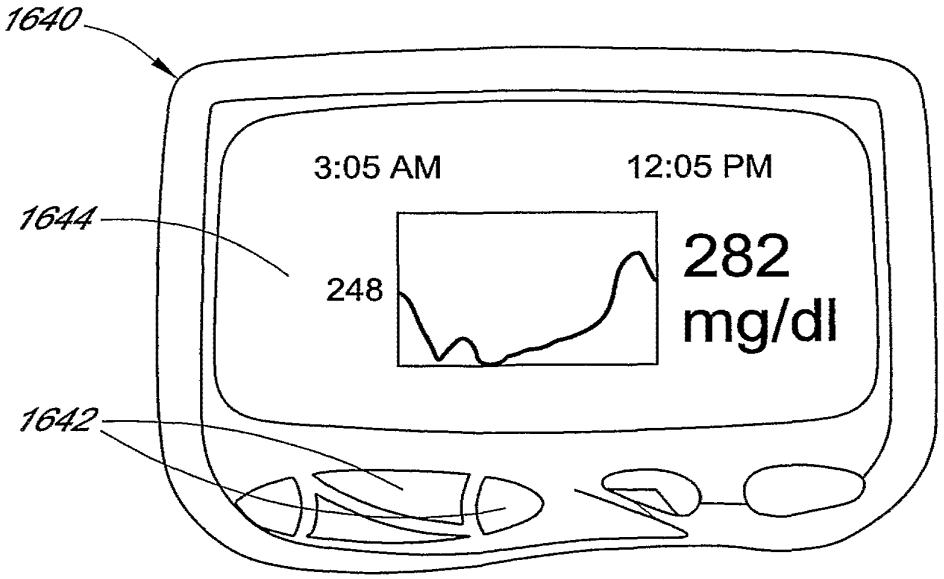


FIG. 16D

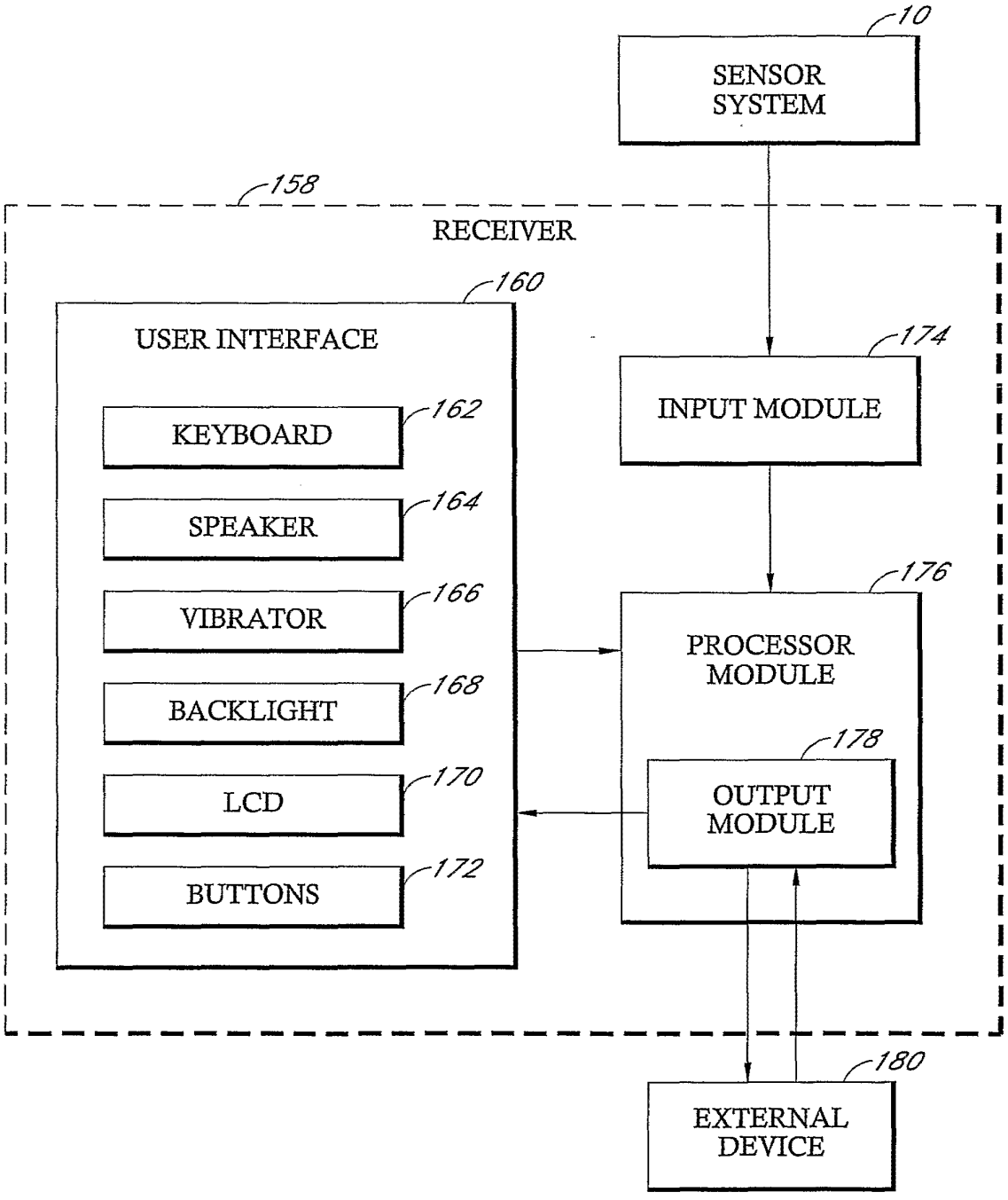

10
SENSOR SYSTEM
158
RECEIVER
160
USER INTERFACE
162
KEYBOARD
164
SPEAKER
166
VIBRATOR
168
BACKLIGHT
170
LCD
172
BUTTONS
174
INPUT MODULE
176
PROCESSOR MODULE
178
OUTPUT MODULE
180
EXTERNAL DEVICE

FIG. 17A

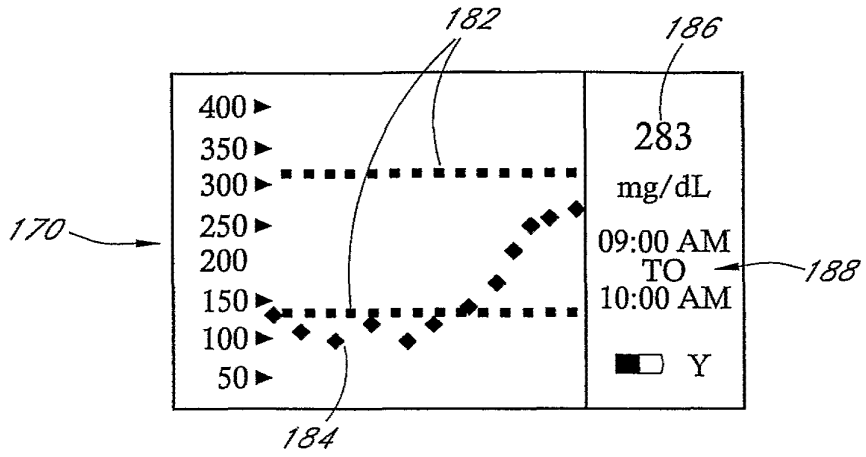


FIG. 17B

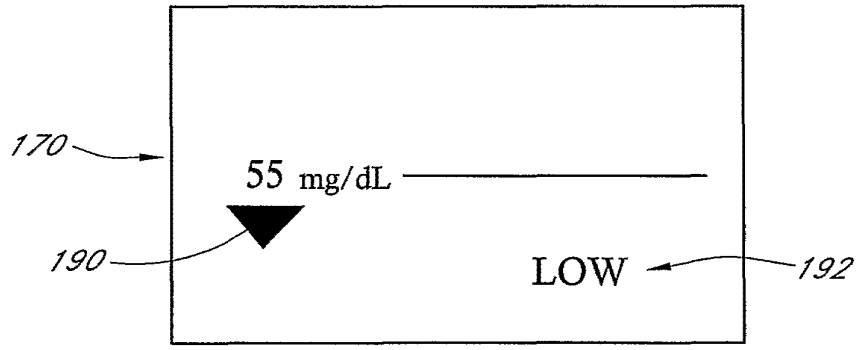


FIG. 17C

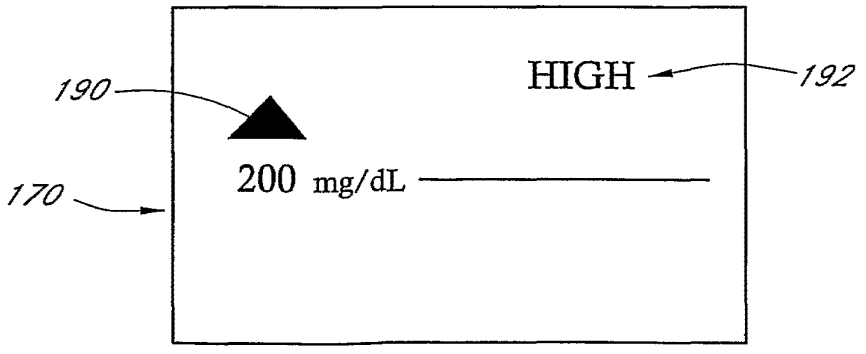


FIG. 17D

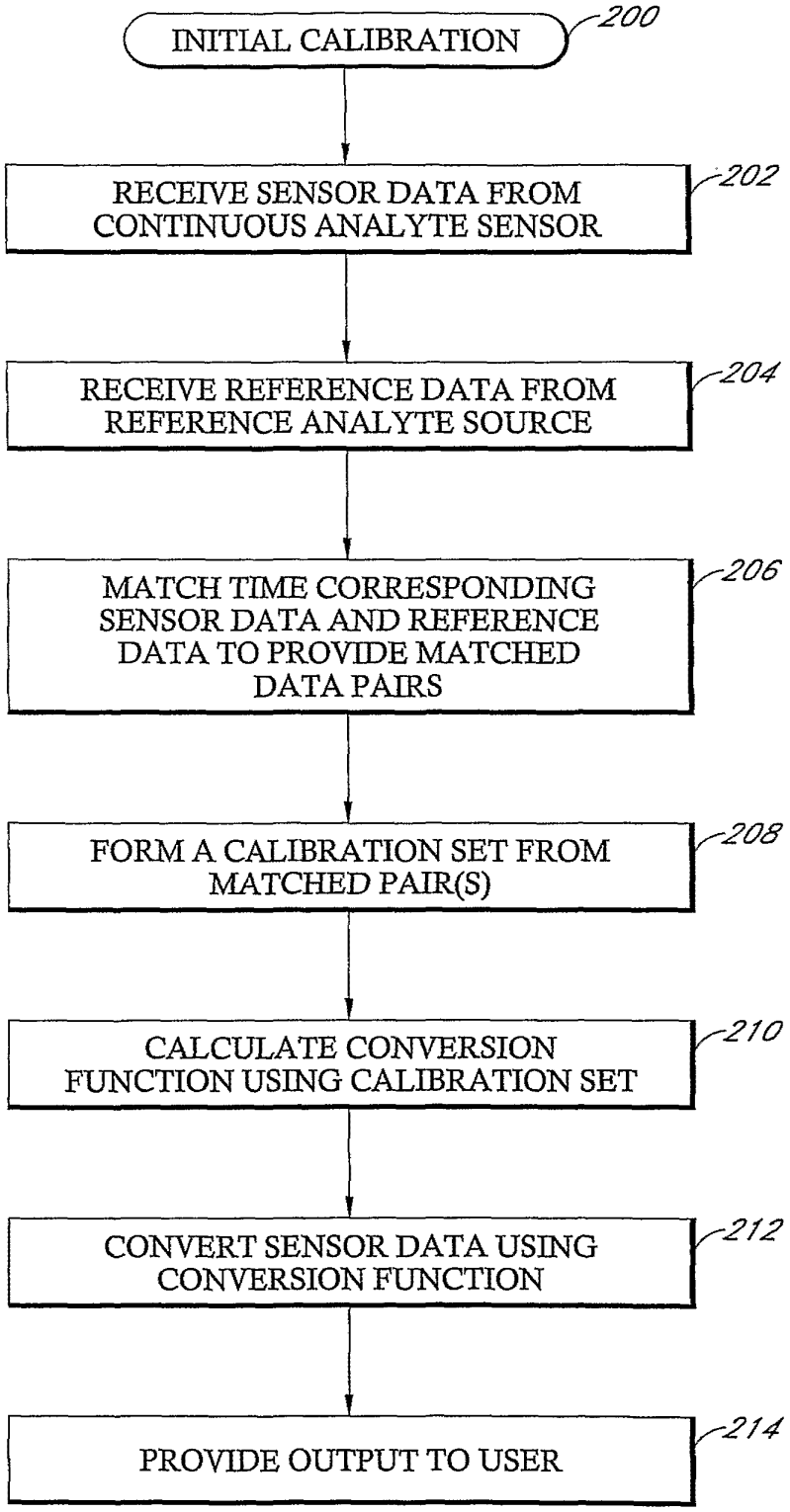

INITIAL CALIBRATION
200
RECEIVE SENSOR DATA FROM CONTINUOUS ANALYTE SENSOR
202
RECEIVE REFERENCE DATA FROM REFERENCE ANALYTE SOURCE
204
MATCH TIME CORRESPONDING SENSOR DATA AND REFERENCE DATA TO PROVIDE MATCHED DATA PAIRS
206
FORM A CALIBRATION SET FROM MATCHED PAIR(S)
208
CALCULATE CONVERSION FUNCTION USING CALIBRATION SET
210
CONVERT SENSOR DATA USING CONVERSION FUNCTION
212
PROVIDE OUTPUT TO USER
214

FIG. 18A

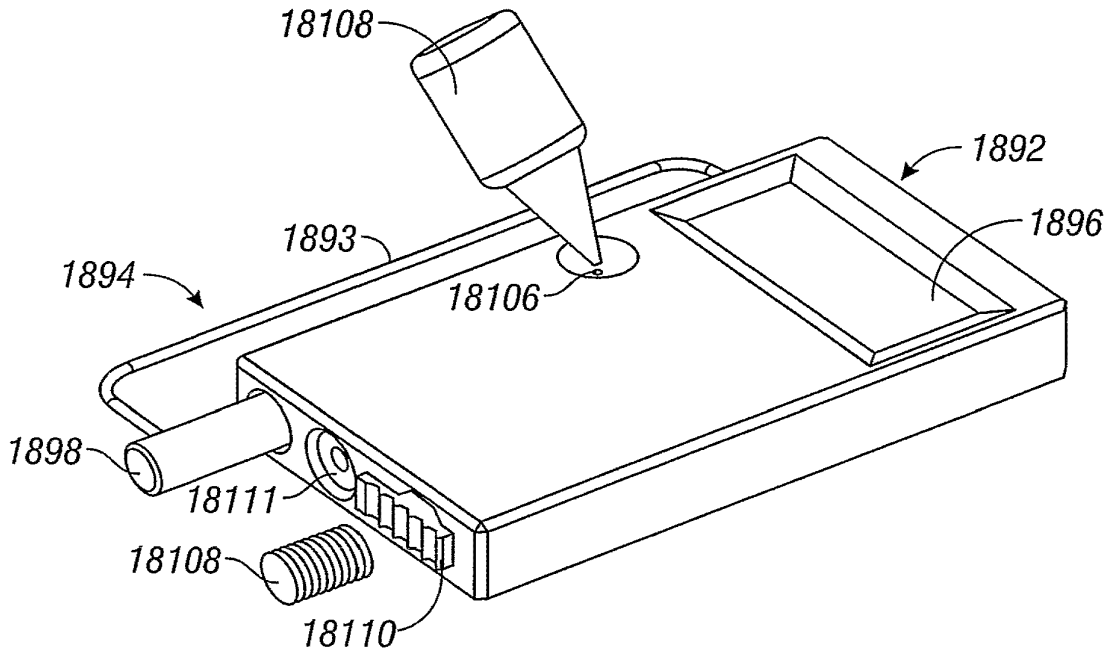


FIG. 18B

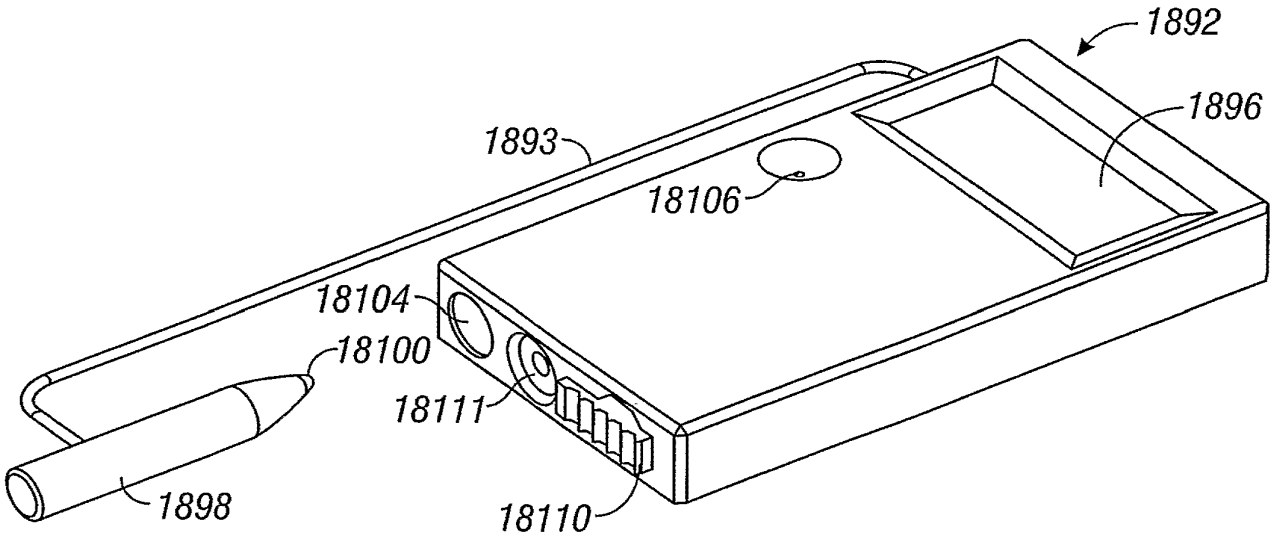


FIG. 18C

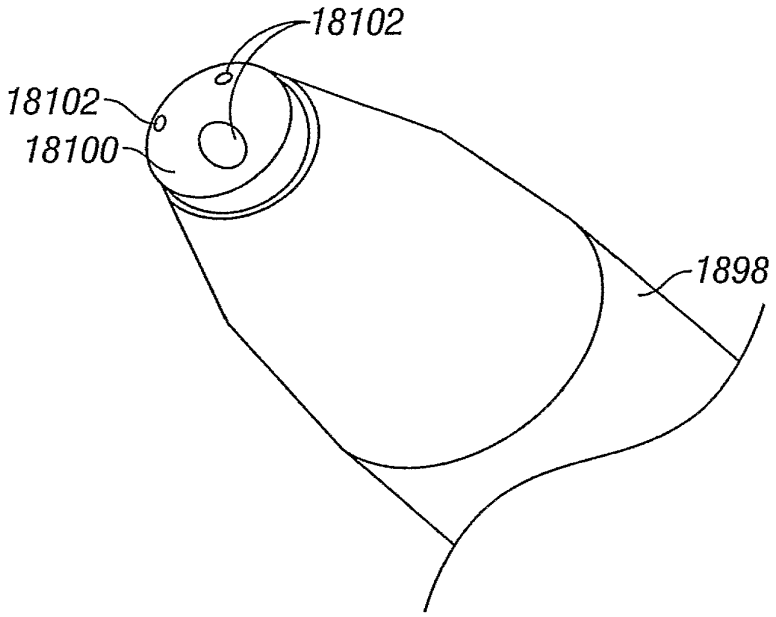


FIG. 18D

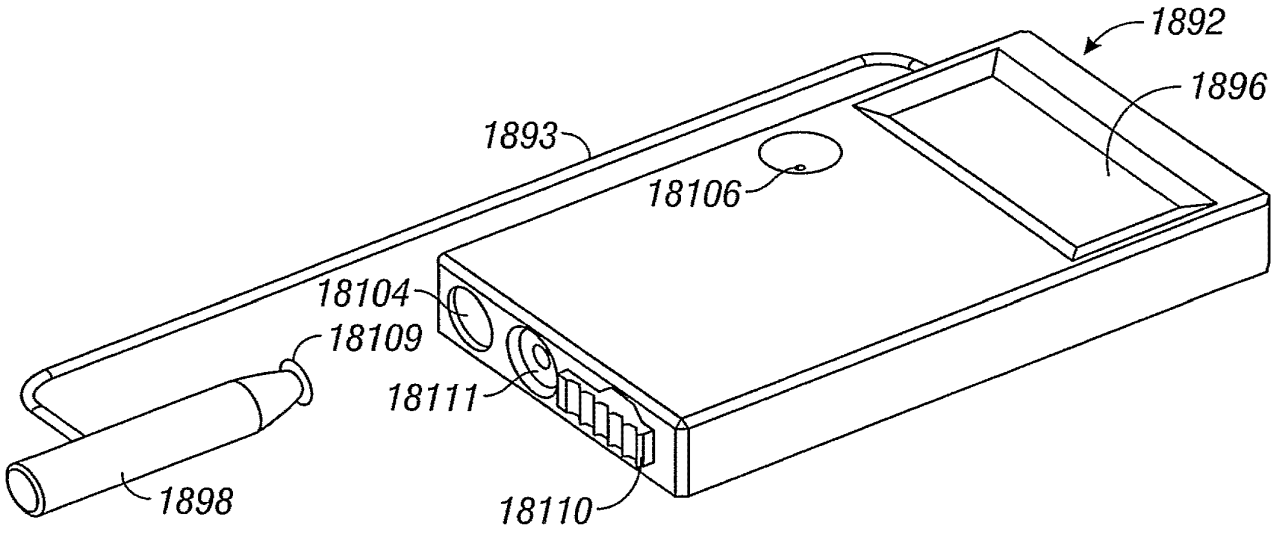


FIG. 18E

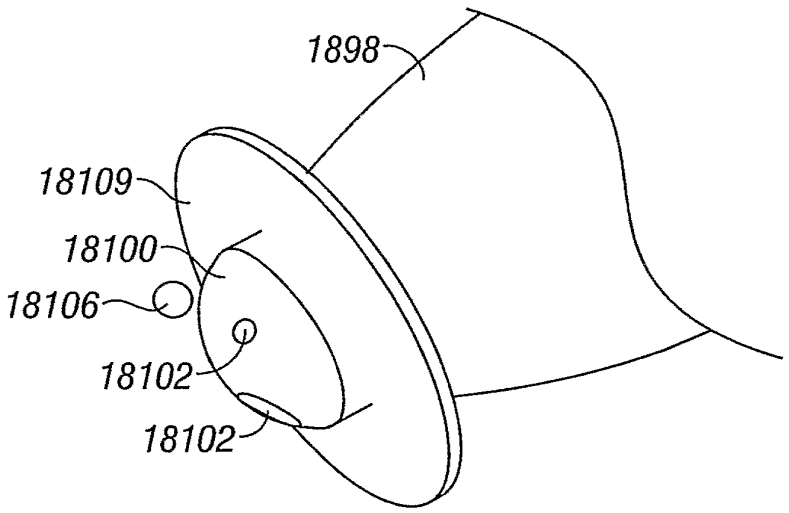


FIG. 18F

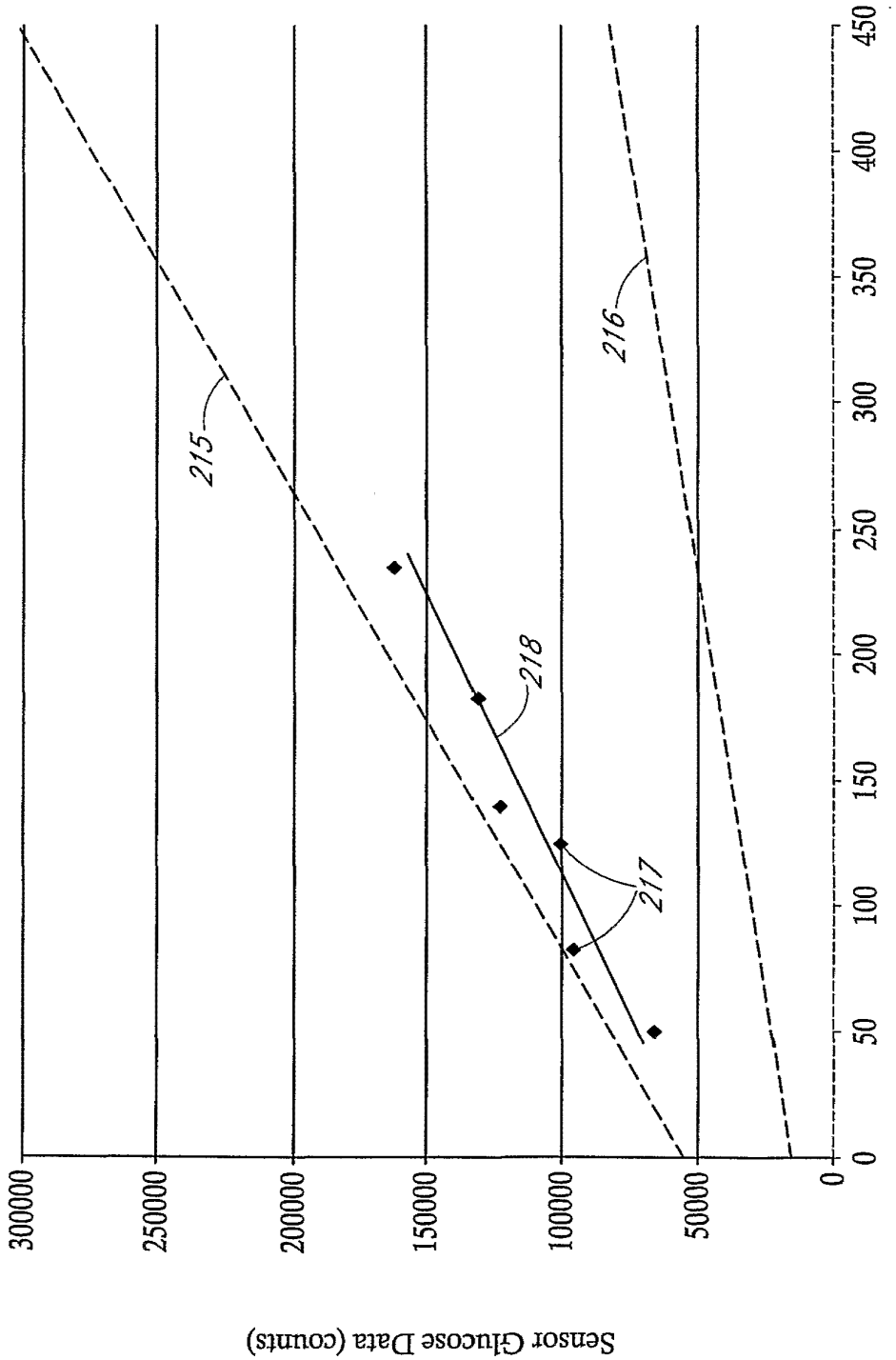

Sensor Glucose Data (counts)
300000
250000
200000
150000
100000
50000
0
0
50
100
150
200
250
300
350
400
450
Reference Glucose Data (mg/dL)
215
216
217
218

FIG. 18G

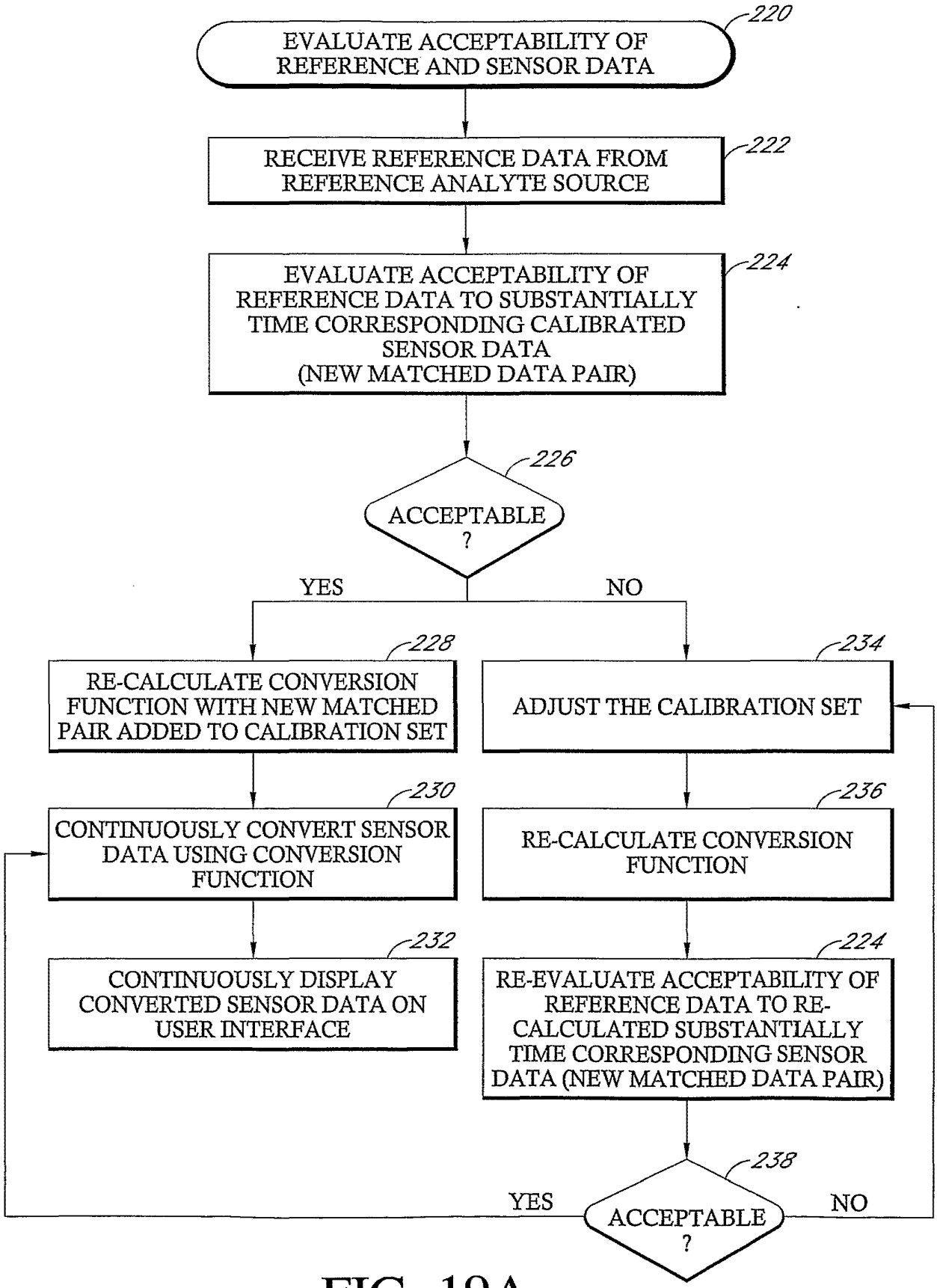

220
EVALUATE ACCEPTABILITY OF REFERENCE AND SENSOR DATA
222
RECEIVE REFERENCE DATA FROM REFERENCE ANALYTE SOURCE
224
EVALUATE ACCEPTABILITY OF REFERENCE DATA TO SUBSTANTIALLY TIME CORRESPONDING CALIBRATED SENSOR DATA (NEW MATCHED DATA PAIR)
226
ACCEPTABLE ?
YES
NO
228
RE-CALCULATE CONVERSION FUNCTION WITH NEW MATCHED PAIR ADDED TO CALIBRATION SET
234
ADJUST THE CALIBRATION SET
230
CONTINUOUSLY CONVERT SENSOR DATA USING CONVERSION FUNCTION
236
RE-CALCULATE CONVERSION FUNCTION
232
CONTINUOUSLY DISPLAY CONVERTED SENSOR DATA ON USER INTERFACE
224
RE-EVALUATE ACCEPTABILITY OF REFERENCE DATA TO RE-CALCULATED SUBSTANTIALLY TIME CORRESPONDING SENSOR DATA (NEW MATCHED DATA PAIR)
238
ACCEPTABLE ?
YES
NO

FIG. 19A

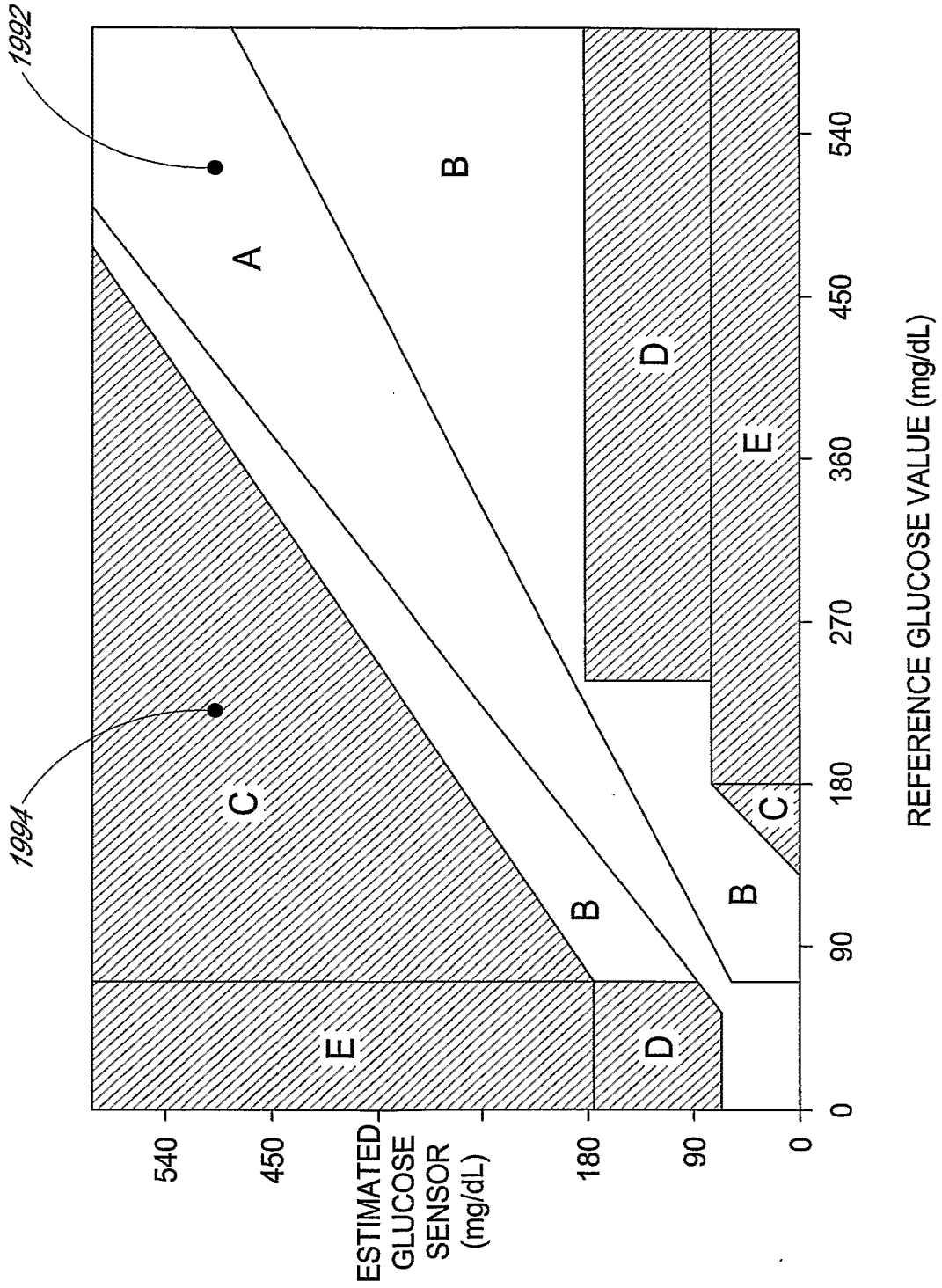

1992
1994
A
B
C
D
E
ESTIMATED GLUCOSE SENSOR (mg/dL)
0
90
180
450
540
REFERENCE GLUCOSE VALUE (mg/dL)
0
90
180
270
360
450
540

FIG. 19B

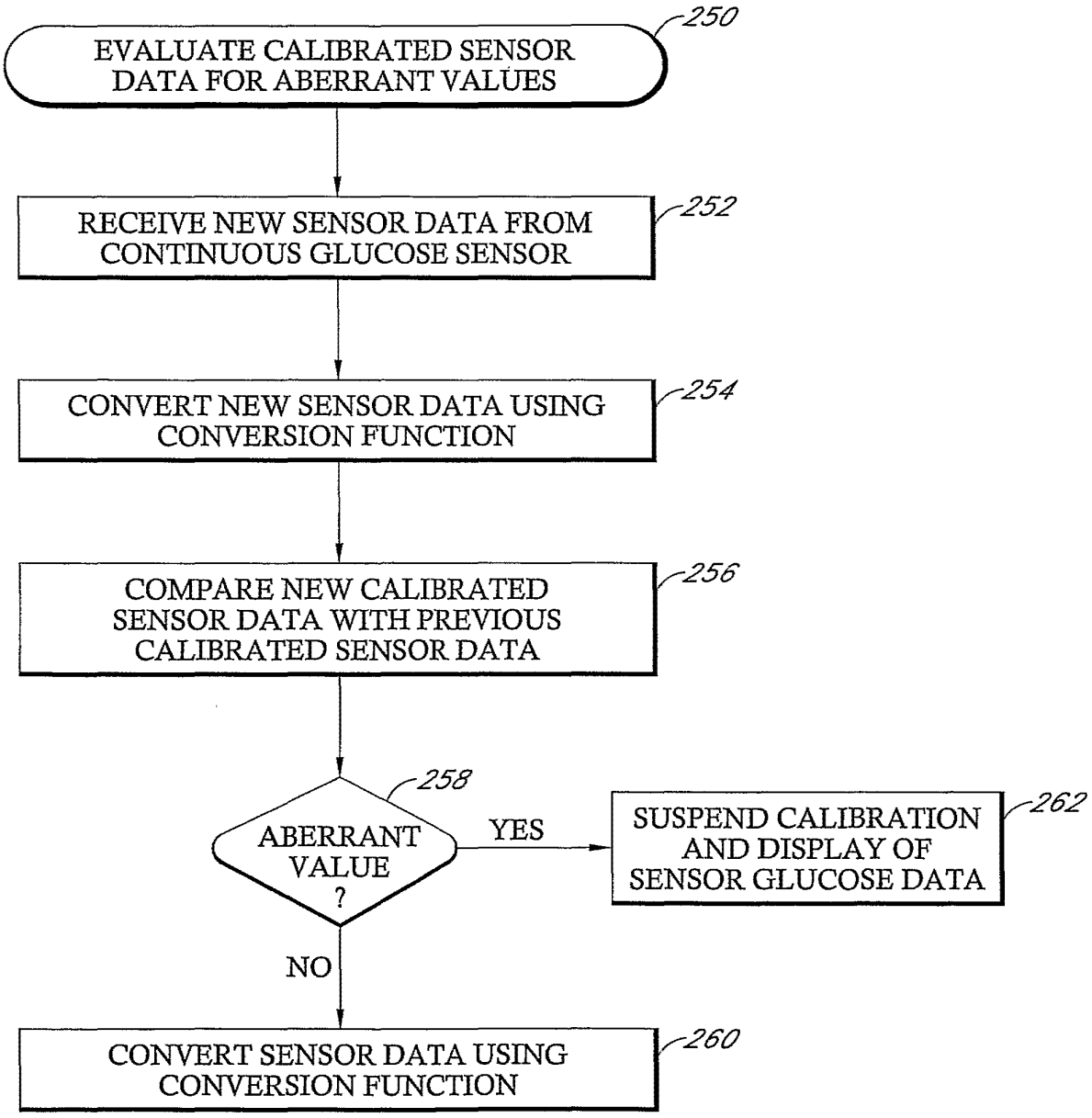

250
EVALUATE CALIBRATED SENSOR DATA FOR ABERRANT VALUES
252
RECEIVE NEW SENSOR DATA FROM CONTINUOUS GLUCOSE SENSOR
254
CONVERT NEW SENSOR DATA USING CONVERSION FUNCTION
256
COMPARE NEW CALIBRATED SENSOR DATA WITH PREVIOUS CALIBRATED SENSOR DATA
258
ABERRANT VALUE ?
YES
262
SUSPEND CALIBRATION AND DISPLAY OF SENSOR GLUCOSE DATA
NO
260
CONVERT SENSOR DATA USING CONVERSION FUNCTION

FIG. 20

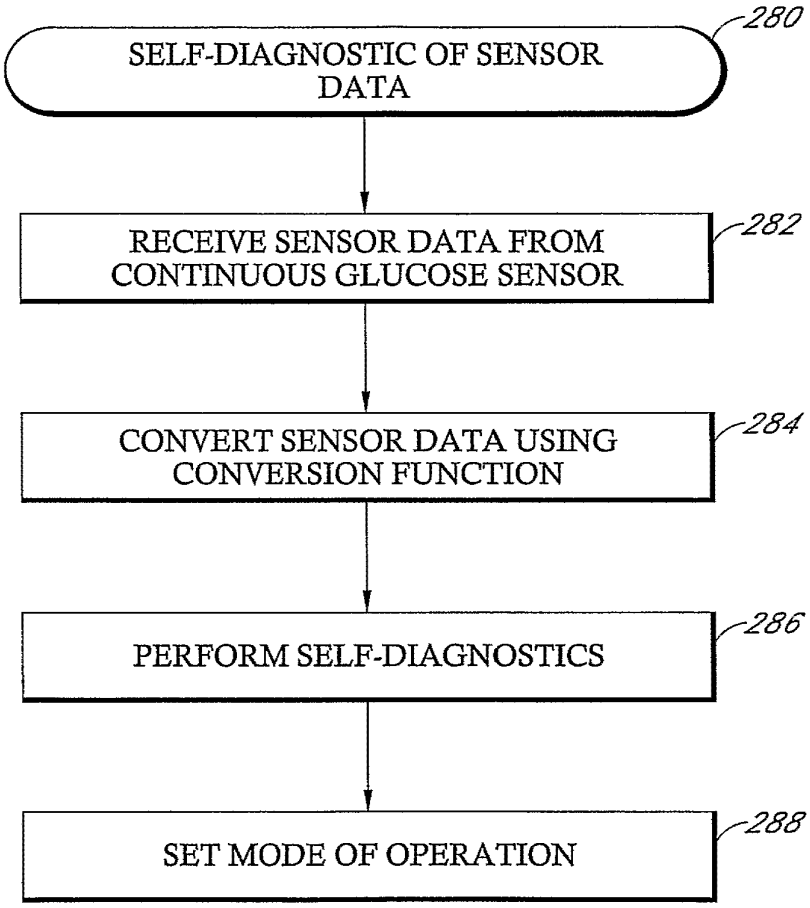

280
SELF-DIAGNOSTIC OF SENSOR DATA
282
RECEIVE SENSOR DATA FROM CONTINUOUS GLUCOSE SENSOR
284
CONVERT SENSOR DATA USING CONVERSION FUNCTION
286
PERFORM SELF-DIAGNOSTICS
288
SET MODE OF OPERATION

FIG. 21

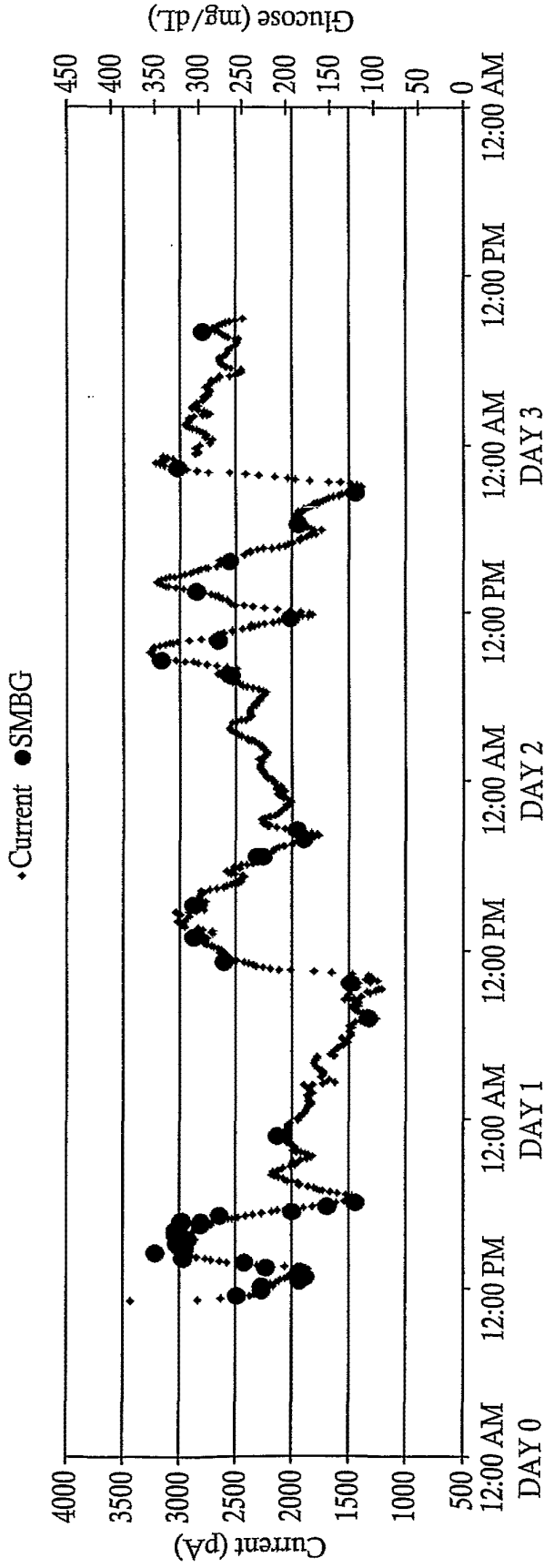

Glucose (mg/dL)
450
400
350
300
250
200
150
100
50
0
Current (pA)
4000
3500
3000
2500
2000
1500
1000
500
Current
SMBG
12:00 AM
DAY 0
12:00 PM
12:00 AM
DAY 1
12:00 PM
12:00 AM
DAY 2
12:00 PM
12:00 AM
DAY 3
12:00 PM
12:00 AM

FIG. 22A

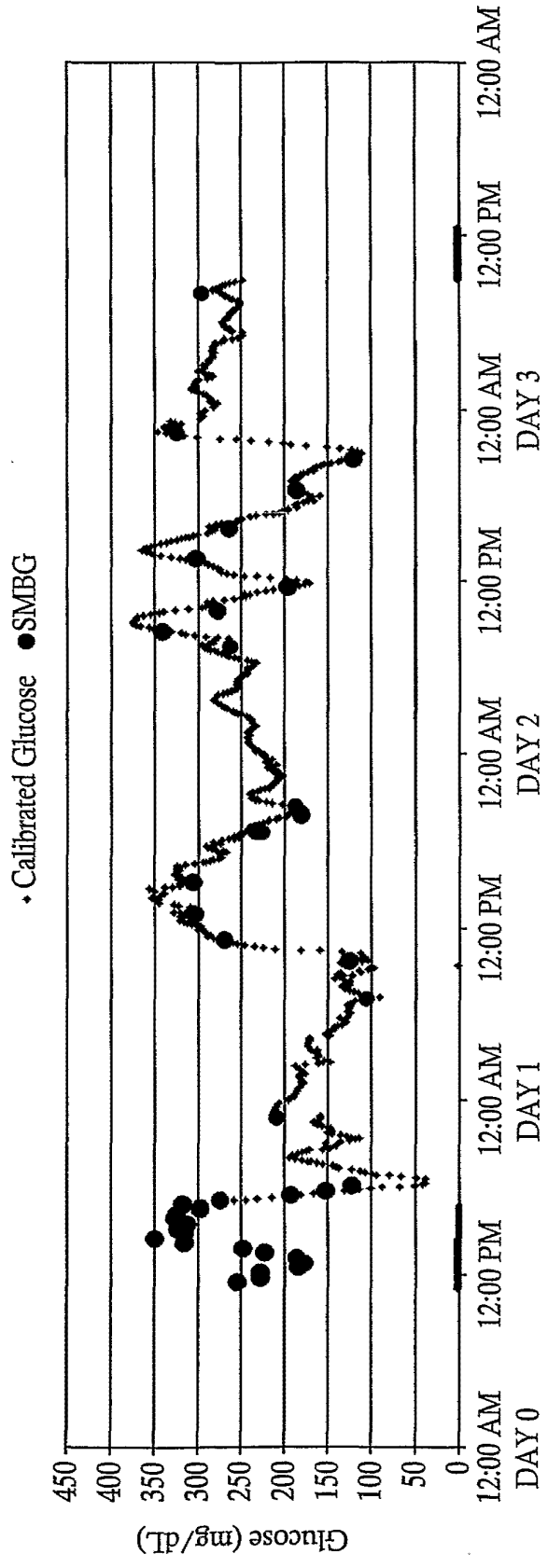

Calibrated Glucose
SMBG
Glucose (mg/dL)
450
400
350
300
250
200
150
100
50
0
12:00 AM
DAY 0
12:00 PM
12:00 AM
DAY 1
12:00 PM
12:00 AM
DAY 2
12:00 PM
12:00 AM
DAY 3
12:00 PM
12:00 AM

FIG. 22B

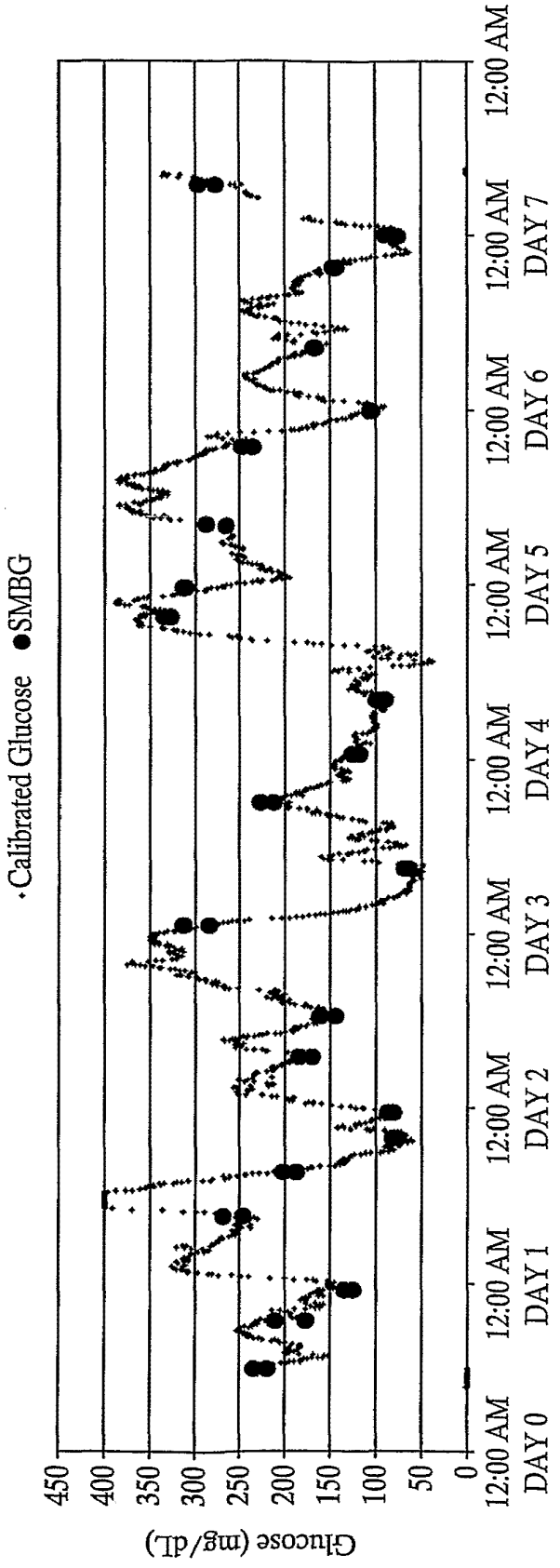

Calibrated Glucose
SMBG
Glucose (mg/dL)
450
400
350
300
250
200
150
100
50
0
12:00 AM DAY 0
12:00 AM DAY 1
12:00 AM DAY 2
12:00 AM DAY 3
12:00 AM DAY 4
12:00 AM DAY 5
12:00 AM DAY 6
12:00 AM DAY 7
12:00 AM

FIG. 23A

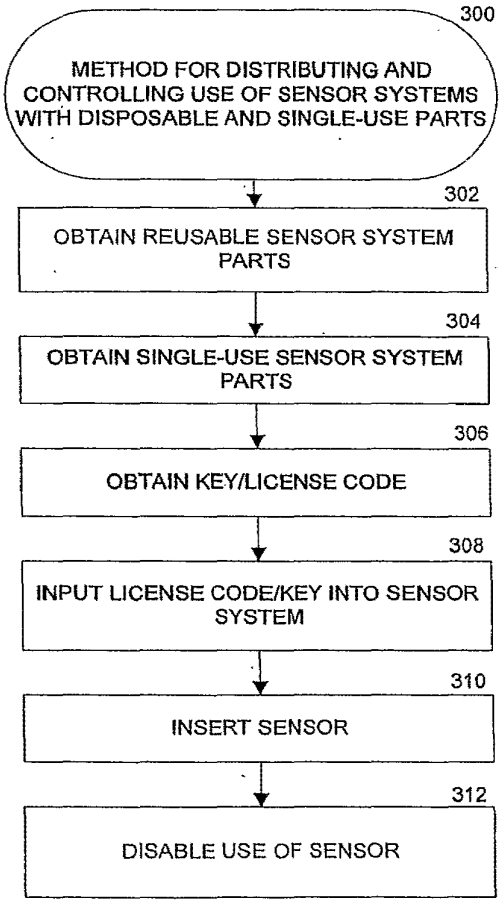

300
METHOD FOR DISTRIBUTING AND CONTROLLING USE OF SENSOR SYSTEMS WITH DISPOSABLE AND SINGLE-USE PARTS
302
OBTAIN REUSABLE SENSOR SYSTEM PARTS
304
OBTAIN SINGLE-USE SENSOR SYSTEM PARTS
306
OBTAIN KEY/LICENSE CODE
308
INPUT LICENSE CODE/KEY INTO SENSOR SYSTEM
310
INSERT SENSOR
312
DISABLE USE OF SENSOR

FIG. 23B

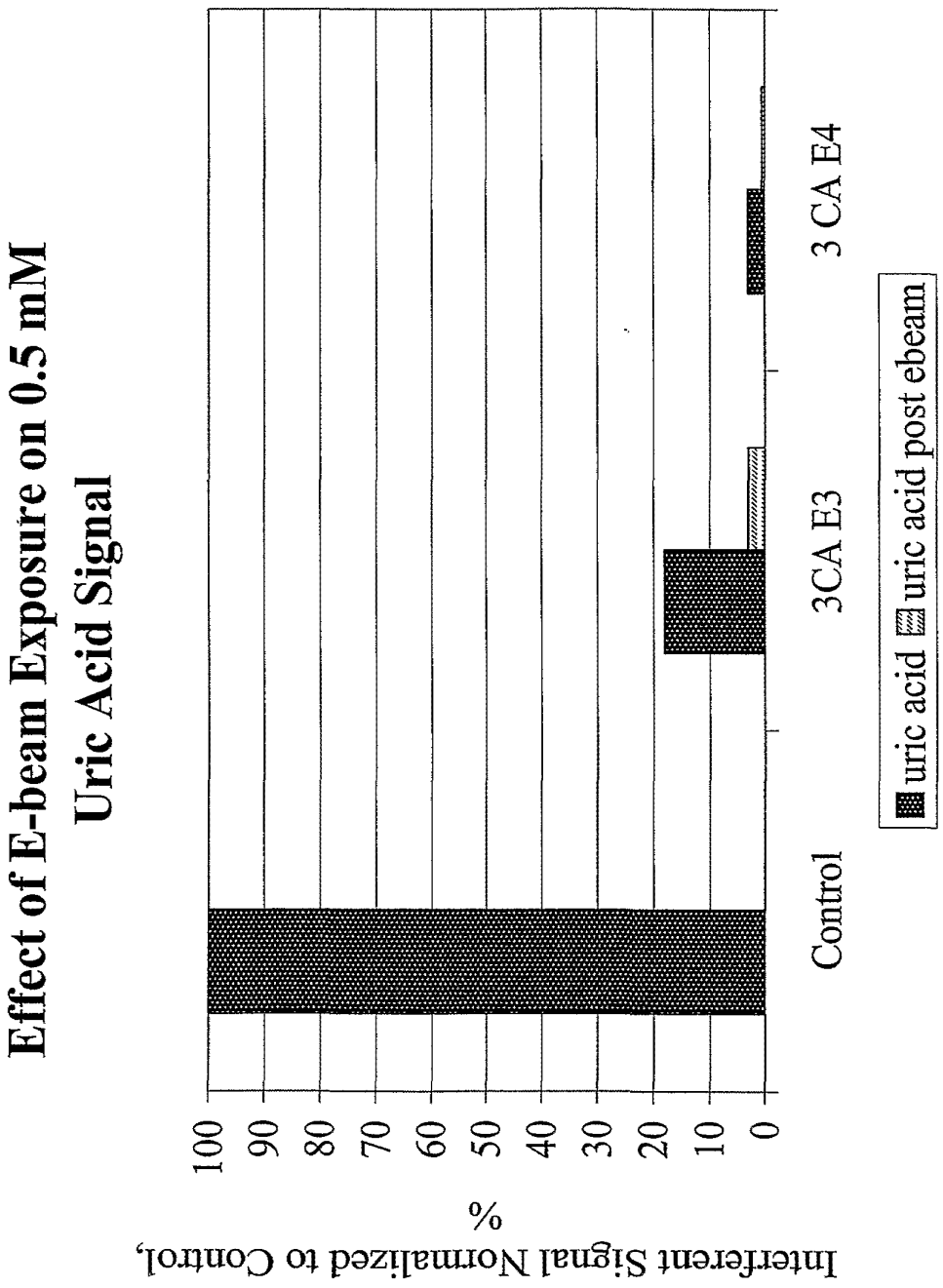

Effect of E-beam Exposure on 0.5 mM Uric Acid Signal
Interferent Signal Normalized to Control, %
100
90
80
70
60
50
40
30
20
10
0
Control
3CA E3
3 CA E4
uric acid
uric acid post ebeam

FIG.24A

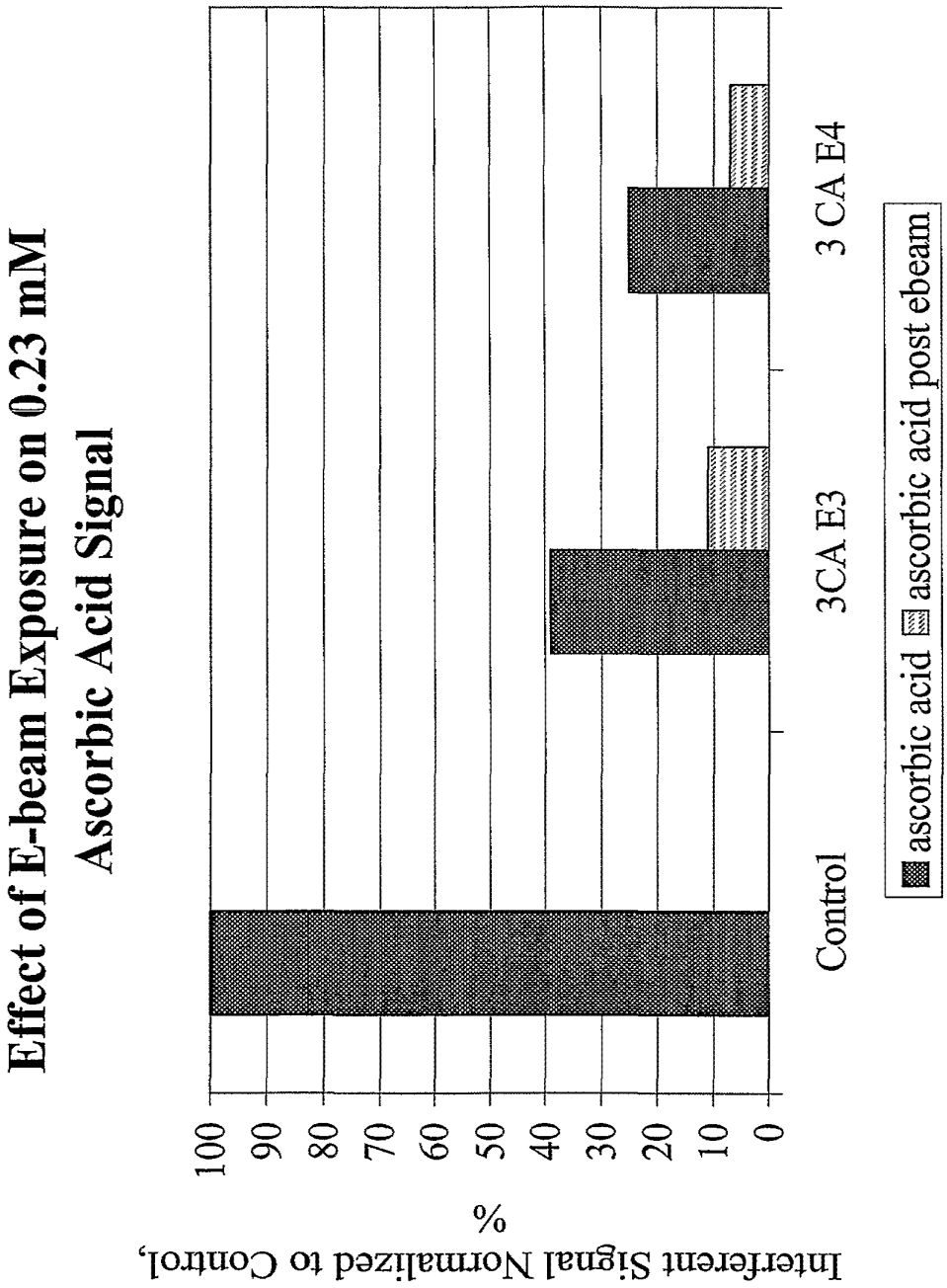

Effect of E-beam Exposure on 0.23 mM Ascorbic Acid Signal
Interferent Signal Normalized to Control, %
100
90
80
70
60
50
40
30
20
10
0
Control
3CA E3
3 CA E4
ascorbic acid
ascorbic acid post ebeam

FIG. 24B

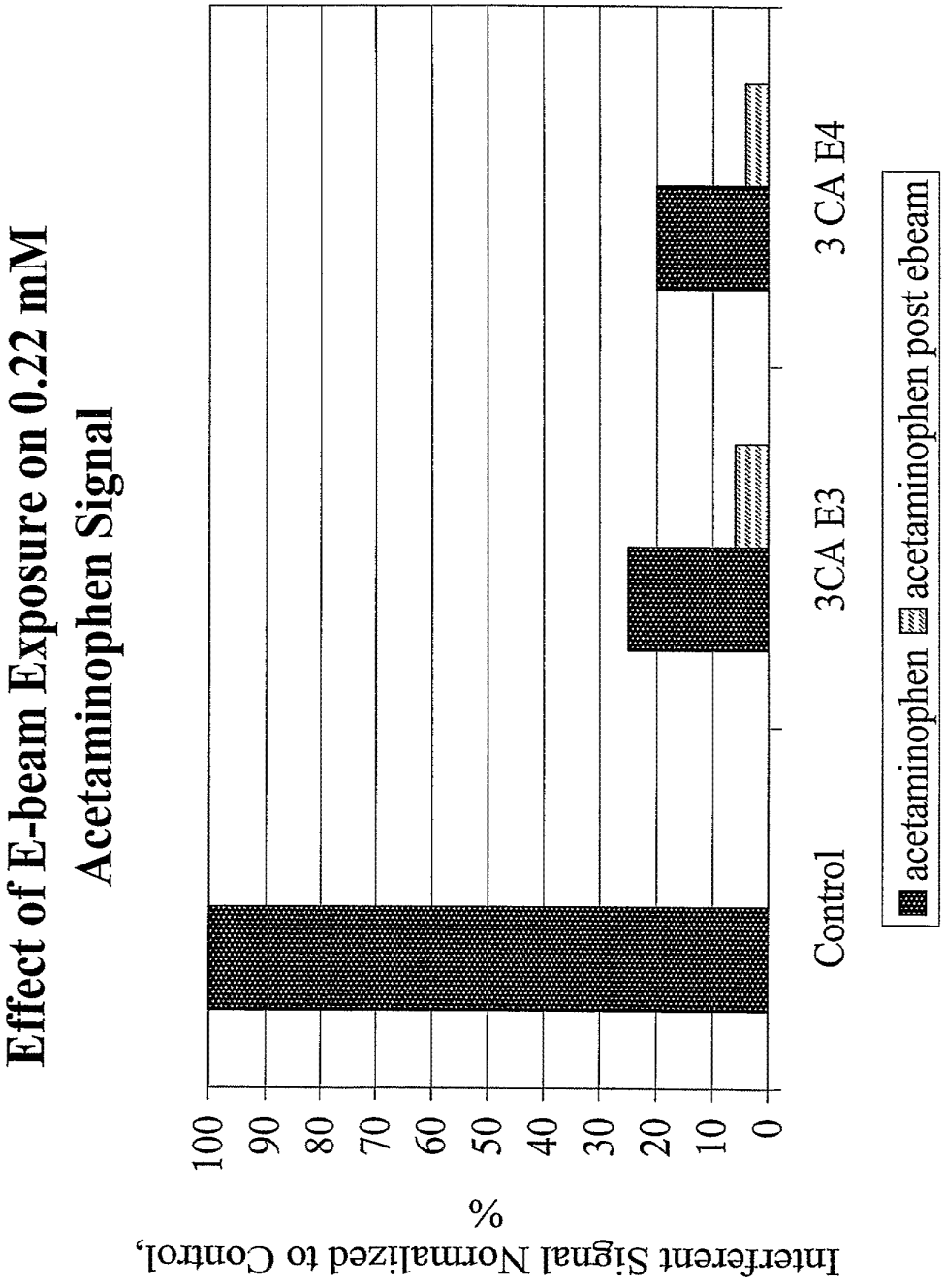

Effect of E-beam Exposure on 0.22 mM Acetaminophen Signal
Interferent Signal Normalized to Control, %
100
90
80
70
60
50
40
30
20
10
0
Control
3CA E3
3 CA E4
acetaminophen
acetaminophen post ebeam

FIG. 24C

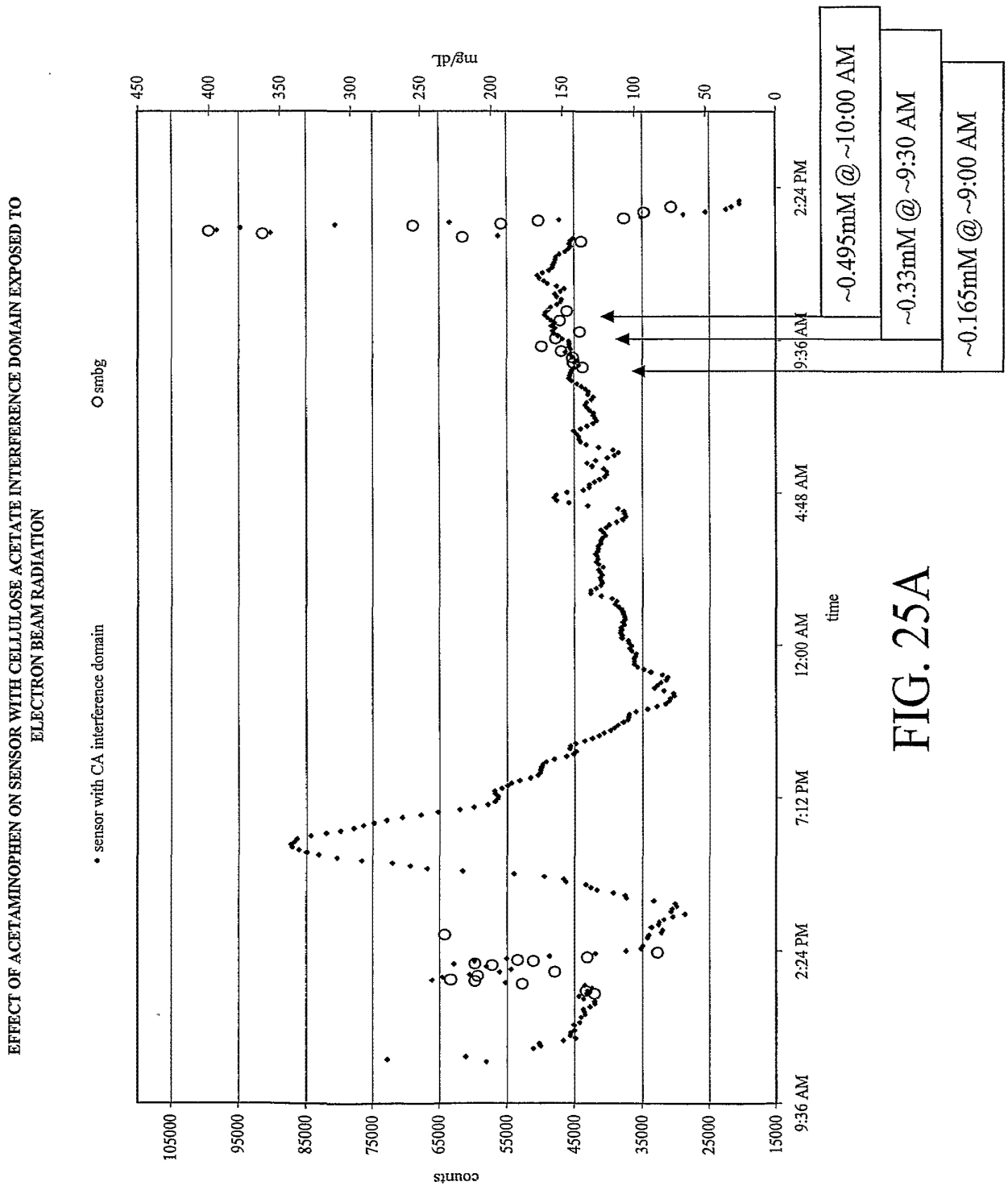

EFFECT OF ACETAMINOPHEN ON SENSOR WITH CELLULOSE ACETATE INTERFERENCE DOMAIN EXPOSED TO ELECTRON BEAM RADIATION
• sensor with CA interference domain
O smbg
counts
mg/dL
time
~0.495mM @ ~10:00 AM
~0.33mM @ ~9:30 AM
~0.165mM @ ~9:00 AM

FIG. 25A

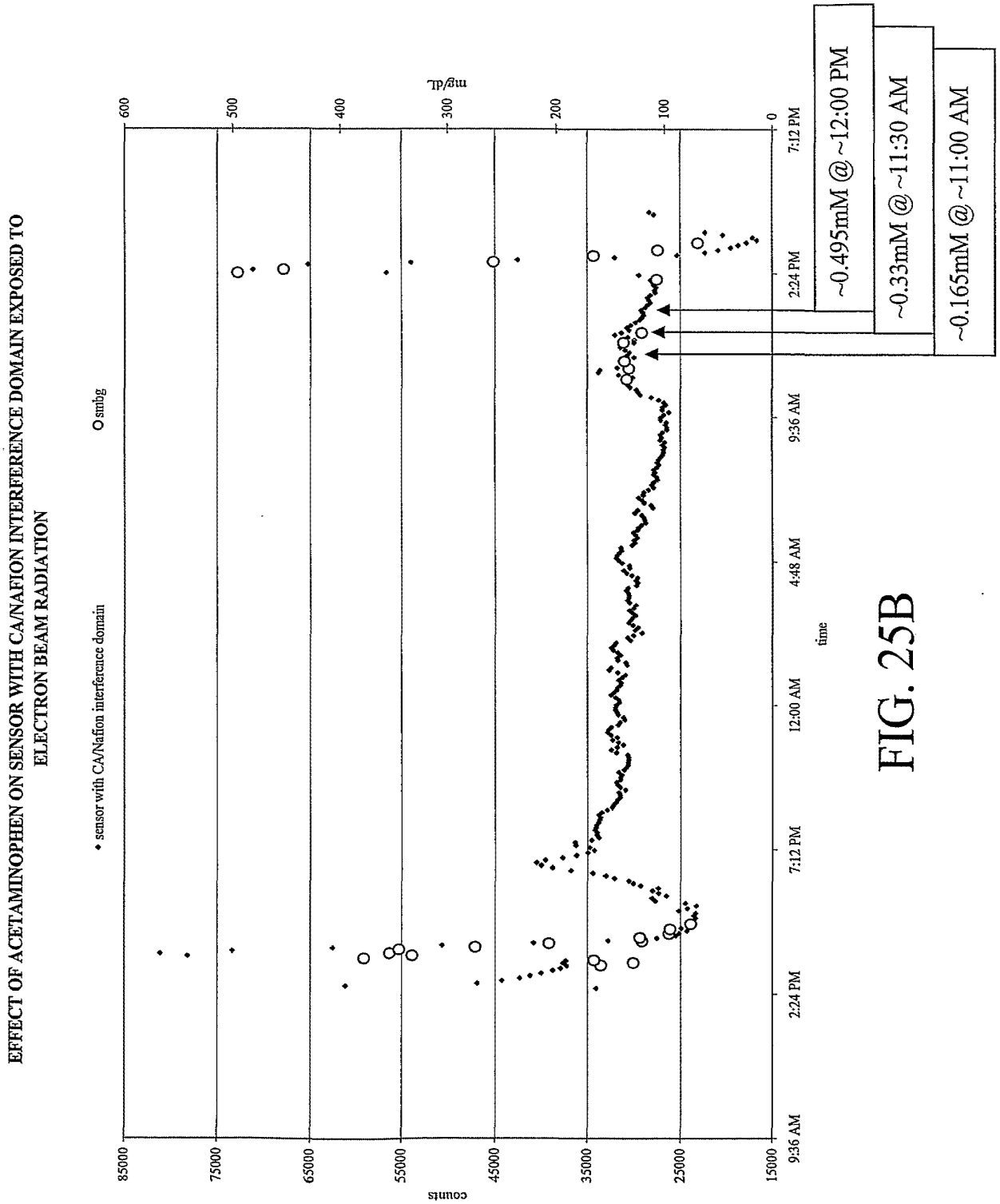

EFFECT OF ACETAMINOPHEN ON SENSOR WITH CA/NAFION INTERFERENCE DOMAIN EXPOSED TO ELECTRON BEAM RADIATION
sensor with CA/Nafion interference domain
smbg
counts
mg/dL
time
~0.495mM @ ~12:00 PM
~0.33mM @ ~11:30 AM
~0.165mM @ ~11:00 AM

FIG. 25B

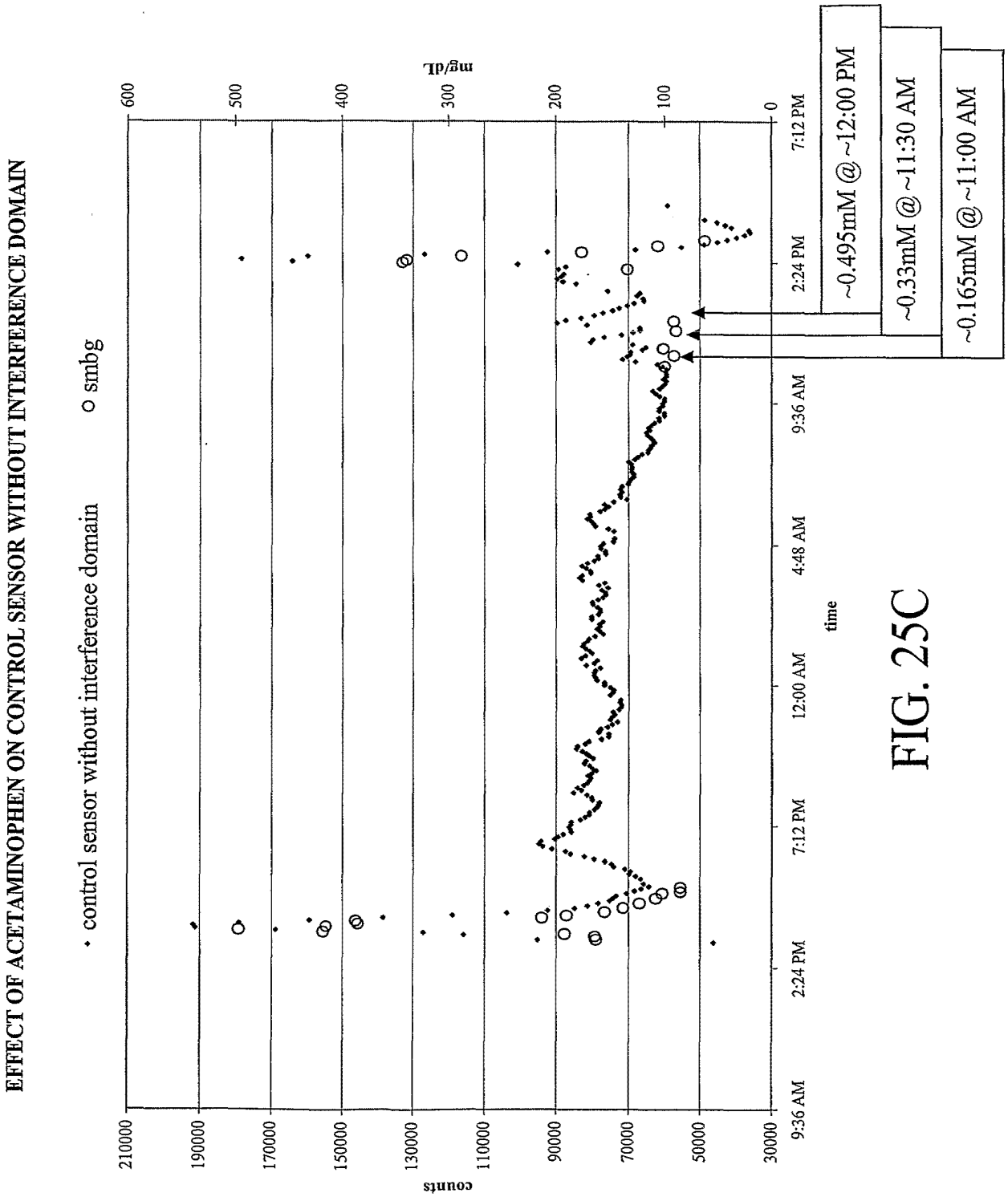

EFFECT OF ACETAMINOPHEN ON CONTROL SENSOR WITHOUT INTERFERENCE DOMAIN
• control sensor without interference domain
o smbg
counts
mg/dL
time
~0.495mM @ ~12:00 PM
~0.33mM @ ~11:30 AM
~0.165mM @ ~11:00 AM

FIG. 25C

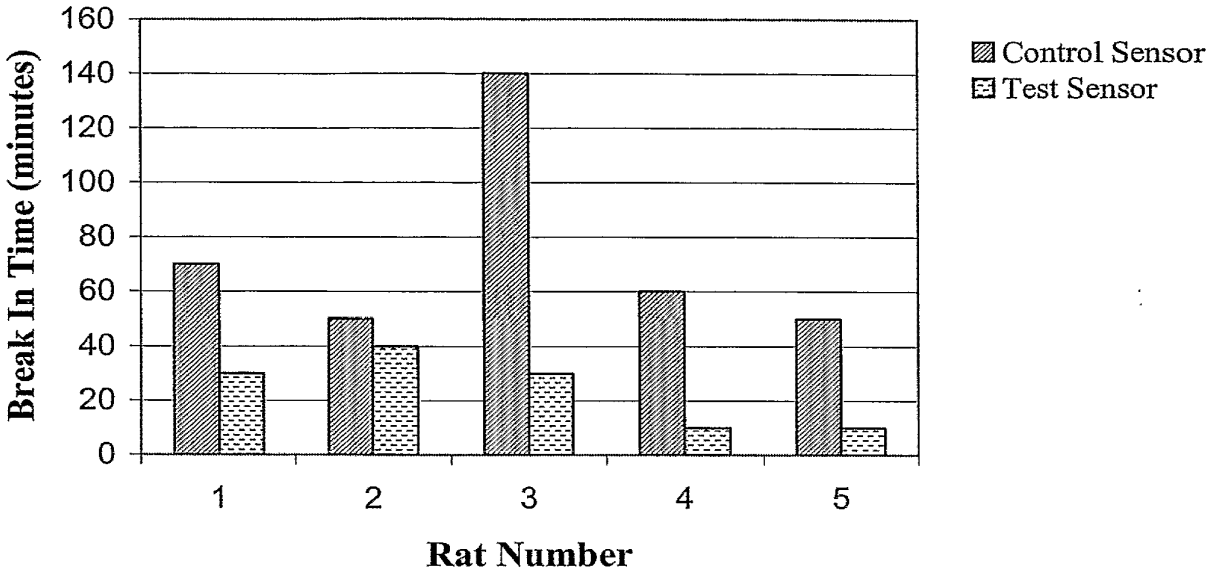


FIG.26A

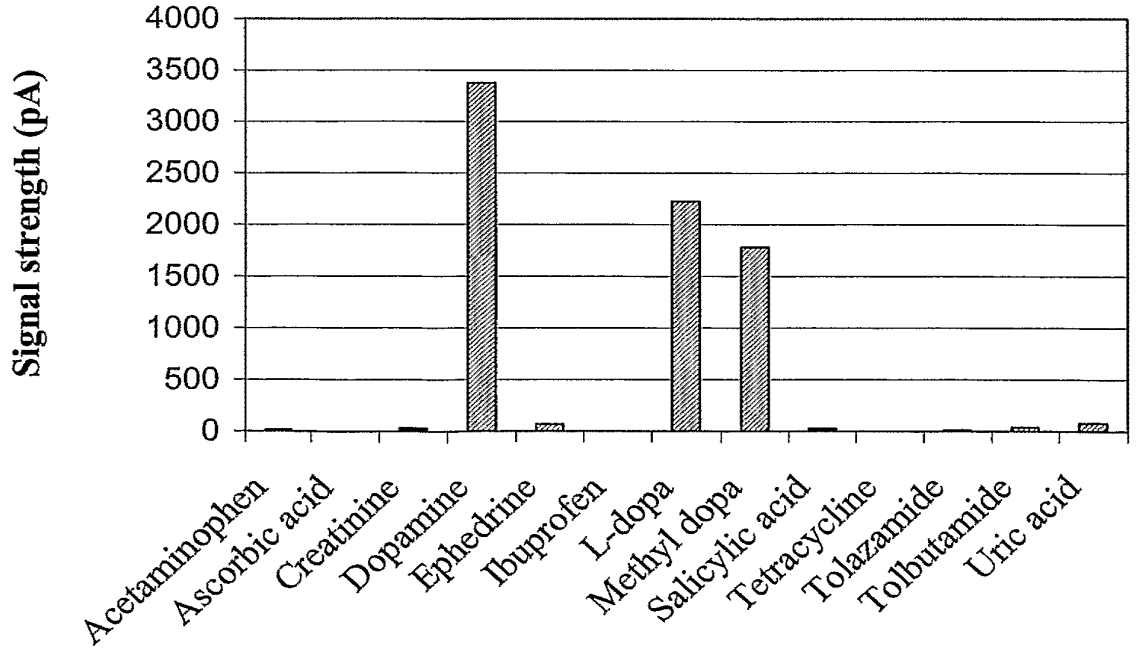


FIG. 26B

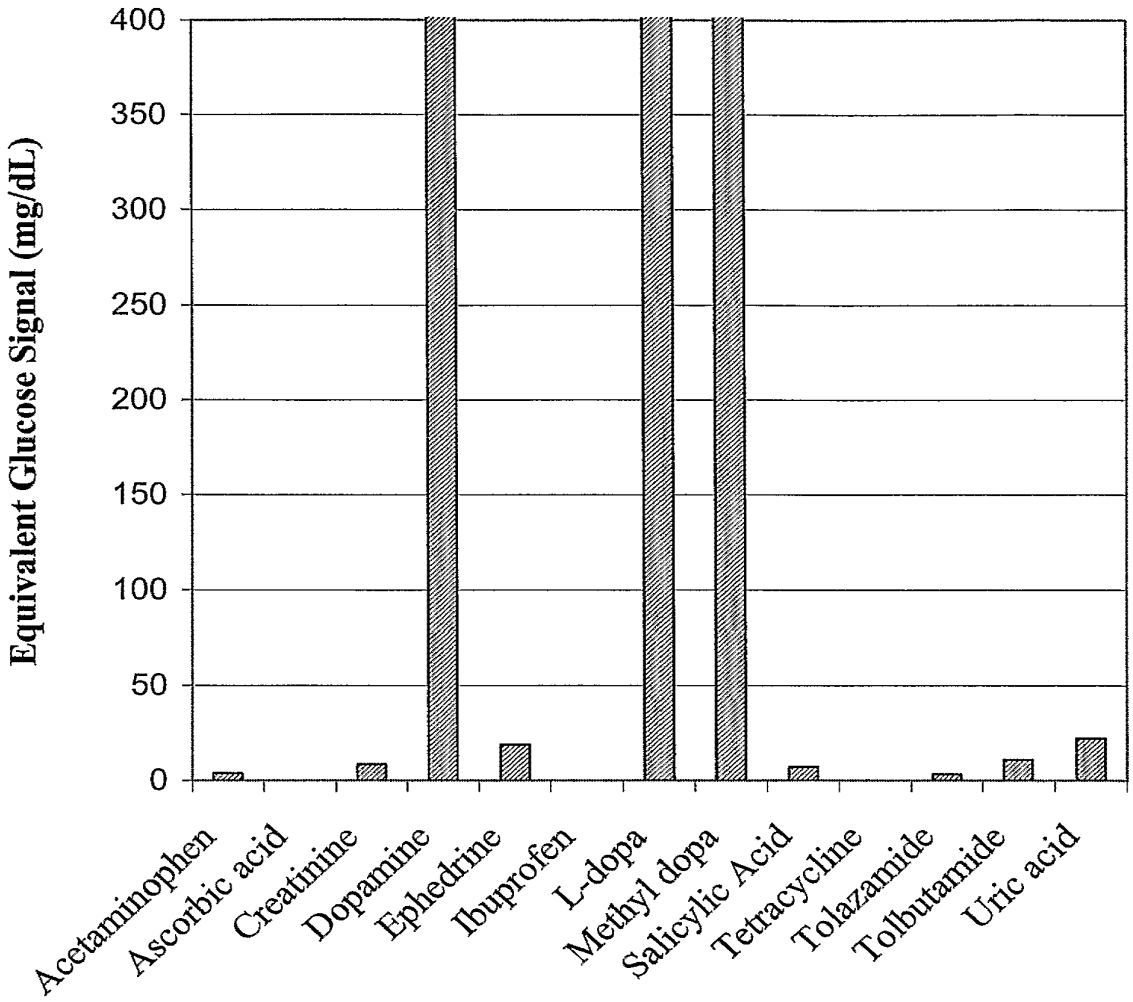

Equivalent Glucose Signal (mg/dL)
400
350
300
250
200
150
100
50
0
Acetaminophen
Ascorbic acid
Creatinine
Dopamine
Ephedrine
Ibuprofen
L-dopa
Methyl dopa
Salicylic Acid
Tetracycline
Tolazamide
Tolbutamide
Uric acid

FIG. 26C

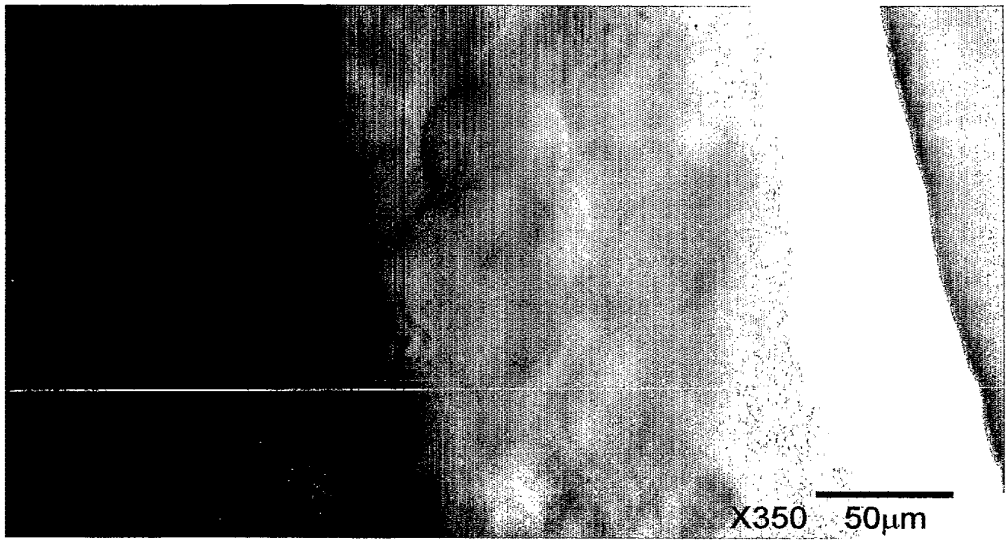


FIG. 27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/06574

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **A61B 5/00**(2006.01),**5/05**(2006.01);**C12M 1/00**(2006.01),**1/40**(2006.01),**1/42**(2006.01);**C25B 9/00**(2006.01);**G01N 27/26**(2006.01),**33/52**(2006.01),**33/49**(2006.01)

USPC: 600/345,347,365;204/403.01,403.05,403.1,415

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)
U.S. : 600/345,347,365; 204/403.01, 403.05, 403.1, 415

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2006/0016700 A1 (BRISTER et al.) 26 January 2006 (26.01.2006), figs. 1-14; paragraphs 97-182, 191-222, 238-285,371-385	1,5-14, 16, 17, 20-26, 30, 31, 34-47, 49, 52-59, 71, 73, 74, 76-83, 85, 86, 95-101, 104, 106-111, 114-132 --- 2-4, 18, 19, 48, 103, 103, 112, 113, 60-70, 72, 75, 84, 87, 88-94
A	US 64989941 B1 (JACKSON) 24 December 2002 (24.12.2002), entire document	15, 27-29, 32, 33, 50, 51, 105

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent 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
25 June 2006 (25.06.2006)

Date of mailing of the international search report
04 AUG 2006

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/06574

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- A	US 6045671 (WU et al.) 04 April 2000 (04.04.2000), col. 11, lines 1-34.	18, 19 --- 15
Y	US 6,520,326 B2 (McIVOR et al.) 18 February 2003 (18.02.2003), figure 9; col. 7, lines 42-51.	48,102,103,112,113
Y	US 4,675,346 A (LIN et al.) 23 June 1987 (23.06.1987), entire document	60-70,72,88-94
Y	US 2006/0001550 A1 (MANN et al.) 05 January 2006 (01.05.2006), figs. 2, 6, 7; paragraphs 27, 35, 36.	65
Y	US 6,498,941 B1 (JACKSON) 24 December 2002 (24.12.2002), col. 5, lines 60-65	75
Y	US 5,673,694 A (RIVERS) 07 October 1997 (07.10.1997), col. 5, lines 52-56	84, 87
Y	US 4,286,039 A (LANDA et al.) 25 August 1981 (25.08.1981), col. 4, lines 37-46.	88-94

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/06574

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 133-144
because they relate to subject matter not required to be searched by this Authority, namely:
Please See Continuation Sheet

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Box II Observations where certain claims were found unsearchable 1. because they relate to subject matter not required to be searched by this Authority, namely:
Claims 133 recites the limitation "on-skin housing" and "on-skin housing is adhered to the skin". Claim141 recites the limitation "on-skin housing" In both cases, the human skin, being a part of the human body, is non-statuttory subject matter and cannot positvely be claimed.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 February 2008 (21.02.2008)

PCT

(10) International Publication Number
WO 2008/021913 A2

(51) International Patent Classification:
A61B 5/05 (2006.01)

(21) International Application Number:
PCT/US2007/075522

(22) International Filing Date: 8 August 2007 (08.08.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/463,582 9 August 2006 (09.08.2006) US

(71) Applicant *(for all designated States except US)*: **ABBOTT DIABETES CARE, INC.** [US/US]; 1360 South Loop Rod, Alameda, CA 94502 (US).

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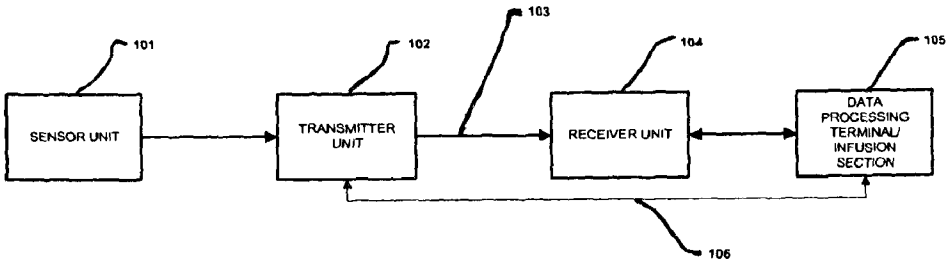
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(54) **Title:** METHOD AND SYSTEM FOR PROVIDING CALIBRATION OF AN ANALYTE SENSOR IN AN ANALYTE MONITORING SYSTEM



(57) **Abstract:** Method and apparatus for providing calibration of analyte sensor including applying a control signal, detecting a measured response to the control signal, determining a variance in the detected measured response, and estimating a sensor parameter based on the variance in the detected measured response is provided.

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METHOD AND SYSTEM FOR PROVIDING CALIBRATION OF AN ANALYTE SENSOR IN AN ANALYTE MONITORING SYSTEM

PRIORITY

This PCT Application claims priority to United States Patent Application No. 11/463,582, filed August 9, 2006 titled "Method and System for Providing Calibration of an Analyte Sensor in an Analyte Monitoring System", and is hereby incorporated by reference.

BACKGROUND

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

To obtain accurate data from the analyte sensor, calibration is necessary. Typically, blood glucose measurements are periodically obtained using, for example, a blood glucose meter, and the measured blood glucose values are used to calibrate the sensors. Indeed, the patient must calibrate each new analyte sensor using for example, capillary blood glucose measurements. This may be inconvenient for the patient.

In view of the foregoing, it would be desirable to have a method and system for calibrating analyte sensors of an analyte monitoring system that does not inconveniently require periodic blood glucose measurements for sensor calibration.

SUMMARY OF THE INVENTION

In view of the foregoing, in accordance with the various embodiments of the present invention, there is provided a method and system for providing substantially automatic and substantially real time calibration of analyte sensors for use in an analyte monitoring system.

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

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a block diagram of a data monitoring and management system for practicing one embodiment of the present invention;

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 invention;

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 invention;

FIG. 4 is a flowchart illustrating analyte sensor sensitivity estimation procedure in accordance with one embodiment of the present invention;

FIG. 5 is a flowchart illustrating the analyte sensor sensitivity estimation procedure in accordance with another embodiment of the present invention;

FIG. 6 is a flowchart illustrating an analyte sensor parameter estimation procedure in accordance with one embodiment of the present invention;

FIG. 7A illustrates the transmission of the control signal from the transmitter processor in accordance with one embodiment of the present invention;

FIG. 7B illustrates the measured response to the control signal from the transmitter processor shown in FIG. 7A in accordance with one embodiment of the present invention;

FIG. 8 is a tabular illustration of a lookup table for sensor sensitivity for use with the calibration procedure in accordance with one embodiment of the present invention; and

FIG. 9 is a flowchart illustrating the analyte sensor sensitivity estimation procedure in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION

As described in detail below, in accordance with the various embodiments of the present invention, there is provided a method and system for determining sensor sensitivity of an analyte sensor which may be used to calibrate the analyte sensor in the analyte monitoring system. In particular, within the scope of the present invention, there is provided method and system for automatically calibrating subcutaneous or transcutaneously positioned analyte sensors such that the frequency of capillary blood glucose measurement for calibration of the sensors may be minimized.

More specifically, 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 invention. 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.

Analytes that may be monitored include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be monitored.

The analyte monitoring system 100 includes a sensor 101, a transmitter unit 102 coupled to the sensor 101, and a receiver unit 104 which is configured to communicate with the transmitter unit 102 via a communication link 103. The receiver unit 104 may be further configured to transmit data to a data processing terminal 105 for evaluating the data received by the receiver unit 104. Moreover, the data processing terminal in one embodiment may be configured to receive data directly from the transmitter unit 102 via a communication link 106 which may optionally be configured for bi-directional communication.

Only one sensor 101, transmitter unit 102, receiver unit 104, communication link 103, and data processing terminal 105 are shown in the embodiment of the analyte monitoring system 100 illustrated in FIG. 1. However, it will be appreciated by one of ordinary skill in the art that the analyte monitoring system 100 may include one or more sensor 101, transmitter unit 102, receiver unit 104, communication link 103, and data processing terminal 105. Moreover, within the scope of the present invention, the analyte monitoring system 100 may be a continuous monitoring system, or semi-continuous, or a discrete monitoring system. In a multi-component environment, each device is configured to be uniquely identified by each of the other devices in the system so that communication conflict is readily resolved between the various components within the analyte monitoring system 100.

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

In one embodiment, the analyte monitoring system 100 is configured as a one-way RF communication path from the transmitter unit 102 to the receiver unit 104. In

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

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

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

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

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

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

In this embodiment, the data processing terminal 105 which may include an insulin pump, may be configured to receive the analyte signals from the transmitter unit 102, and thus, incorporate the functions of the receiver 103 including data processing for managing the patient's insulin therapy and analyte monitoring. In one embodiment, the communication link 103 may include one or more of an RF

communication protocol, an infrared communication protocol, a Bluetooth enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPPA requirements) while avoiding potential data collision and interference.

FIG. 2 is a block diagram of the transmitter of the data monitoring and detection system shown in FIG. 1 in accordance with one embodiment of the present invention. Referring to the Figure, the transmitter unit 102 in one embodiment includes an analog interface 201 configured to communicate with the sensor 101 (FIG. 1), a user input 202, and a temperature detection 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, guard contact, reference electrode, and counter electrode, each operatively coupled to the analog interface 201 of the transmitter unit 102 for connection to the sensor unit 201 (FIG. 1). In one embodiment, each of the work electrode, guard contact, reference electrode, and counter electrode may be made using a conductive material that is either printed or etched, for example, such as carbon which may be printed, or metal foil (e.g., gold) which may be etched.

Further shown in FIG. 2 are a transmitter serial communication section 205 and an RF transmitter 206, each of which is also operatively coupled to the transmitter processor 204. Moreover, a power supply 207 such as a battery is also provided in the transmitter unit 102 to provide the necessary power for the transmitter unit 102. Additionally, as can be seen from the Figure, clock 208 is provided to, among others, supply real time information to the transmitter processor 204.

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

analog interface 201 to serial communication section 205, thereafter to the processor 204, and then to the RF transmitter 206. As such, in one embodiment, via the data path described above, the transmitter unit 102 is configured to transmit to the receiver unit 104 (FIG. 1), via the communication link 103 (FIG. 1), processed and encoded data signals received from the sensor 101 (FIG. 1). Additionally, the unidirectional communication data path between the analog interface 201 and the RF transmitter 206 discussed above allows for the configuration of the transmitter unit 102 for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

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

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

Moreover, as shown in FIG. 2, while the power supply unit 207 is shown as coupled to the processor 204, and as such, the processor 204 is configured to provide

control of the power supply unit 207, it should be noted that within the scope of the present invention, the power supply unit 207 is configured to provide the necessary power to each of the components of the transmitter unit 102 shown in FIG. 2.

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

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

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

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 invention. Referring to FIG. 3, the receiver unit 104 includes a blood glucose

test strip interface 301, an RF receiver 302, an input 303, a temperature detection section 304, and a clock 305, each of which is operatively coupled to a receiver processor 307. As can be further seen from the Figure, the receiver unit 104 also includes a power supply 306 operatively coupled to a power conversion and monitoring section 308. Further, the power conversion and monitoring section 308 is also coupled to the receiver processor 307. Moreover, also shown are a receiver serial communication section 309, and an output 310, each operatively coupled to the receiver processor 307.

In one embodiment, the test strip interface 301 includes a glucose level testing portion to receive a manual insertion of a glucose test strip, and thereby determine and display the glucose level of the test strip on the output 310 of the 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 receiver unit 104 is configured to allow the user to enter information into the 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 receiver unit 104 to the receiver processor 307, while the clock 305 provides, among others, real time information to the receiver processor 307.

Each of the various components of the 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 receiver unit 104 for effective power management and to alert the user, for example, in the event of power usage which renders the 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 receiver unit 104) is turned on. Moreover, the power conversion and monitoring section 308 may additionally be configured to include a reverse polarity protection circuit such as a field effect transistor (FET) configured as a battery activated switch.

The serial communication section 309 in the 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 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 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 receiver unit 104 also includes an electro-luminescent lamp configured to provide backlighting to the output 310 for output visual display in dark ambient surroundings.

Referring back to FIG. 3, the 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 receiver unit 104, operatively coupled to the processor 307. The processor 307 is further configured to perform Manchester decoding as well as error detection and correction upon the encoded data signals received from the transmitter unit 102 via the communication link 103.

Referring back to the Figures, as described in further detail below, in one embodiment of the present invention, the transmitter processor 204 may be configured to transmit a control signal to the analog interface 201 to determine the poise voltage between the work electrode and the reference electrode of the sensor unit 101, each of which are operatively coupled to the analog interface 201 of the transmitter unit 102.

More specifically, in one embodiment, a control processor component of the transmitter unit 102 processor 204 is configured to provide a perturbation control signal to the analog interface 201. The analog interface 201 is configured to translate the received perturbation control signal to a perturbation that affects the sensor response. For example, the control signal in one embodiment may be configured to control the voltage level that is applied to the sensor 101 between the work and reference electrodes (i.e., the poise voltage). In one embodiment, the analog interface 201of the transmitter unit 102 is configured to translate the sensor response to the perturbation to a corresponding response signal that is acquired by the signal processing component of the processor 204 of the transmitter unit 102. The signal processing component of the processor 204 in the transmitter unit 102 in one embodiment may be configured to determine the desired sensor parameter estimation which is transmitted to the receiver unit 104. Alternatively, the signal processing component of the processor 204 in the transmitter unit 102 may be configured to preprocess the data, which are then transmitted to the receiver unit for sensor parameter estimation determination.

More specifically, FIG. 4 is a flowchart illustrating analyte sensor sensitivity estimation procedure in accordance with one embodiment of the present invention. Referring to FIG. 4, at step 410, the transmitter processor 204 (FIG. 2) in one embodiment is configured to provide a control signal to the analog interface 201 (for example a poise voltage control circuit) of the transmitter unit 102. In one aspect, the control signal provides a perturbation input to determine the poise voltage between the work electrode and the reference electrode of the sensor unit 101. In one aspect, the poise voltage may be in the range of approximately -600 mV and 600 mV, and the analog interface 201 may be configured to control the poise voltage and apply the poise voltage to the electrodes of the sensor unit 101.

One embodiment of the control signal perturbations is shown in FIG. 7A which illustrates the control signal from the transmitter processor 204 so as to provide a poise voltage waveform that is a square wave of 50% duty cycle with a one minute time period interval. In one embodiment, the poise voltage square wave amplitude

may be switched from 40mV to -600mV from, for example, the normal operating poise voltage to a predetermined level such as -600 mV which effectively shuts down the current signal on the work electrode.

Referring back to FIG, 4, at step 420, the analog interface 201 in one embodiment is configured to determine a measured response to the received control signal, for example, a voltage signal which is substantially proportional to the current signal level on the work electrode of the sensor unit 101. An aspect of the measured response is illustrated in FIG. 7B. As shown, in one aspect, the current signal level is associated with the analyte level of the patient and may be modulated by the poise voltage perturbations driven by the control signal from the transmitter processor 204. Thereafter at step 430, the transmitter processor 204 may be optionally configured to synchronize the measured response from the analog interface 201 with the control signal. The transmitter processor 204 may be further configured to store the measured response and the associated control signal in a storage unit (not shown) such as a memory device.

Referring again to FIG. 4, the transmitter processor 204 in one embodiment is configured to determine the difference or variance in the measured response based on the control signal, and the sensor sensitivity may be determined based on the determined difference in measured response. That is, in one embodiment, the difference in measured response is compared to a look up table stored, for example, in the transmitter processor 204 memory unit which includes calculated measured response difference for the sensor based on characteristics of the sensor unit 101.

By way of an example, for a measured response difference of 47 analog to digital counts, the lookup table for sensor sensitivity (FIG. 8) indicates 34.5pA/(mg/dL) for the sensor. Then, the determined sensor sensitivity may be applied to the work electrode current to determine the corresponding calibrated analyte value. That is, the calibrated analyte value may be determined by dividing the work electrode current signal by the sensor sensitivity.

FIG. 5 is a flowchart illustrating the analyte sensor sensitivity estimation procedure in accordance with another embodiment of the present invention.

Referring to FIG. 5, at step 510, a perturbation control signal is applied to the sensor 101 (FIG. 1), and then the response to the perturbation control signal is measured at step 520. Based on the measured response to the perturbation control signal, at step 530 the sensor parameter(s) is estimated and at step 540, the analyte level is estimated based on the measured response to the perturbation control signal. In one embodiment, the procedure shown in FIG. 5 is repeated continuously.

In accordance with the various embodiments of the present invention, different estimates may be determined including, for example, estimation of sensor properties such as sensitivity and response time, the analyte level, and analyte level validity/accuracy. In one embodiment, there are several mechanisms that may be used to perturb the sensor 101 (FIG. 1), for example, the variable poise voltage. In a further aspect, the one or more of the perturbation control signals may include, for example, square waves. Also, in one aspect, the one or more physical sensor responses that is measured may include, for example, work electrode current variation due to poise voltage perturbation. In addition, signal processing may be used in one embodiment to estimate the sensor parameter or analyte level from the sensor response to the perturbation as described above.

FIG. 6 is a flowchart illustrating an analyte sensor parameter estimation procedure in accordance with one embodiment of the present invention. Referring to FIG. 6, a control signal is applied, for example, to the analog interface 201 of the transmitter unit 102 (FIG. 1). That is, in one embodiment, the processor 204 of the transmitter unit 102 may be configured to provide a control signal to a poise voltage control circuit (for example, incorporated in the processor 204 of the transmitter unit 102 as shown in FIG. 2, but which may, in one embodiment, may be separately provided within the transmitter unit 102) of the transmitter unit 102.

In one aspect, the control signal may be configured to provide a perturbation input signal to determine the poise voltage between the work electrode and the reference electrode of the sensor unit 101. In one embodiment, the poise voltage may be in the range of approximately -600 mV and 600 mV, and the analog interface 201

may be configured to control the poise voltage and apply the poise voltage to the electrodes of the sensor unit 101.

As described in further detail below, an embodiment of the control signal perturbations is shown in FIG. 7A which illustrates the control signal from the processor 204 (FIG. 2) to provide a poise voltage waveform that is a square wave of 50% duty cycle with a one minute time period interval. Referring to FIG. 7A, in one embodiment, the poise voltage square wave amplitude may be switched from 40mV to -600mV from, for example, the normal operating poise voltage to a predetermined level such as -600 mV which effectively shuts down the current signal on the work electrode.

Referring back to FIG 6, the analog interface 201 in one embodiment is configured to determine a measured response to the received control signal, for example, a voltage signal which is substantially proportional to the current signal level on the work electrode of the sensor unit 101 (FIG. 1). As discussed in further detail below, one embodiment of the measured response is shown in FIG. 7B. Referring to FIG. 7B, in one embodiment, the average signal level for half of the duty cycle is associated with the analyte level of the patient, but the transient within the half-duty cycle period, caused by the poise voltage perturbations driven by the control signal from the transmitter processor 204, is associated with the sensitivity parameter of the sensor 101. The transmitter processor 204 may be further configured to store the measured response and the associated control signal in a storage unit (not shown) such as a memory device.

Referring again to FIG. 6, the transmitter processor 204 in one embodiment is configured to determine the amplitude difference of the transient from the start of the half-duty cycle to the end (referred to sometimes as the "on" period) in the measured response, and the sensor sensitivity may be determined based on the determined difference in the response. That is, in one embodiment, the difference in measured response is compared to a predetermined sensor parameter such as sensor sensitivity that may be stored in a look up table, for example, in the transmitter processor 204 memory unit. In one aspect, the look up table may include a calculated measured

response difference for the sensor unit 101 and corresponding sensor sensitivities based on characteristics of the sensor unit 101.

By way of an example, for a measured response difference of 47 analog to digital counts, the lookup table for sensor sensitivity as shown in FIG. 8 indicates 34.5pA/(mg/dL) for the sensor. In one embodiment, the transmitter may be configured to determine this sensitivity value once per minute, and to transmit the sensitivity value it to the receiver unit 104 (FIG. 1) in addition to data or signal corresponding to the work current signal level, determined at the end of the "on" period, and skin temperature.

In one embodiment, the receiver unit 104 (FIG. 1) may be configured to apply the determined sensor sensitivity to the temperature compensated work electrode current signal in order to determine the corresponding calibrated analyte value or level. That is, the calibrated analyte value may be determined by dividing the temperature compensated work electrode current signal by the determined sensor sensitivity. In one aspect, a time-series of the calibrated analyte values may be acquired by the receiver unit 104 (FIG. 1) in real-time, and may be used to determine analyte rate-of-change and other analyte signal metrics and/or statistics. In addition, the calibrated analyte values may also be used to drive alarms or alerts that inform the patient whose analyte is being monitored of analyte level conditions that require attention. In addition, in accordance with one aspect of the present invention, the receiver unit 104 may be configured to determine whether the sensor sensitivity range is within a valid range.

FIG. 7A illustrates the transmission of the control signal from the transmitter processor in accordance with one embodiment of the present invention. More particularly, FIG. 7A illustrates the poise voltage square wave with 50% duty cycle with one minute time periods is shown, where the poise voltage square wave amplitude is switched from 40 mV to -600 mV as in normal operating mode. FIG. 7B illustrates the measured response to the control signal from the transmitter processor shown in FIG. 7A in accordance with one embodiment of the present invention. More specifically, the measured response which is associated with the analyte level

measured by the sensor unit 101 from the interstitial fluid of a patient as modulated by the control signal from the transmitter processor 204 is illustrated with one minute time periods

FIG. 8 is a tabular illustration of a lookup table for sensor sensitivity for use with the calibration procedure in accordance with one embodiment of the present invention. More specifically, in one embodiment, the lookup table shown in FIG. 8 is stored in a memory unit (not shown) of the transmitter unit 102 (or alternatively, in the transmitter processor 204) and may be accessed by the transmitter processor 204 to retrieve a corresponding sensitivity value associated with the determined measured response difference.

FIG. 9 is a flowchart illustrating the analyte sensor sensitivity estimation procedure in accordance with another embodiment of the present invention. Referring to FIG. 9, in one embodiment, a control signal from the transmitter processor 204 (FIG. 2) is provided to the transmitter unit 102 analog interface 201, and a response to the applied control signal is determined. Thereafter, the difference or variance in the determined response to the control signal between the beginning and end of the half duty cycle is determined. As can be seen, in one embodiment, steps 910 to 930 are substantially similar to steps 610 to 630, respectively described above.

Referring back to FIG. 9, after determining the measured response variance or difference between the beginning and end of the half duty cycle, it is determined whether the number of transmitted or applied control signals exceed a predetermined number or count. If it is determined that the number of transmitted or applied control signals do not exceed the predetermined number or count, then a control signal counter (for example, provided in the transmitter unit 102) is incremented by one count, and the routine returns to the beginning where another control signal is provided to the analog interface 201 of the transmitter unit 102.

On the other hand, if it is determined that the number of transmitted or applied control signals exceed the predetermined number or count, then the sensor sensitivity may be determined based on the determined difference in the response. That is, as

discussed above, the difference in measured response in one embodiment is compared to a predetermined sensor parameter such as sensor sensitivity that may be stored in a look up table, for example, in the transmitter processor 204 memory unit. In one aspect, the look up table may include a calculated measured response difference for the sensor and corresponding sensor sensitivities based on characteristics of the sensor. Furthermore, as discussed above, in one embodiment, the calibrated analyte value or level may be determined by, for example, dividing the corresponding sensor signal (e.g., work electrode current signal) level by the determined sensor sensitivity value.

Within the scope of the present invention, the perturbations to the analyte sensors may be provided by, for example, altering the poise voltage in time. Alternatively, an additional electrical current signal may be provided to the sensor work or counter electrodes via an AC coupling, where the level of the additional electrical current signal may be varied in time by the control signal in a manner similar as discussed above. Still in accordance with another embodiment, the work/counter electrode current path may be opened and closed in a time varying manner controlled by the control signal. Yet still another embodiment may provide a variable resistance in the work/counter electrode current path, where the variable resistance is varied in time as controlled by the control signal.

In another aspect of the present invention, the transcutaneously positioned sensor may be perturbed with a mechanical transducer controlled in time and amplitude by a predetermined control signal. In one embodiment, mechanical transducers may include those that can provide physical signals of vibration, acoustics, thermal or electro-magnetic media, for example. Broadly, any suitable mechanism to apply perturbations to the transcutaneously positioned sensor may be used to the extent that the measured response may be analyzed by the signal processing component such as, for example, the transmitter unit processor 204 to estimate one or more sensor properties based on the signal response induced by the perturbations. For example, vibration perturbations may induce fluctuations in the sensor membrane that could be detected in the measured response transients, which

may be correlated with membrane thickness and thus provide a measure of the sensitivity of the sensor.

In addition, in accordance with the various embodiments of the present invention, there are provided a variety of time-varying controls signals that may be applied, along with a variety of techniques used to analyze the measured response and estimate the sensor parameter of interest. Some of these control signals may be appropriate to induce a measured response that is more informative about a specific sensor parameter than other control signals, and some control signals may be more practical to implement than others. As discussed previously, a square-wave control signal may be employed in one embodiment. Variations in this type of control signal may be suitably used where the positive and negative amplitudes are at different levels, the duty cycle is other than 50%, or the period is other than 1 minutes.

In another embodiment of the present invention, a feedback mechanism may be provided where the duty cycle is varied to achieve a desired response, such as a specific transient response time. In this case, the final duty cycle is the parameter that is correlated with the sensor parameter to be estimated. This feedback technique may be extended to other types of control signals, mentioned below, and other characteristics of the signal such as phase, amplitude and frequency may be varied to achieve a desired response.

Alternatively, a sine wave may be used as the control signal discussed above rather than a square wave. Still alternatively, a series of sine waves at different frequencies, or a chirp signal may be used as control signals in one embodiment of the present invention. The measured response of these perturbation signals may then be analyzed using standard spectral analysis techniques. Based on the spectral analysis, metrics may be determined that are correlated with the sensor parameter to be estimated.

In accordance with yet another embodiment, an impulse signal, or a series of impulse signals may be alternatively used as control signals. The measured response of these perturbation signals may be analyzed using known impulse response analysis techniques. For example, the maximum height of the measured response may be used

to determine the associated sensor sensitivity. Alternatively, other signal metrics such as the time to reach the maximum height of the measured response, the area under the curve of the measured response, the slope of the measured response may be correlated with the sensor parameter to be estimated.

In still another embodiment, psuedo-random modulation similar to those used in spread-spectrum communication systems may be used as the control signals. The measured response of these perturbation signals may be analyzed using known spread-spectrum analysis techniques. Based on this analysis, metrics may be determined that are correlated with the sensor parameter to be estimated. In addition, the response signal may be demodulated using spread-spectrum techniques to recover the analyte level.

For some of the control signal/response measurement analysis techniques discussed above, the relative phase between the control signal and the measured response may be used to analyze the measured response to the perturbation. For some of the control signal/response measurement analysis techniques discussed above, multiple metrics may be determined. One or more of these metrics may be used to estimate the sensor parameter of interest. For example, in one embodiment, a multidimensional table lookup may be used where one dimension includes the sensor parameter of interest, and the other dimensions may each be associated with a different metric that characterizes the measured response. More specifically, by way of illustration, in the impulse response approach described above, both the maximum height and the time to reach the height of the measured response may be determined. In this case, a three dimensional lookup table may be used.

As discussed above, in one embodiment, a lookup table may be used to correlate a metric associated with the measured response with a sensor parameter of interest (for example, sensitivity). Alternatively, a mathematical function that relates the measured response metric with the sensor parameter may be used. The sensor parameter may then be determined based on the measured response metric as an input. In another aspect, the estimate of the sensor parameter may be determined for many measurements using, for example, the least squares approach.

In addition, within the scope of the present invention, the control signal may be transmitted to the analog interface 201 at predetermined time periods during the life of the sensor. Alternatively, the transmitter processor 204 may be configured to transmit the control signal only during the time periods when sensor calibration is desired or if some other factor, such as a detection of sensitivity instability, determines that sensor calibration is required.

Moreover, in one embodiment, other system parameters in addition to sensitivity may be associated with the measured response from the analog interface 201 in response to the control signal from the transmitter processor 204. These include, but are not limited to, sensor response time, sensor response linearity, sensitivity stability and sensor failure. Accurately estimated sensor response time can be useful for incorporation into algorithms that compensate for errors due to lag in the analyte measurement system. Knowledge of the non-linearity in the sensor response (non-linearity means that the sensitivity is not constant over the entire range to measured response) allows for compensation of errors caused by this non-linearity.

Detection of sensitivity instability (that is, detection when the sensitivity has changed value) may be used to accurately determine the new sensitivity. For example, if instability has been detected by the signal processing component, it can direct the control processing component such as the transmitter unit processor 204 to initiate a control signal that is more appropriate to accurately estimating the sensitivity. Also, detecting a sudden, substantial change in sensitivity may be used to identify that a sensor may have failed.

While the control signal may be used to determine the sensor sensitivity, in one embodiment, the resulting modulation in the measured response may be removed by, for example, one or more signal filters to recover the glucose signal. In one aspect, a standard signal filter may be used to remove the high frequency content of the signal due to modulation by the perturbation control signal, and recover the lower frequency content that represents the analyte level. In another aspect, the modulation may be deconvolved using the control signal, the calculated sensor response and the estimated sensitivity.

Furthermore, there are several approaches to measure a sensor's response to the perturbation signals in order to estimate desired properties or characteristics of the sensor. For example, in one embodiment, the electrical current that flows through the work (and counter) electrode may be measured. Alternatively, the perturbation response in the counter electrode voltage may be alternatively measured. The measured counter voltage response may be analyzed using same or similar techniques as the measured work current response. In another embodiment, both work current and counter voltage responses may be measured and analyzed.

In the manner described above, within the scope of the present invention, there is provided method and system for performing calibration of analyte sensors based on the sensor dynamic behavior and on a substantially real time basis such that sensor calibrations based on blood glucose measurements may be minimized and further to improve the accuracy of the analyte sensor data.

In accordance with the various embodiments of the present invention, the transmitter processor 204 may include a microcontroller, or alternatively, may be implemented with digital logic such as a gate array or similar logic devices. In addition, in one embodiment, the measured response variance as well as the estimated sensor sensitivity determined by the transmitter processor 204 may be transmitted to the receiver unit 104 (FIG. 1) in the analyte monitoring system 100 in addition to the analyte sensor measurements (for example, the work electrode current measurements detected by the sensor unit 101).

In a further aspect, some of the processing may be performed by the receiver unit 104 (FIG. 1) rather than by the transmitter processor 204 such that the transmitter unit 102 may be configured to periodically transmit the measured response variance to the receiver unit 104, and the receiver unit processing and storage unit 307 (FIG. 3) may be configured to perform the sensor sensitivity determination based on the lookup table which may be stored in a memory device (not shown) in the receiver unit 104.

A method of calibrating an analyte sensor in one embodiment includes applying a control signal, detecting a measured response to the control signal,

determining a variance in the detected measured response, and estimating a sensor parameter based on the variance in the detected measured response.

The level of the control signal may in one embodiment vary in time.

In one aspect, the control signal may include a square wave signal.

The control signal in a further aspect may be applied to a poise voltage.

In a further aspect, detecting the measured response may include determining a work electrode current signal.

In still another aspect, the variance may be determined based on comparing the difference between the beginning and end of the half duty cycle of the measured response to the control signal.

Moreover, estimating the sensor parameter may include retrieving a predetermined sensor sensitivity corresponding to the determined variance in the detected measured response.

The method may also include determining a validity of the estimated sensor parameter.

In addition, the method may also include determining analyte level based on the estimated sensor parameter.

The sensor in one embodiment may include an analyte sensor.

An analyte sensor calibration device in accordance with another embodiment includes a processor configured to apply a control signal, detect a measured response to the control signal, determine a variance in the detected measured response, and estimate a sensor parameter based on the variance in the detected measured response.

The processor may be configured to vary the level of the control signal with time.

In another aspect, the processor may be configured to apply a control signal to a poise voltage.

The processor in a further aspect may be configured to determine a work electrode current signal of an analyte sensor operatively coupled to the processor.

Moreover, the processor may be configured to determine the variance based on comparing the difference between the beginning and end of the half duty cycle of the measured response to the control signal.

In addition, the processor in a further aspect may be configured to retrieve a predetermined sensor sensitivity corresponding to the determined variance in the detected measured response.

The processor may be operatively coupled to a data receiver unit configured to determine a validity of the estimated sensor parameter, where the data receiver unit may be configured to determine an analyte level based on the estimated sensor parameter.

The various processes described above including the processes performed by the transmitter processor 204 in the software application execution environment in the transmitter unit 102 including the processes and routines described in conjunction with FIGS. 4-6 and 9, may be embodied as computer programs developed using an object oriented language that allows the modeling of complex systems with modular objects to create abstractions that are representative of real world, physical objects and their interrelationships. The software required to carry out the inventive process, which may be stored in the memory (not shown) of the transmitter unit 102 may be developed by a person of ordinary skill in the art and may include one or more computer program products.

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 invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A method of calibrating an analyte sensor, comprising:

applying a control signal;

detecting a measured response to the control signal;

determining a variance in the detected measured response; and

estimating a sensor parameter based on the variance in the detected measured response.

2. The method of claim 1 wherein the level of the control signal varies in time.

3. The method of claim 1 wherein the control signal includes a square wave signal.

4. The method of claim 1 wherein the control signal is applied to a poise voltage.

5. The method of claim 1 wherein detecting the measured response includes determining a work electrode current signal.

6. The method of claim 1 wherein the variance is determined based on comparing the difference between the beginning and end of the half duty cycle of the measured response to the control signal.

7. The method of claim 1 wherein estimating the sensor parameter includes retrieving a predetermined sensor sensitivity corresponding to the determined variance in the detected measured response.

8. The method of claim 1 further including determining a validity of the estimated sensor parameter.

9. The method of claim 1 further including determining analyte level based on the estimated sensor parameter.

10. The method of claim 1 wherein the sensor includes an analyte sensor.

11. An analyte sensor calibration device, comprising:

a processor configured to apply a control signal, detect a measured response to the control signal, determine a variance in the detected measured response, and estimate a sensor parameter based on the variance in the detected measured response.

12. The device of claim 11 wherein the processor is configured to vary the level of the control signal with time.

13. The device of claim 11 wherein the control signal includes a square wave signal

14. The device of claim 11 wherein the processor is configured to apply the control signal to a poise voltage.

15. The device of claim 11 wherein the processor is configured to determine a work electrode current signal of an analyte sensor operatively coupled to the processor.

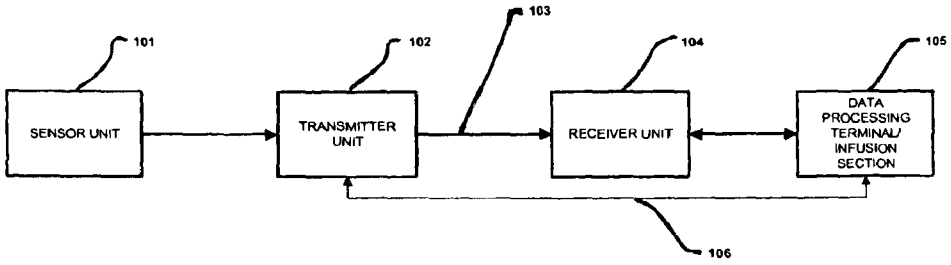
16. The device of claim 11 wherein the processor is configured to determine the variance based on comparing the difference between the beginning and end of the half duty cycle of the measured response to the control signal.

17. The device of claim 11 wherein the processor is configured to retrieve a predetermined sensor sensitivity corresponding to the determined variance in the detected measured response.

18. The device of claim 11 wherein the processor is operatively coupled to a data receiver unit configured to determine determining a validity of the estimated sensor parameter.

19. The device of claim 18 wherein the data receiver unit is configured to determine an analyte level based on the estimated sensor parameter.

20. The device of claim 11 wherein the processor is operatively coupled to an analyte sensor.



100

FIGURE 1

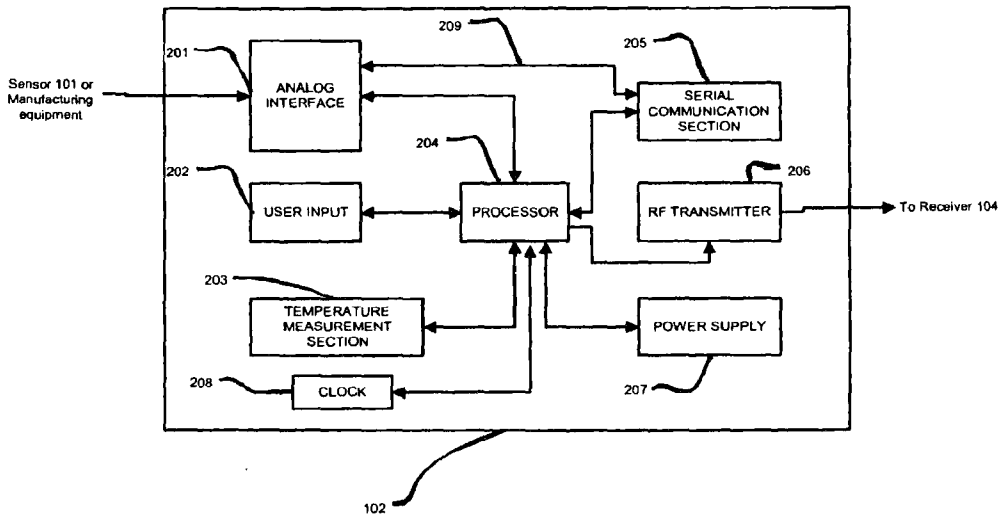


FIGURE 2

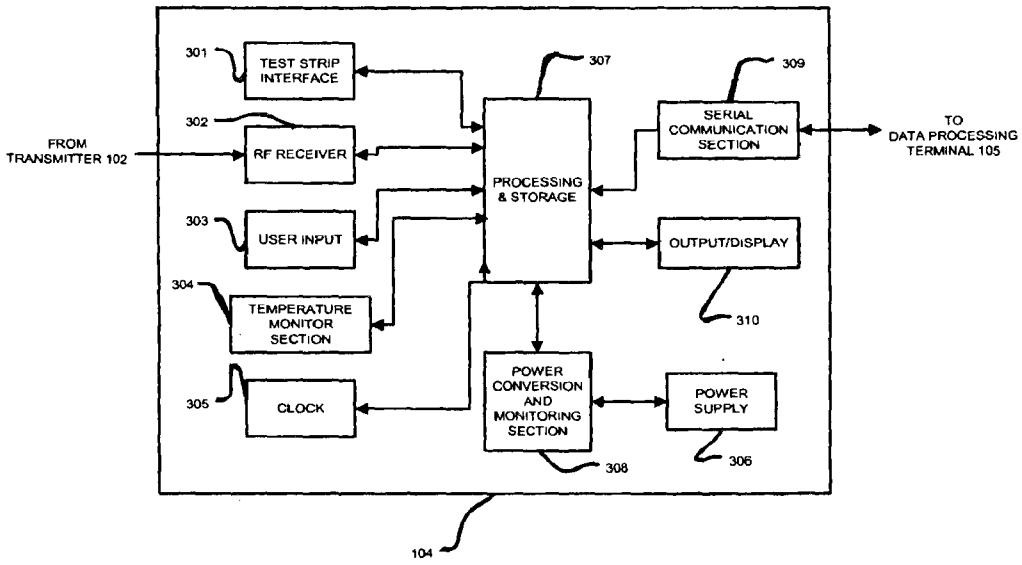

301
TEST STRIP INTERFACE
302
RF RECEIVER
FROM TRANSMITTER 102
303
USER INPUT
304
TEMPERATURE MONITOR SECTION
305
CLOCK
307
PROCESSING & STORAGE
309
SERIAL COMMUNICATION SECTION
TO DATA PROCESSING TERMINAL 105
OUTPUT/DISPLAY
310
POWER CONVERSION AND MONITORING SECTION
308
POWER SUPPLY
306
104

FIGURE 3

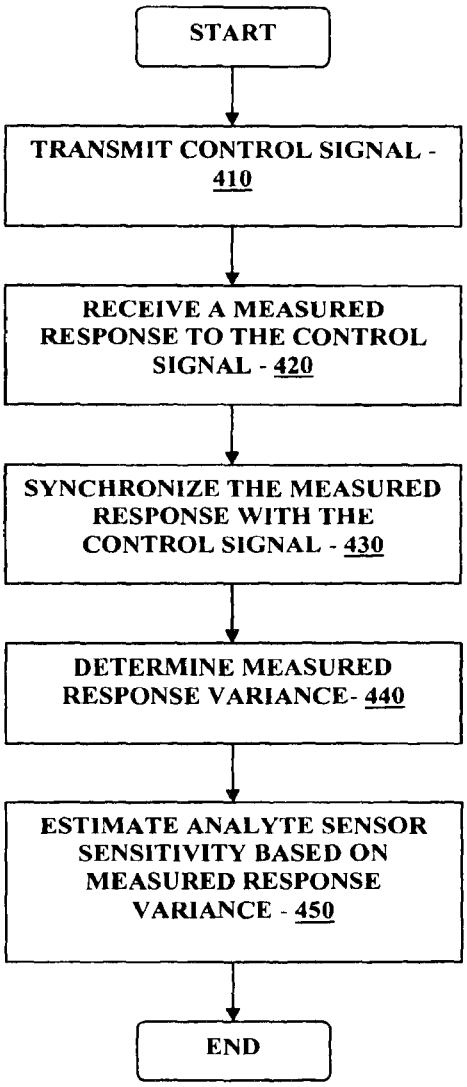

START
TRANSMIT CONTROL SIGNAL - 410
RECEIVE A MEASURED RESPONSE TO THE CONTROL SIGNAL - 420
SYNCHRONIZE THE MEASURED RESPONSE WITH THE CONTROL SIGNAL - 430
DETERMINE MEASURED RESPONSE VARIANCE- 440
ESTIMATE ANALYTE SENSOR SENSITIVITY BASED ON MEASURED RESPONSE VARIANCE - 450
END

FIGURE 4

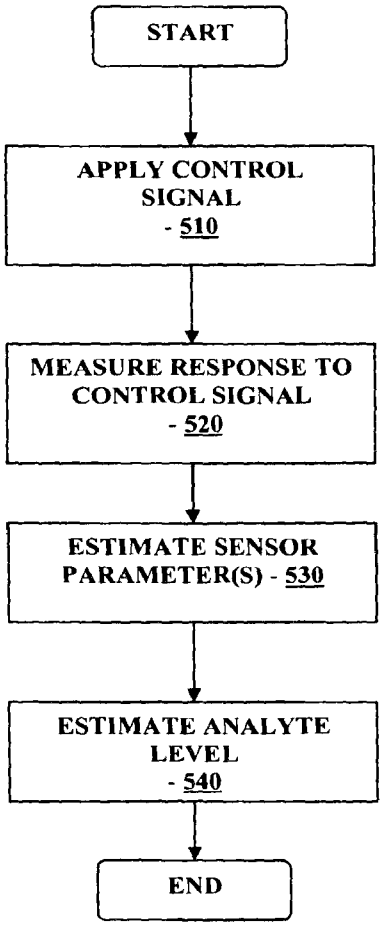

START
APPLY CONTROL SIGNAL - 510
MEASURE RESPONSE TO CONTROL SIGNAL - 520
ESTIMATE SENSOR PARAMETER(S) - 530
ESTIMATE ANALYTE LEVEL - 540
END

FIGURE 5

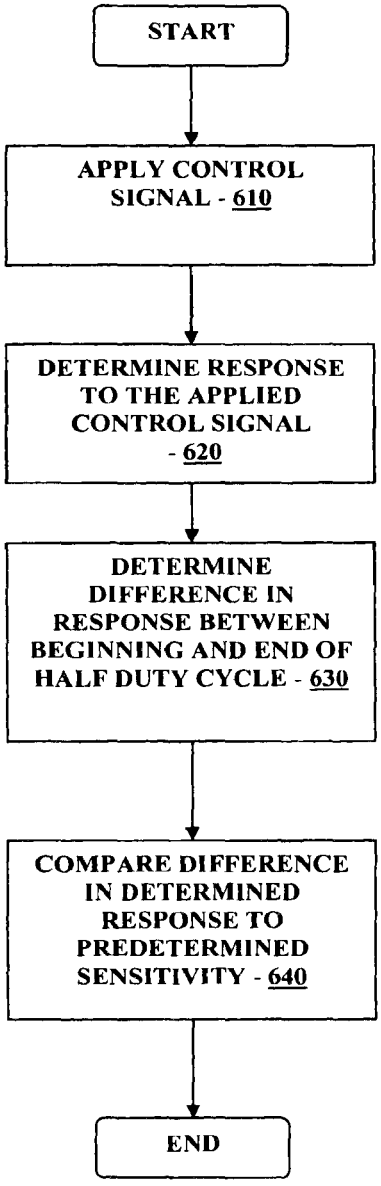

START
APPLY CONTROL SIGNAL - 610
DETERMINE RESPONSE TO THE APPLIED CONTROL SIGNAL - 620
DETERMINE DIFFERENCE IN RESPONSE BETWEEN BEGINNING AND END OF HALF DUTY CYCLE - 630
COMPARE DIFFERENCE IN DETERMINED RESPONSE TO PREDETERMINED SENSITIVITY - 640
END

FIGURE 6

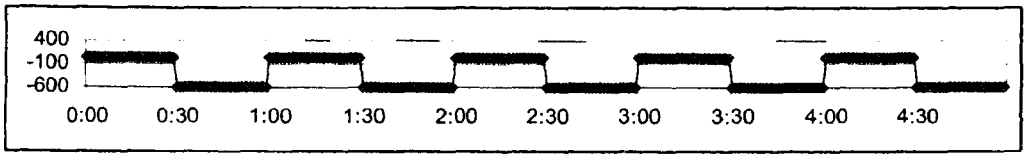


FIGURE 7A

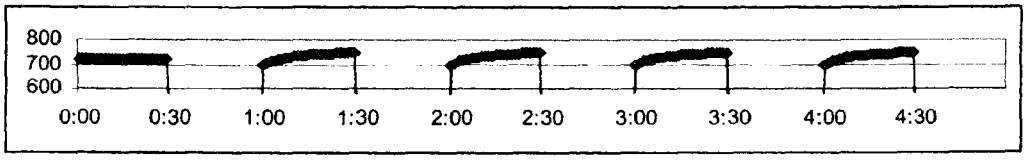


FIGURE 7B

	Measurement Response Difference	Sensor Sensitivity
	(ADC counts)	pA/(mg/dL)
	....	
	43	33.7
	44	33.9
	45	34.1
	46	34.3
→	47	**34.5**
	48	34.7
	49	34.9
	50	35.1
	51	35.3
		....

FIGURE 8

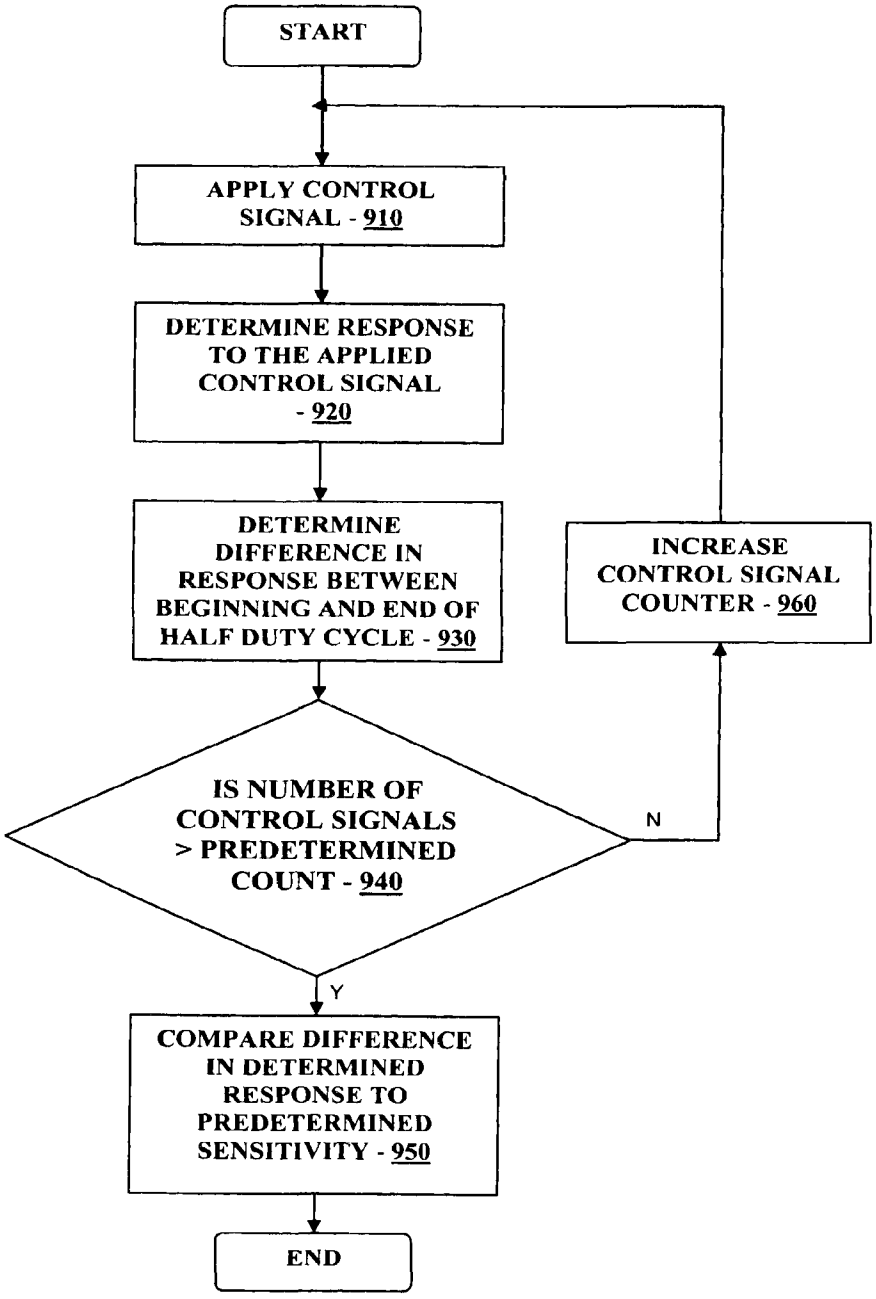

START
APPLY CONTROL SIGNAL - 910
DETERMINE RESPONSE TO THE APPLIED CONTROL SIGNAL - 920
DETERMINE DIFFERENCE IN RESPONSE BETWEEN BEGINNING AND END OF HALF DUTY CYCLE - 930
IS NUMBER OF CONTROL SIGNALS > PREDETERMINED COUNT - 940
N
INCREASE CONTROL SIGNAL COUNTER - 960
Y
COMPARE DIFFERENCE IN DETERMINED RESPONSE TO PREDETERMINED SENSITIVITY - 950
END

FIGURE 9

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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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(54) Title: CONTINUOUS ANALYTE MONITORING ASSEMBLY AND METHOD OF FORMING THE SAME

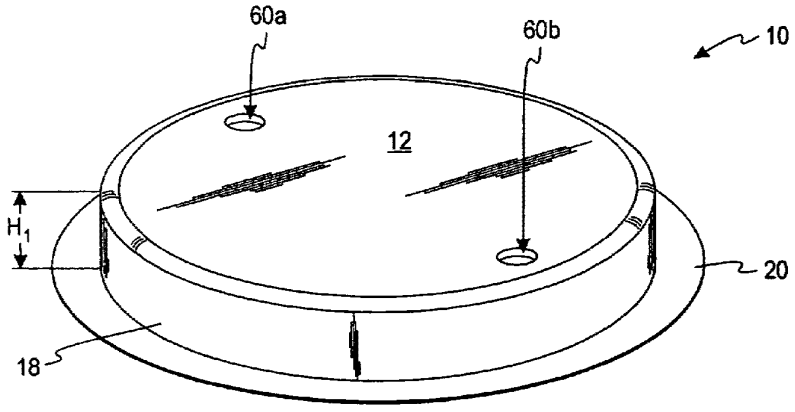


Fig. 1

(57) Abstract: A continuous analyte monitoring assembly is adapted to assist in determining an analyte level of a fluid. The monitoring assembly includes a housing, electronics, an implantable sensor and a cannula. The housing has a bottom in which the bottom forms a recess. The electronics are located within the housing and assist in determining an analyte level of a fluid sample. The sensor moves from a retracted position to an inserted position using the recess. The cannula assists in placing the implantable sensor.

WO 2008/115409 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

CONTINUOUS ANALYTE MONITORING ASSEMBLY AND METHOD OF FORMING THE SAME

FIELD OF THE INVENTION

[001] The present invention relates generally to a continuous analyte monitoring assembly and methods of using the same. More particularly, the invention relates to a continuous analyte monitoring assembly that includes an implantable sensor that is adapted to be placed in the body to assist in determining the analyte level (e.g., a concentration) of a fluid (e.g., blood).

BACKGROUND OF THE INVENTION

[002] The quantitative determination of analytes in body fluids is of great importance in the diagnoses and maintenance of certain physiological abnormalities. For example, lactate, cholesterol, and bilirubin should be monitored in certain individuals. In particular, determining glucose in body fluids is important to diabetic individuals who must frequently check the glucose level in their body fluids to regulate the glucose intake in their diets. The results of such tests may be used to determine what, if any, insulin or other medication needs to be administered.

[003] The analyte may be continuously monitored using a sensor. One of the challenges of using a continuous analyte monitoring process is to minimize the number of acts to (a) attach the sensor/electronics to the skin and (b) insert the implantable sensor that assists in determining the analyte level of a fluid (e.g., blood). It would be desirable to minimize such acts in a continuous analyte monitoring process. Additionally, it would be desirable to make the continuous analyte monitoring assembly as small as possible to reduce any interference with normal activities of a user. It would also be desirable to control location (especially depth) of the sensor in the skin.

[004] It would be desirable to have a continuous analyte monitoring assembly and methods of using the same that provide one or more of these desirable benefits.

SUMMARY OF THE INVENTION

[005] In one embodiment, a continuous analyte monitoring assembly is adapted to assist in determining an analyte level of a fluid. The continuous analyte monitoring assembly comprises a housing, electronics, an implantable sensor and a cannula. The housing has a bottom in which the bottom forms a recess. The electronics are located within the housing

and the electronics are adapted to assist in determining an analyte level of a fluid sample. The implantable sensor is adapted to move from a retracted position to an inserted position. The implantable sensor is adapted to move through the recess. The cannula is adapted to assist in the placement of the implantable sensor.

[006] According to one method, a continuous analyte monitoring assembly is formed. Housing is provided having a bottom in which the bottom forms a recess. Electronics are located within the housing. The electronics are adapted to assist in determining an analyte level of a fluid sample. An implantable sensor is located at least partially within the housing. The implantable sensor is adapted to move from a retracted position to an inserted position. At least a portion of the implantable sensor is adapted to move through the recess to the inserted position. A cannula is provided that is adapted to assist in the placement of the implantable sensor. The cannula is adapted to move between a retracted position and an inserted position.

[007] According to another method, a method of using a continuous analyte monitoring assembly is performed. A continuous analyte monitoring assembly is provided. The continuous analyte monitoring assembly includes housing, electronics, an implantable sensor, and a cannula. The electronics are adapted to assist in determining an analyte level of a fluid sample. The cannula is adapted to assist in placing of the implantable sensor. The continuous analyte monitoring assembly is attached to the skin. The implantable sensor is inserted into the skin from a retracted position to an inserted position by rotating a portion of the continuous analyte monitoring assembly with respect to the remainder of the continuous analyte monitoring assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

[008] FIG. 1 is a top perspective view of a continuous analyte monitoring assembly according to one embodiment.

[009] FIG. 2 is a cut-away view of FIG. 1.

[0010] FIG. 3 is an exploded view of the continuous analyte monitoring assembly of FIG. 1.

[0011] FIG. 4a is an exploded view of a disposable assembly of the continuous analyte monitoring assembly of FIG. 1.

[0012] FIG. 4b is a top perspective view of an assembled disposable assembly of FIG. 4a.

[0013] FIG. 5a is an exploded view of a reusable assembly of the continuous analyte monitoring assembly of FIG. 1.

[0014] FIG. 5b is a side cutaway view of the assembled reusable assembly of FIG. 5a.

[0015] FIG. 6a is a bottom perspective view of the continuous analyte monitoring assembly of FIG. 1 in a retracted position.

[0016] FIG. 6b is an enlarged bottom perspective view of a cannula according to one embodiment in the continuous analyte monitoring assembly of FIG. 1 in a retracted position.

[0017] FIG. 7 is a side view of the continuous analyte monitoring assembly of FIG. 1 in an inserted position.

[0018] FIG. 8 is a partial cutaway bottom perspective view of an inserter according to one embodiment with a loaded continuous analyte monitoring assembly of FIG. 1.

[0019] FIG. 9 is a continuous analyte monitoring assembly according to one embodiment.

[0020] FIG. 10 is a continuous analyte monitoring assembly in communication with a receiving module according to one embodiment.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0021] The present invention relates generally to a continuous analyte monitoring assembly and methods of using the same. More particularly, the continuous analyte monitoring assembly uses an implantable sensor that is adapted to be placed in the body to assist in determining the analyte level of a fluid (e.g., blood). The implantable sensor is adapted to be placed in the subcutaneous region of the skin. It is contemplated that the sensor may be placed in other regions of the skin such as the dermis. The implantable sensor is adapted to be placed into the body for up to 3 days in one method. In another method, the implantable sensor is adapted to be placed into the body for up to 5 or 7 days. It is contemplated that the implantable sensor may be placed in the body for even longer time periods.

[0022] The implantable sensor assists in determining the "level" of the desired analyte. The term "level" is defined herein as including any information related to, for example, the amount, relative concentration and absolute concentration. The term "level" as defined herein also includes changes in the amount, relative and absolute concentrations, whether in a percentage or absolute context. These "level" changes may be used over a selected duration of time such as, for example, a time change in amount or concentration.

The "level" may refer to a time change in amount or concentration, and compared to a later time change.

[0023] Analytes that may be measured include glucose, lipid profiles (e.g., cholesterol, triglycerides, LDL, and HDL), fructose, lactate, and/or bilirubin. Analytes could also include therapeutic drugs, metabolites of the therapeutic drug or other substances that are affected by the therapeutic drug being analyzed. It is contemplated that other analyte levels may be determined. One non-limiting example of the sensor's use is to determine the glucose concentration of the fluid. The fluid may be an intercellular fluid or an intracellular fluid. These fluids include interstitial fluid (ISF), blood, plasma and other fluids.

[0024] Referring to FIGs. 1-3, a continuous analyte monitoring assembly 10 is shown according to one embodiment. The continuous analyte monitoring assembly 10 includes a cover 12, electronics mounted on a printed circuit board 14, printed circuit board housing 16, disposable housing 18, an adhesive liner 20, an implantable sensor 22, a cannula 24 and a connector 26 (FIG. 3). The continuous analyte monitoring assembly 10 of FIG. 1 is shown as being generally circular. It is contemplated that the continuous analyte monitoring assembly may be of other shapes.

[0025] The continuous analyte monitoring assembly may further include a battery. The battery is typically located on the printed circuit board. The battery may be a rechargeable battery such as an inductively rechargeable battery. The battery may be recharged by being loaded into a docking station.

[0026] The continuous analyte monitoring assembly may be a disposable assembly, a reusable assembly, or a combination thereof. For example, the continuous analyte monitoring assembly 10 includes a disposable assembly 40 (see FIGs. 4a, 4b) and a reusable assembly 50 (see FIGs. 5a, 5b). In this embodiment, the disposable assembly 40 of FIGs. 4a, 4b includes the disposable housing 18, the adhesive liner 20, the implantable sensor 22, the cannula 24 and the connector 26. As will be discussed below, the cannula 24 assists in locating the sensor 22 in the skin. The connector 26 assists in mechanically and electrically connecting the implantable sensor 22 and the electronics (e.g., printed circuit board 14). The connector may include an anode portion 26a and a cathode portion 26b. It is contemplated that other connections may be used to connect the sensor 22 and the printed circuit board 14 of the continuous analyte monitoring assembly 10. For example, a connector may have a plurality of contact points (e.g., 3-6 contact points) that assist in mechanically and electrically

connecting the implantable sensor and the printed circuit board. The connector may include contacts points such as a reference portion or a temperature-monitoring component.

[0027] The reusable assembly 50 of FIGs. 5a, 5b includes the cover 12, the printed circuit board 14 and the printed circuit board housing 16. When the reusable assembly 50 is placed into the disposable assembly 40, the implantable sensor 22 is mechanically and electrically connected to the electronics mounted on the printed circuit board 14 in the reusable assembly 50. The connector 26 of the disposable assembly 40 extends through an aperture 66 formed in the printed circuit board housing 16 to mechanically and electrically connect the sensor 22 and the printed circuit board 14. To connect the reusable assembly 50 and the disposable assembly 40 in one method, the reusable assembly 50 is inserted and rotated into the disposable assembly 40. It is contemplated that the reusable assembly and the disposable assembly may be connected together by other methods. In one method, the reusable assembly and the disposable assembly are rotated and snapped into each other.

[0028] Referring back to FIGs. 1-3, the cover 12 assists in protecting the remainder of the continuous analyte monitoring assembly 10. Specifically, the cover 12 assists in preventing or inhibiting contaminants from reaching the electronics mounted on the printed circuit board 14. Non-limiting examples of contaminants include moisture, liquid or particles such as dust. It is contemplated that the cover 12 may assist in preventing or inhibiting other contaminants from reaching the printed circuit board 14. The cover 12 also forms a plurality of apertures 60a, 60b to assist in coupling or connecting with an inserter that will be discussed below in detail with respect to FIG. 8. It is contemplated that the cover may include a different number or different shaped apertures to assist in connecting with an inserter. It is also contemplated that the cover may include other features to assist in coupling the continuous analyte monitoring assembly and an inserter.

[0029] The printed circuit board housing 16 also assists in preventing or inhibiting contaminants from reaching the printed circuit board 14 such as those contaminants previously discussed. The printed circuit board housing 16 assists in maintaining the location of the printed circuit board 14. The printed circuit board housing 16 also assists in electrically insulating the printed circuit board 14.

[0030] The cover 12 and the printed circuit board housing 16 may be made from a variety of materials. One example of a material that may be used in forming the cover and the printed circuit board housing is polymeric material. Non-limiting examples of polymeric

materials that may be used to form the cover and the printed circuit board housing include ABS, polycarbonate and acrylic.

[0031] The printed circuit board 14 contains the electronics that are used in the continuous analyte monitoring assembly 10. It is contemplated that the electronic components used in the continuous analyte monitoring assembly 10 may be located on a device other than a printed circuit board. The electronic components in one embodiment include three subassemblies -- a power supply, a potentiostat and a communications link. In one embodiment, the electronic components assist in operating the implantable sensor, monitoring the signals from the sensor, converting analog signals to digital signals, and storing data from the sensor. The printed circuit board 14 assists in processing the information by directing and collecting data for the analysis. The printed circuit board may be a potentiostat if an electrochemical analysis is to be performed. The continuous analyte monitoring assembly 10 may include two modules in which a first module is used to collect/analyze the data with a second module being used to transmit or communicate the data. It is contemplated that the electronic components may assist in performing additional functions in the continuous analyte monitoring assembly 10.

[0032] The disposable housing 18 assists in preventing or inhibiting contaminants such as those previously discussed from reaching the sensor 22 and also from reaching the cannula 24 and the connector 26. The disposable housing 18 also assists in holding components such as the connector 26 and the cannula 24 in specific locations therein. The disposable housing 18 is attached to the adhesive liner 20.

[0033] The adhesive liner 20 includes a detachable liner and an adhesive thereon that assists in attaching the continuous analyte monitoring assembly 10 to the skin. The detachable liner is adapted to be peeled off from the remainder of the continuous analyte monitoring assembly before the continuous analyte monitoring assembly is attached to the skin. The adhesive liner 20 forms an aperture 20a that allows the sensor 22 to extend therethrough.

[0034] In one embodiment, the implantable sensor 22 is a wire. The wire typically includes electrically conductive material with a portion of the wire containing reagent that is adapted to react with the desired analyte. The electrically conductive material is typically a noble metal such as platinum or platinum-iridium. It is contemplated that other electrically conductive materials (metal or non-metal) may be used in forming the implantable sensor. The wire is typically coated with an insulating material to assist in (a) protecting the

electrically conductive material from corrosive effects and (b) providing an insulating effect on the electrically conductive material. The insulting material is typically a polymeric material. Non-limiting polymeric materials include polyimides, polytetrafluoroethylene (TEFLON®), ultraviolet-curable polymers, heat-curable polymers, and natural rubber. In one example, a reagent (e.g., glucose oxidase enzyme) may be included with the wire if the desired analyte to be tested in glucose.

[0035] The implantable sensor is typically an electrochemical sensor. It is contemplated, however, that the implantable sensor may be an optical sensor. If the implantable sensor was an optical sensor in one embodiment, a fiber optic may be coated to react with the analyte such that a fluorescence, reflectance or absorption change would be created.

[0036] One non-limiting example of the cannula 24 is best shown in FIGs. 6a, 6b. FIG. 6b is an enlarged view of a portion of the cannula 24 with the adhesive liner 20 having been removed. The cannula 24 has a sharpened end 24a that assists in inserting the implantable sensor 22 into the body. The cannula 24 is shown as extending into a recess 30 formed in a bottom 18a of the disposable housing 18. The recess 30 assists in controlling the depth of the placement of the implantable sensor 22. Specifically, during the process of inserting the implantable sensor 22, the skin extrudes or raises up into the recess 30 when sufficient pressure is applied, resulting in a more consistent location of the implantable sensor 22. The recess 30 also assists in securing the skin contact with the cannula 24. The recess may be formed in different shapes and sizes from that depicted in FIGs. 6a, 6b. It is generally desirable, however, for the recess to be generally wide and shallow to assist in (a) controlling the depth of the placement and (b) extruding or raising up of the skin.

[0037] During the insertion act, the cannula and the implantable sensor are moved together, but during the retraction act only the cannula is moved, which results in the placement of the implantable sensor in the body. To move the cannula between retracted and insertion positions, the continuous analyte monitoring assembly may include two torsion springs in which one torsion spring drives the cannula in the insertion act and the other torsion spring moves the cannula in the retraction act. It is contemplated that the cannula may be moved by other mechanisms. In another method, another mechanical mechanism may be used in combination with a spring. For example, a mechanical mechanism such as cam-like drive system may be used in combination with a retraction spring.

[0038] When using a cannula in a continuous analyte monitoring assembly, the continuous analyte monitoring assembly needs to be sized to accommodate the length of the implantable sensor plus the length of the cannula in the retracted position. The continuous analyte monitoring assembly using a rotary motion to insert the implantable sensor can be smaller than a continuous analyte monitoring assembly using a linear insertion motion because in one embodiment the sensor and the cannula are curved and fit in the circumference of the rotary-motion, continuous analyte monitoring assembly.

[0039] Referring back to FIG. 1, in a generally circular embodiment, the diameter of the continuous analyte monitoring assembly is generally less than about 1 inch. More specifically, the diameter of the continuous analyte monitoring assembly is generally less than about 0.8 inch. The height (H_1) of the continuous analyte monitoring assembly is generally less than about 0.5 inch. More specifically, the height of the continuous analyte monitoring assembly is generally less than about 0.33 or about 0.2 inch. The area of the continuous analyte monitoring assembly is generally less than about 0.5 in^2. More specifically, the area of the continuous analyte monitoring assembly is generally less than about 0.25 or about 0.2 in^2. To reduce interference with normal activities of the user, it is desirable to form a continuous analyte monitoring assembly that is small in size. More specifically, the larger the continuous analyte monitoring assembly 10 (especially in its height – see H_1 of FIG. 1) the easier it is to dislodge or detach from the body or skin.

[0040] It is desirable to minimize the number of acts involved in attaching the continuous analyte monitoring assembly 10 to the skin and inserting the implantable sensor 22 in the body. This is especially important if the user is inserting the implantable sensor at home without any assistance.

[0041] In one method, the continuous analyte monitoring assembly 10 includes the following acts: (a) loading a continuous analyte monitoring assembly with implantable sensor into an inserter, (b) removing the adhesive liner from the remainder of the continuous analyte monitoring assembly; and (c) placing the inserter with the continuous analyte monitoring assembly on the body. In one method, the inserter is pressed down onto the skin. In another method, the inserter may be pressed down and rotated onto the skin. It is contemplated that the continuous analyte monitoring assembly may be attached to the skin by using methods other than an adhesive. The attachment methods may be chemical, mechanical or a combination thereof. In this method, it is not necessary to attach the electronics as a separate act because the electronics are already in communication with the sensor.

[0042] Referring to FIG. 8, an inserter (inserter 110) is shown according to one embodiment. FIG. 8 shows the inserter 110 being partially cut away to better depict the coupling of the continuous monitoring analyte assembly 10 and the inserter 110. The inserter is designed to be reusable. It is contemplated, however, that the inserter may be disposable. The inserter 110 of FIG. 8 is shown with a loaded continuous analyte monitoring assembly 10 therein and, more specifically, the inserter 110 is shown as being placed over the top of the cover 12 of the continuous analyte monitoring assembly 10. The inserter 110 forms an opening or cavity that is adapted to receive the continuous analyte monitoring assembly 10. In this opening, the inserter 110 includes a plurality of projections or pins 112a, 112b that extend generally downward. The pins 112a, 112b correspond with the apertures 60a, 60b formed in the cover 12 and the apertures 62a, 62b of the printed circuit board housing 16 (see FIG. 3). Thus, the pins 112a, 112b extend through the apertures 60a,b, 62a,b and desirably form a snug fit therein to couple the continuous analyte monitoring assembly 10 and the inserter 110.

[0043] In one method, the continuous analyte monitoring assembly 10 is applied to the skin using an adhesive. The adhesive liner 20 is then removed from the remainder of the continuous analyte monitoring assembly 10. It is contemplated that the adhesive liner 20 may be removed from the remainder of the continuous analyte monitoring assembly 10 prior to being loaded into the inserter 110. This, however, is generally not desirable because the adhesive is prematurely exposed, which may lead to adhesive getting in unwanted locations. One non-limiting example of an adhesive is a cyanoacrylate. It is contemplated that other attachment methods may be used such as a chemical attachment, a mechanical attachment or a combination thereof. One mechanical attachment method is an arm or leg band. Another type of mechanical attachment method uses a vacuum or other pressure to attach the continuous analyte monitoring assembly 10.

[0044] In this method, the inserter 110 may then be cocked by rotating, for example, a plunger 114 a quarter turn and then back. The cocking of the inserter 110 may be performed before or after the inserter 110 with the loaded continuous analyte monitoring assembly 10 is pressed against the skin. In this method, the inserter and the continuous analyte monitoring assembly 10 are pressed hard to reach a predetermined force such that the plunger 114 is pressed down and the sensor 22 is driven under the skin. The design of the continuous analyte monitoring assembly assists in facilitating a simple rotary motion to insert the sensor in the body. The inserter 110 is typically spring-loaded such the reusable assembly 40

(including the cover 12 and the printed circuit board housing 16) are rotated at a sufficient force to penetrate and drive the sensor 22 into the skin. In this embodiment, the spring force pressure must be overcome before the plunger is depressed. The predetermined force may be set by a spring rate and designed at a pressure where the skin extrudes into the recess 30. One example of a spring that may be used is a torsion spring. It is contemplated that other types of springs may be used to rotate and drive the sensor into the skin.

[0045] To assist in preventing or inhibiting accidental insertion of the sensor 22, a safety button 116 may be included on the inserter that would need to be activated before the plunger 114 could be moved. It is also contemplated that other mechanisms may be used to rotate and drive the sensor into the skin. For example, a small release button may be used instead of a plunger.

[0046] When using the cannula 24, during the rotation of the continuous analyte monitoring assembly 10, the disposable housing 18 is stationary. The remainder of the components of the continuous analyte monitoring assembly 10 are rotated with respect to the disposable housing 18. The rotation may be done in the counterclockwise direction in one method. In another method, the rotation may be done in the clockwise direction. The continuous analyte monitoring assembly 10 is shown in FIG. 7 as being in the retracted position on skin 80.

[0047] The rotary motion of the continuous analyte monitoring assembly 10 is desirable because it results in a smaller footprint for the continuous analyte monitoring assembly. This results in a smaller footprint because the implantable sensor may be curved to fit in the circumference of the continuous analyte monitoring assembly. In such an embodiment, the cannula may also be curved to fit in the circumference of the continuous analyte monitoring assembly. Additionally, the rotary motion is desirable because an angle is used with the insertion of the sensor, which results in improved depth control in the locating of the implantable sensor.

[0048] After the implantable sensor 22 has been driven under the skin, the cannula 24 is retracted. The inserter 110 is then removed from the continuous analyte monitoring assembly and is ready to be reused if desired.

[0049] In one embodiment, the continuous analyte monitoring assembly is connected to a remote-monitoring system over a communications link. The communications link between the continuous analyte monitoring assembly and the remote-monitoring system may be wireless, hard wired or a combination thereof. The wireless communications link may

include an RF link, an infrared link or an inductive magnetic link. The wireless implementation may include an internet connection. The continuous analyte monitoring assembly may communicate via its communication interface with devices such as a computer, e-mail server, cell phone or telephone. It is contemplated that the continuous analyte monitoring assembly may include other devices that are adapted to store, send and/or receive information.

[0050] The remote-monitoring system enables an individual such as a physician to monitor the analyte. The remote-monitoring system may be located in, for example, a hospital. The physician may be able to access information from the continuous analyte monitoring assembly via its communications interface using, for example, a computer or telephone. The remote-monitoring system is especially desirable for patients who are less lucid and need assistance with monitoring the analyte. It is desirable for the remote-monitoring system to be able to display, calibrate and store information received from the continuous analyte monitoring assembly.

[0051] The remote-monitoring system may be used to send back instructional information to the patients. In such an embodiment, a continuous analyte monitoring assembly includes a communications link that has a receiver component to receive instructions from the remote-monitoring system in addition to a transmitter component to transmit information to the remote-monitoring system.

[0052] In one method, the continuous analyte monitoring assembly may forward information over a communications link in real-time. In another method, the continuous analyte monitoring assembly may store and process the data before forwarding the information over a communications link in another embodiment.

[0053] Referring to FIG. 9, a continuous analyte monitoring assembly 310 includes a processor 332, memory 334 and a communication interface 336. It is contemplated that the continuous analyte monitoring assembly 10 may include a processor, memory and a communications interface as described above in monitoring assembly 310. Referring to FIG. 10, the continuous analyte monitoring assembly 310 is shown in communication with a receiving module 340 (e.g., a remote-monitoring station) over a communications link 350.

ALTERNATIVE EMBODIMENT A

[0054] A continuous analyte monitoring assembly adapted to assist in determining an analyte level of a fluid, the continuous analyte monitoring assembly comprising:

a housing having a bottom, the bottom forming a recess;

electronics located within the housing, the electronics being adapted to assist in determining an analyte level of a fluid sample;

an implantable sensor being adapted to move from a retracted position to an inserted position, the implantable sensor being adapted to move through the recess; and

a cannula being adapted to assist in placing the implantable sensor.

ALTERNATIVE EMBODIMENT B

[0055] The assembly of Alternative Embodiment A, wherein the electronics is a printed circuit board.

ALTERNATIVE EMBODIMENT C

[0056] The assembly of Alternative Embodiment A, further including a removable adhesive liner, the adhesive liner being adapted to attach to skin.

ALTERNATIVE EMBODIMENT D

[0057] The assembly of Alternative Embodiment A, wherein the housing includes disposable housing and reusable housing, the reusable housing being adapted to contain the electronics.

ALTERNATIVE EMBODIMENT E

[0058] The assembly of Alternative Embodiment D, wherein the disposable housing includes the implantable sensor, the cannula and an adhesive liner.

ALTERNATIVE EMBODIMENT F

[0059] The assembly of Alternative Embodiment A, wherein the implantable sensor is a wire that includes a reagent.

ALTERNATIVE EMBODIMENT G

[0060] The assembly of Alternative Embodiment A, wherein the implantable sensor is an electrochemical sensor.

ALTERNATIVE EMBODIMENT H

[0061] The assembly of Alternative Embodiment A, wherein the implantable sensor is an optical sensor.

ALTERNATIVE EMBODIMENT I

[0062] The assembly of Alternative Embodiment A, wherein the area of the continuous analyte monitoring assembly is less than 0.25 in^2.

ALTERNATIVE EMBODIMENT J

[0063] The assembly of Alternative Embodiment A, wherein the height of the continuous analyte monitoring assembly is less than 0.5 in.

ALTERNATIVE EMBODIMENT K

[0064] The assembly of Alternative Embodiment A, wherein the level of the analyte is a concentration of the analyte.

ALTERNATIVE PROCESS L

[0065] A method of forming a continuous analyte monitoring assembly, the method comprising the acts of:

providing a housing having a bottom, the bottom forming a recess;

locating electronics within the housing, the electronics being adapted to assist in determining an analyte level of a fluid sample;

locating an implantable sensor at least partially within the housing, the implantable sensor being adapted to move from a retracted position to an inserted position, at least a portion of the implantable sensor being adapted to move through the recess to the inserted position; and

providing a cannula being adapted to assist in the placement of the implantable sensor, the cannula being adapted to move between a retracted position and an inserted position.

ALTERNATIVE PROCESS M

[0066] The method of Alternative Process L, further including attaching a removable adhesive liner to the housing.

ALTERNATIVE PROCESS N

[0067] The method of Alternative Process L, wherein the housing includes disposable housing and reusable housing, the reusable housing being adapted to contain the electronics.

ALTERNATIVE PROCESS O

[0068] The method of Alternative Process N, wherein the disposable housing includes the implantable sensor, the cannula and an adhesive liner.

ALTERNATIVE PROCESS P

[0069] The method of Alternative Process L, wherein the implantable sensor is a wire that includes a reagent.

ALTERNATIVE PROCESS Q

[0070] The method of Alternative Process L, wherein the implantable sensor is an electrochemical sensor.

ALTERNATIVE PROCESS R

[0071] The method of Alternative Process L, wherein the implantable sensor is an optical sensor.

ALTERNATIVE PROCESS S

[0072] A method of using a continuous analyte monitoring assembly, the method comprising the acts of:

providing a continuous analyte monitoring assembly, the continuous analyte monitoring assembly including housing, electronics, an implantable sensor, and a cannula, the electronics being adapted to assist in determining an analyte level of a fluid sample, the cannula being adapted to assist in placing the implantable sensor;

attaching the continuous analyte monitoring assembly to the skin; and

inserting the implantable sensor into the skin from a retracted position to an inserted position by rotating a portion of the continuous analyte monitoring assembly with respect to the remainder of the continuous analyte monitoring assembly.

ALTERNATIVE PROCESS T

[0073] The method of Alternative Process S, wherein the continuous analyte monitoring assembly further includes a removable adhesive liner, the removable adhesive liner being attached to the housing.

ALTERNATIVE PROCESS U

[0074] The method of Alternative Process S, wherein the housing includes disposable housing and reusable housing, the reusable housing being adapted to contain the electronics.

ALTERNATIVE PROCESS V

[0075] The method of Alternative Process U, wherein the disposable housing includes the implantable sensor, the cannula and an adhesive liner.

ALTERNATIVE PROCESS W

[0076] The method of Alternative Process S, wherein the implantable sensor is a wire that includes a reagent.

ALTERNATIVE PROCESS X

[0077] The method of Alternative Process S, wherein the implantable sensor is an electrochemical sensor.

ALTERNATIVE PROCESS Y

[0078] The method of Alternative Process S, wherein the implantable sensor is an optical sensor.

ALTERNATIVE PROCESS Z

[0079] The method of Alternative Process S, wherein the continuous analyte monitoring assembly is attached to the skin using an adhesive.

ALTERNATIVE PROCESS AA

[0080] The method of Alternative Process S, wherein the continuous analyte monitoring assembly is attached to the skin using a mechanical method.

ALTERNATIVE PROCESS BB

[0081] The method of Alternative Process S, wherein the analyte is glucose.

ALTERNATIVE PROCESS CC

[0082] The method of Alternative Process S, wherein the analyte is a therapeutic drug, a metabolite of a therapeutic drug or a substance that is affected by a therapeutic drug.

ALTERNATIVE PROCESS DD

[0083] The method of Alternative Process S, wherein the implantable sensor is inserted into the skin using an inserter, the inserter forming an opening or cavity that is adapted to assist in receiving and securing the continuous analyte monitoring assembly.

ALTERNATIVE PROCESS EE

[0084] The method of Alternative Process S, further including the continuous analyte monitoring assembly communicating with a receiving module.

[0085] While the invention is susceptible to various modifications and alternative forms, specific embodiments and methods thereof have been shown by way of example in the drawings and are described in detail herein. It should be understood, however, that it is not intended to limit the invention to the particular forms or methods disclosed, but, to the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

CLAIMS:

1. A continuous analyte monitoring assembly adapted to assist in determining an analyte level of a fluid, the continuous analyte monitoring assembly comprising:

a housing having a bottom, the bottom forming a recess;

electronics located within the housing, the electronics being adapted to assist in determining an analyte level of a fluid sample;

an implantable sensor being adapted to move from a retracted position to an inserted position, the implantable sensor being adapted to move through the recess; and

a cannula being adapted to assist in placing the implantable sensor.

2. The assembly of claim 1, wherein the electronics is a printed circuit board.

3. The assembly of claim 1, further including a removable adhesive liner, the adhesive liner being adapted to attach to skin.

4. The assembly of claim 1, wherein the housing includes disposable housing and reusable housing, the reusable housing being adapted to contain the electronics.

5. The assembly of claim 4, wherein the disposable housing includes the implantable sensor, the cannula and an adhesive liner.

6. The assembly of claim 1, wherein the implantable sensor is a wire that includes a reagent.

7. The assembly of claim 1, wherein the implantable sensor is an electrochemical sensor.

8. The assembly of claim 1, wherein the implantable sensor is an optical sensor.

9. The assembly of claim 1, wherein the area of the continuous analyte monitoring assembly is less than 0.25 in^2.

10. The assembly of claim 1, wherein the height of the continuous analyte monitoring assembly is less than 0.5 in.

11. The assembly of claim 1, wherein the level of the analyte is a concentration of the analyte.

12. A method of forming a continuous analyte monitoring assembly, the method comprising the acts of:

providing a housing having a bottom, the bottom forming a recess;

locating electronics within the housing, the electronics being adapted to assist in determining an analyte level of a fluid sample;

locating an implantable sensor at least partially within the housing, the implantable sensor being adapted to move from a retracted position to an inserted position, at least a portion of the implantable sensor being adapted to move through the recess to the inserted position; and

providing a cannula being adapted to assist in the placement of the implantable sensor, the cannula being adapted to move between a retracted position and an inserted position.

13. The method of claim 12, further including attaching a removable adhesive liner to the housing.

14. The method of claim 12, wherein the housing includes disposable housing and reusable housing, the reusable housing being adapted to contain the electronics.

15. The method of claim 14, wherein the disposable housing includes the implantable sensor, the cannula and an adhesive liner.

16. The method of claim 12, wherein the implantable sensor is a wire that includes a reagent.

17. The method of claim 12, wherein the implantable sensor is an electrochemical sensor.

18. The method of claim 12, wherein the implantable sensor is an optical sensor.

19. A method of using a continuous analyte monitoring assembly, the method comprising the acts of:

providing a continuous analyte monitoring assembly, the continuous analyte monitoring assembly including housing, electronics, an implantable sensor, and a cannula, the electronics being adapted to assist in determining an analyte level of a fluid sample, the cannula being adapted to assist in placing the implantable sensor;

attaching the continuous analyte monitoring assembly to the skin; and

inserting the implantable sensor into the skin from a retracted position to an inserted position by rotating a portion of the continuous analyte monitoring assembly with respect to the remainder of the continuous analyte monitoring assembly.

20. The method of claim 19, wherein the continuous analyte monitoring assembly further includes a removable adhesive liner, the removable adhesive liner being attached to the housing.

21. The method of claim 19, wherein the housing includes disposable housing and reusable housing, the reusable housing being adapted to contain the electronics.

22. The method of claim 21, wherein the disposable housing includes the implantable sensor, the cannula and an adhesive liner.

23. The method of claim 19, wherein the implantable sensor is a wire that includes a reagent.

24. The method of claim 19, wherein the implantable sensor is an electrochemical sensor.

25. The method of claim 19, wherein the implantable sensor is an optical sensor.

26. The method of claim 19, wherein the continuous analyte monitoring assembly is attached to the skin using an adhesive.

27. The method of claim 19, wherein the continuous analyte monitoring assembly is attached to the skin using a mechanical method.

28. The method of claim 19, wherein the analyte is glucose.

29. The method of claim 19, wherein the analyte is a therapeutic drug, a metabolite of a therapeutic drug or a substance that is affected by a therapeutic drug.

30. The method of claim 19, wherein the implantable sensor is inserted into the skin using an inserter, the inserter forming an opening or cavity that is adapted to assist in receiving and securing the continuous analyte monitoring assembly.

31. The method of claim 19, further including the continuous analyte monitoring assembly communicating with a receiving module.

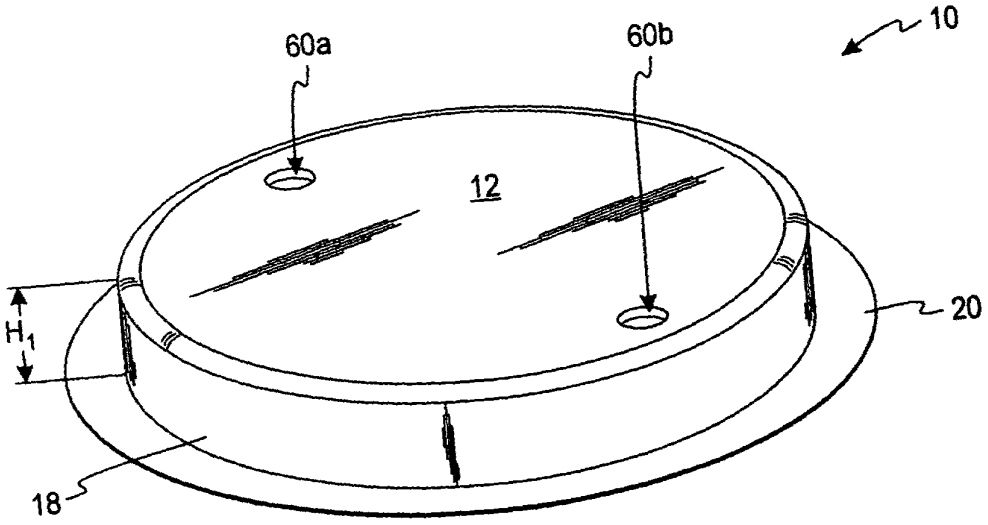


Fig. 1

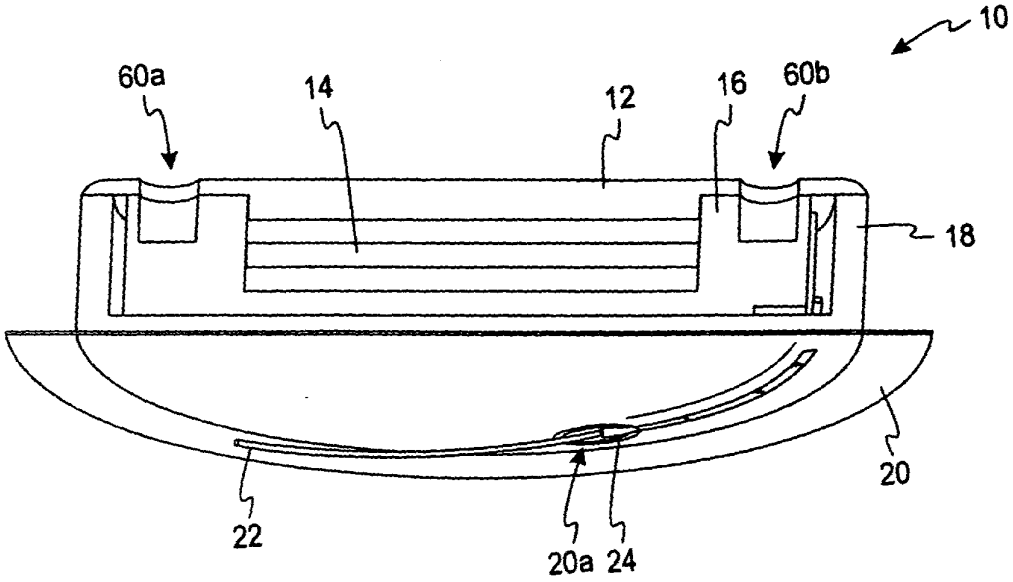


Fig. 2

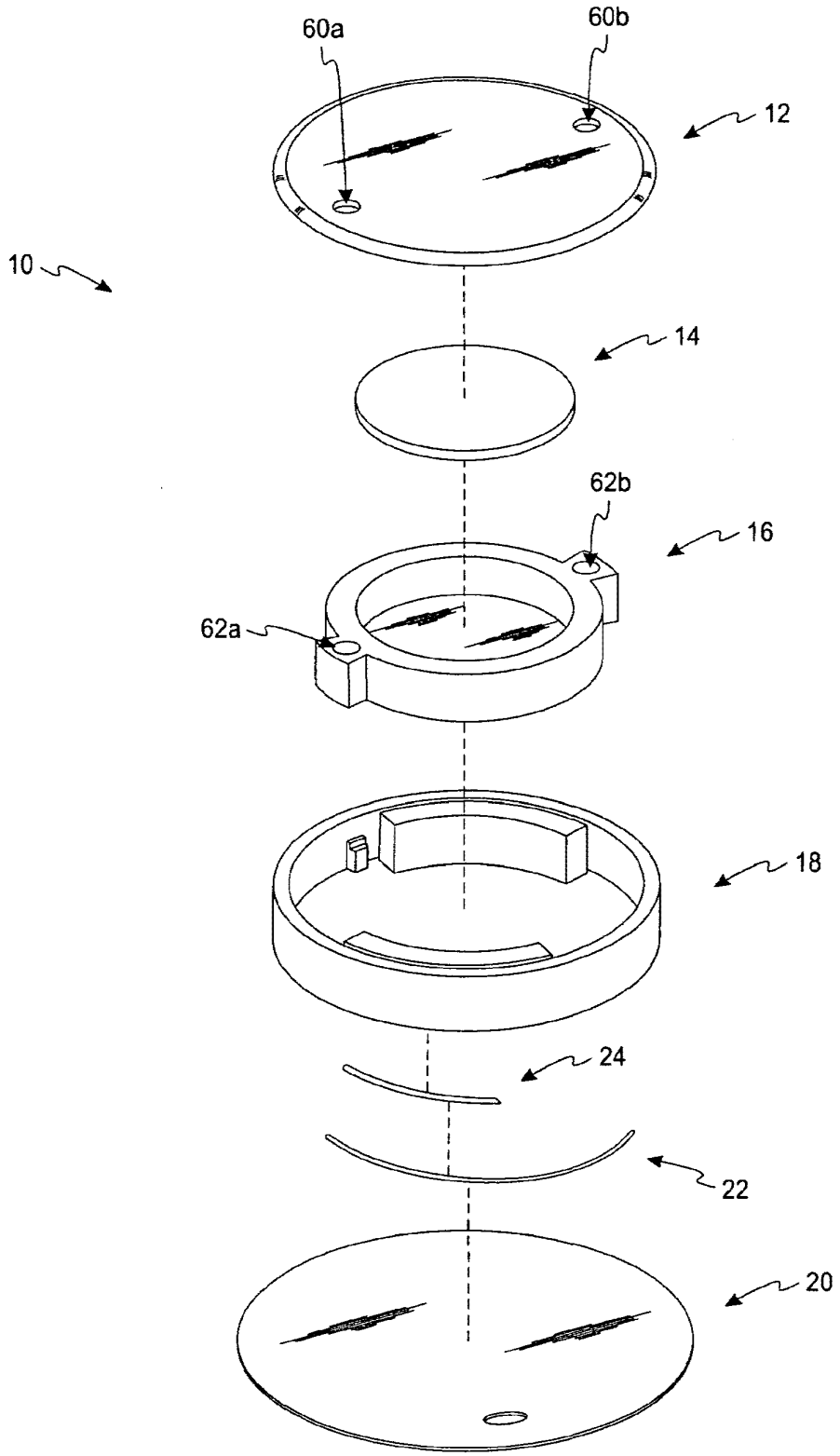


Fig. 3

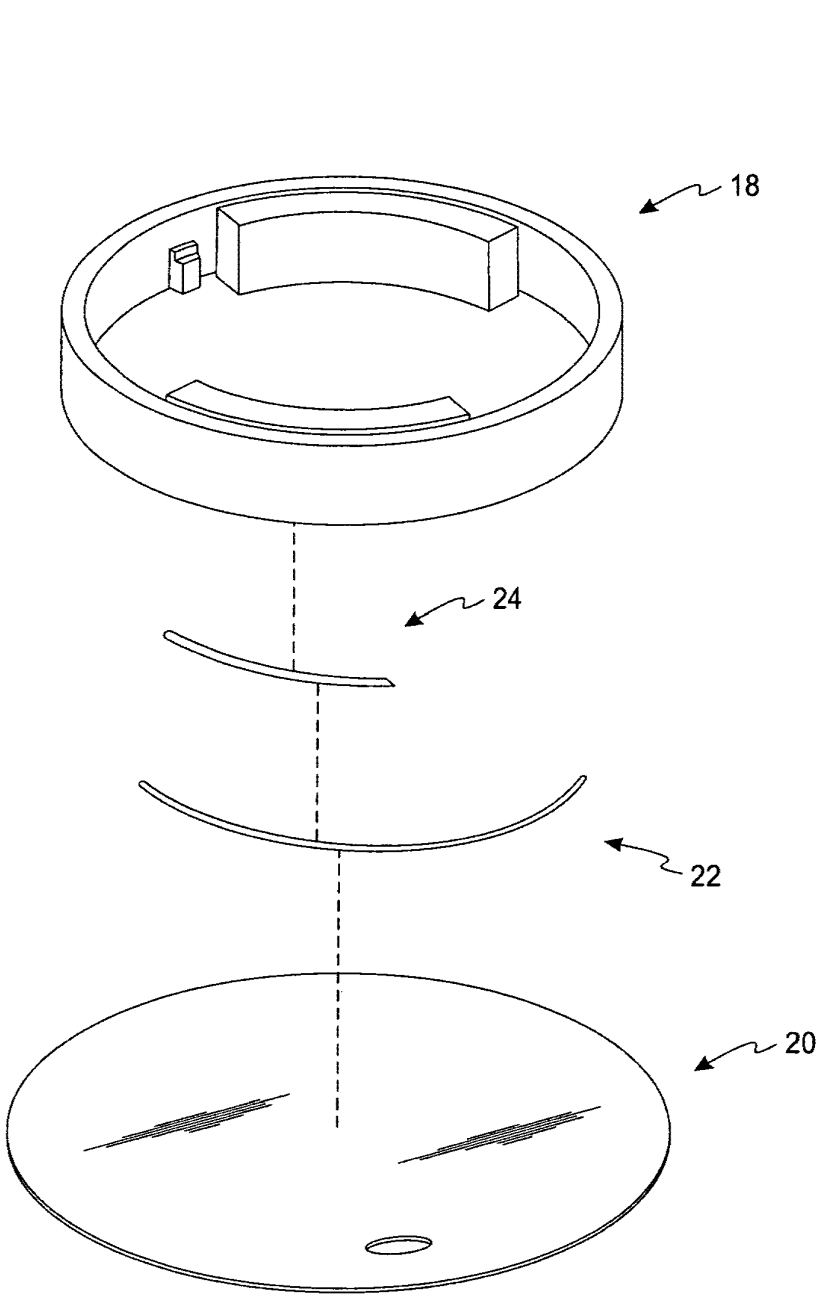


Fig. 4a

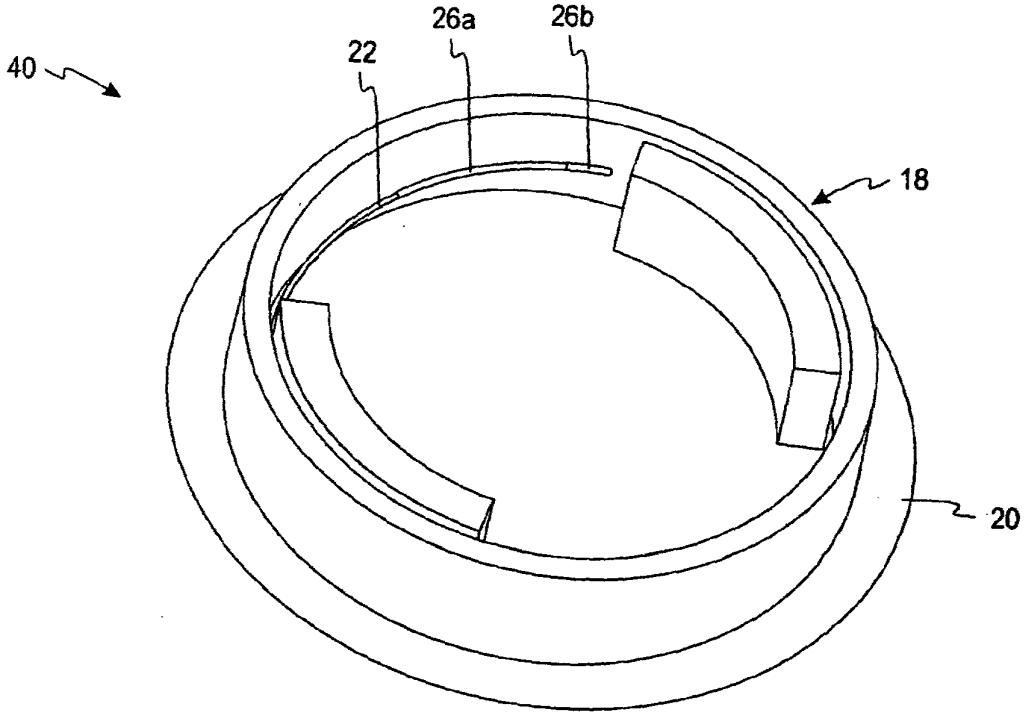


Fig. 4b

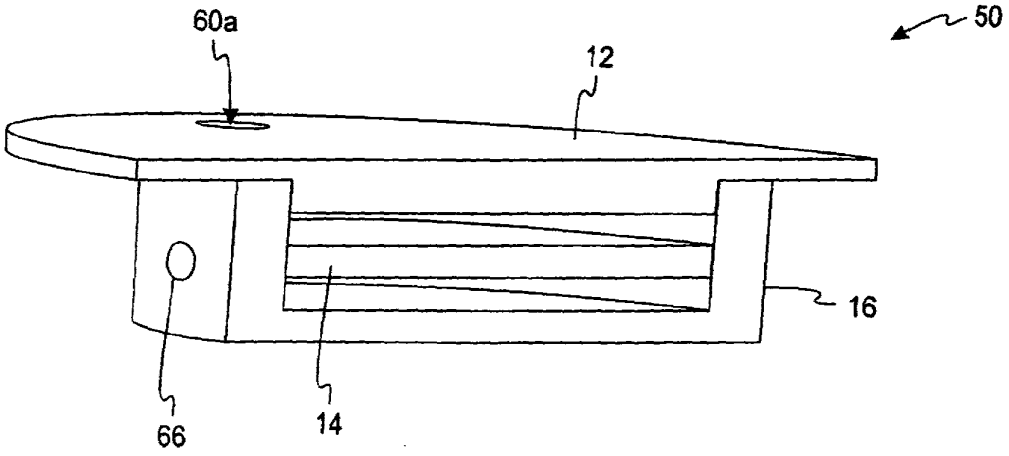


Fig. 5b

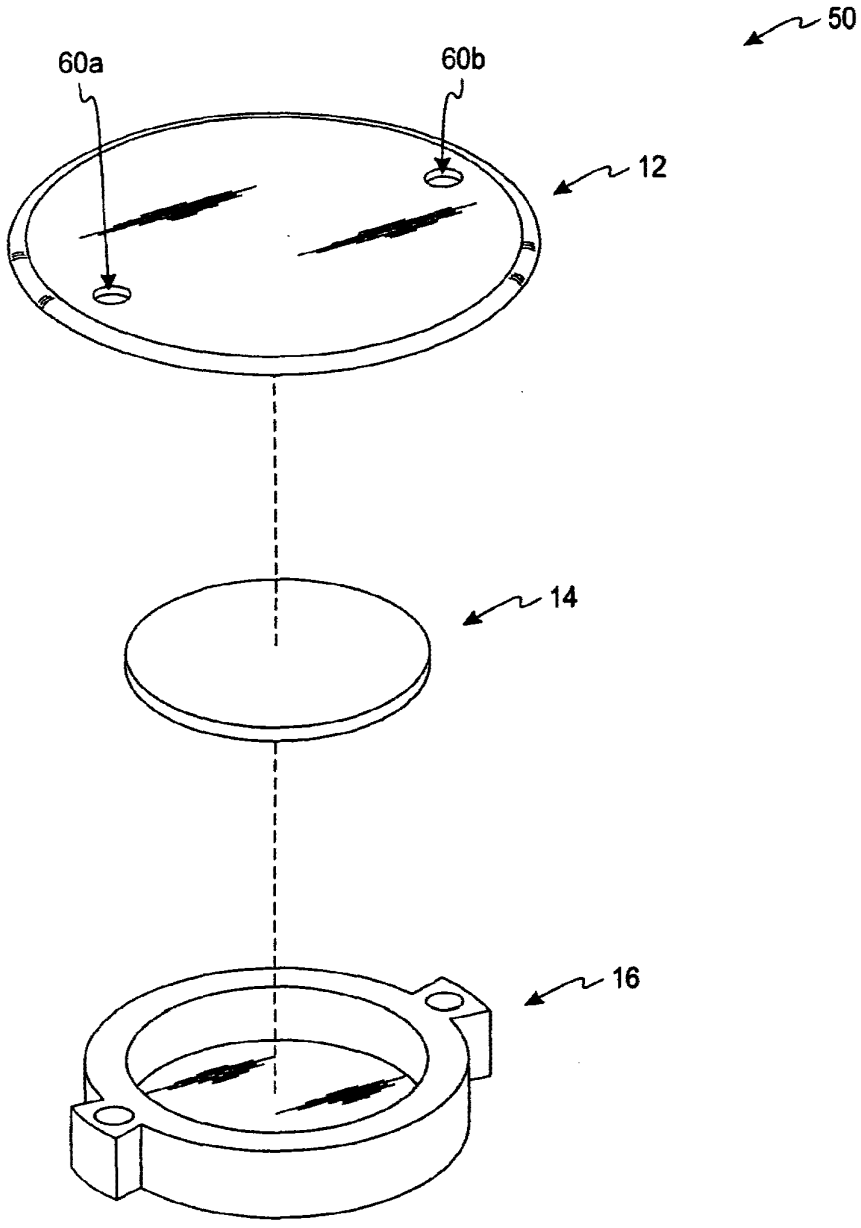


Fig. 5a

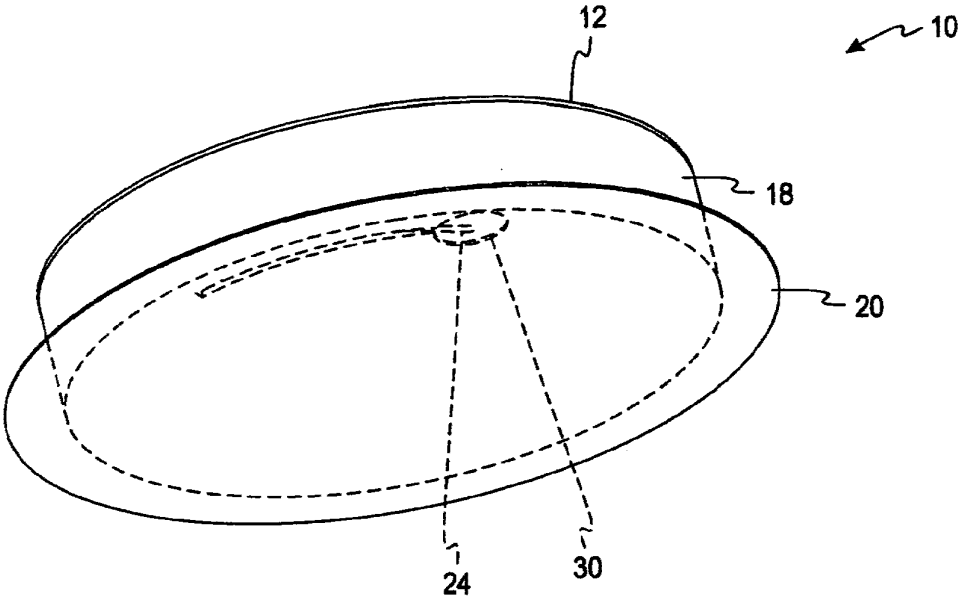


Fig. 6a

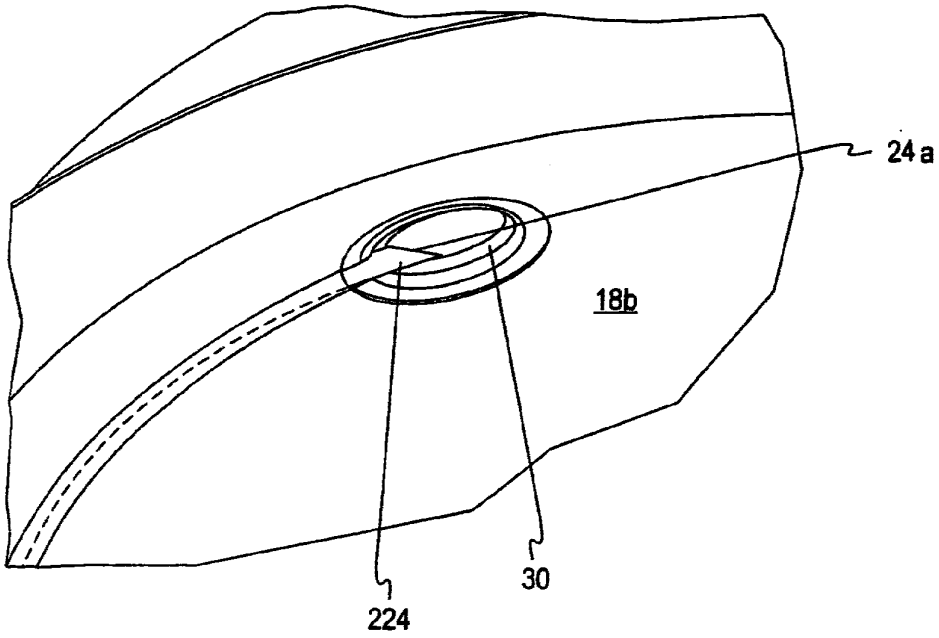


Fig. 6b

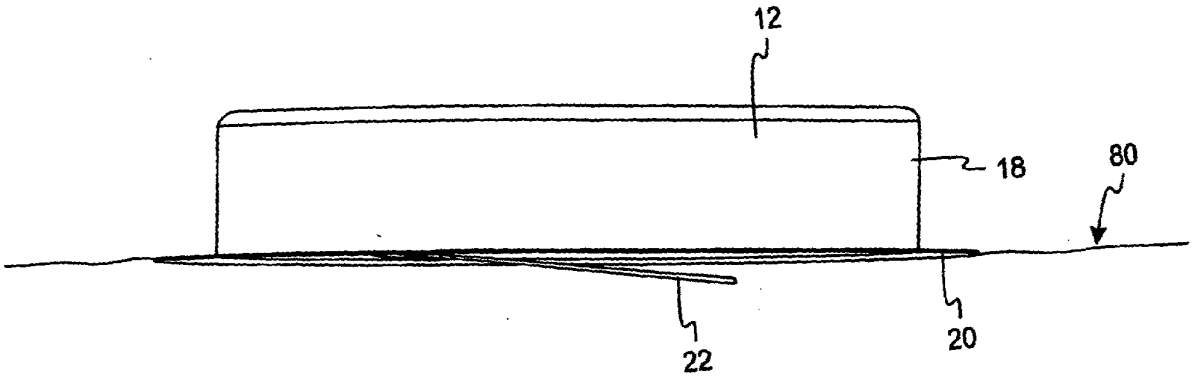


Fig. 7

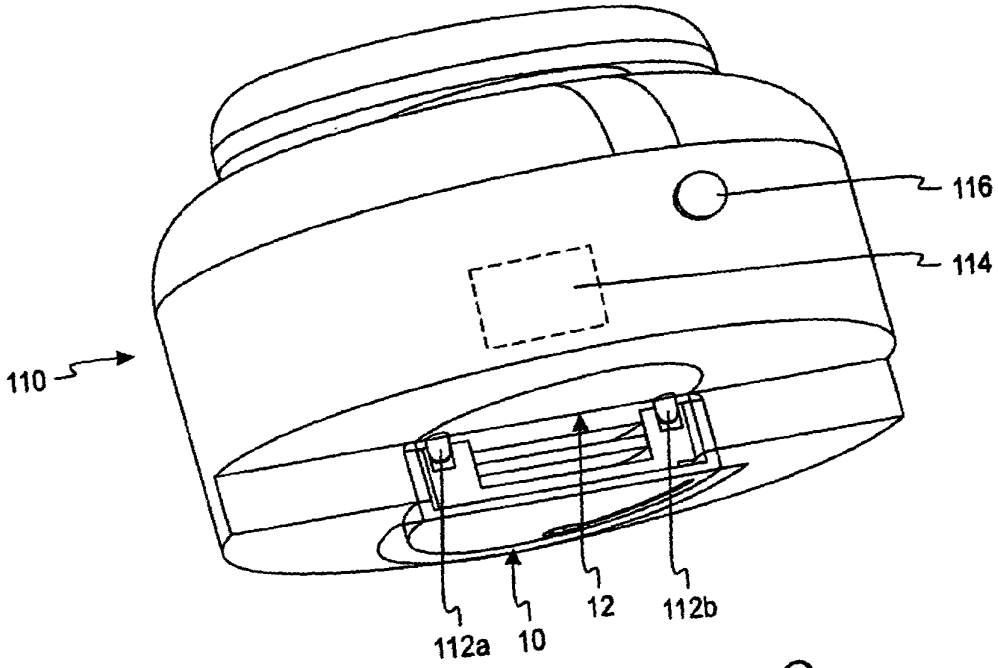


Fig. 8

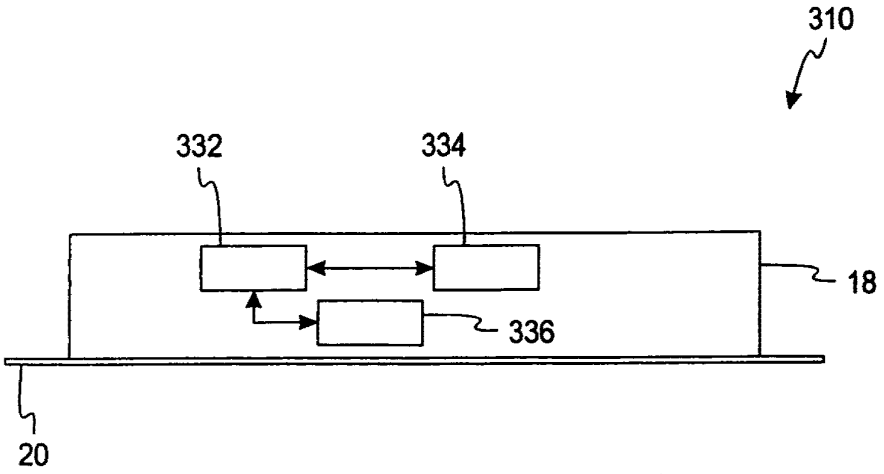


Fig. 9

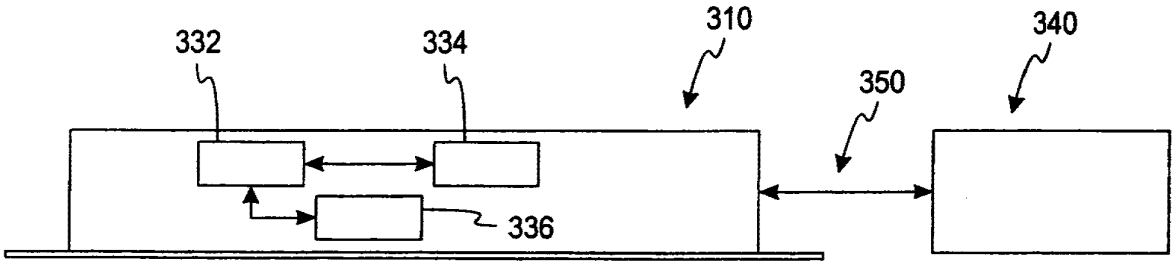


Fig. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/003375

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2006/195029 A1 (SHULTS MARK C [US] ET AL) 31 August 2006 (2006-08-31) paragraph [0101] - paragraph [0139] paragraph [0200] - paragraph [0248] figures 11a,b	1-7,9-17 8,18
Y	WO 2005/063115 A (HADVARY PAUL [CH]; HANSJOERG TSCHIRKY [CH]) 14 July 2005 (2005-07-14) page 9, last paragraph - page 13, paragraph 3	8,18

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 July 2008	23/07/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hooper, Martin

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/003375

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 19-31
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery - the step of inserting the implantable sensor into the skin renders the claimed method surgical.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/003375

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006195029 A1	31-08-2006	NONE	
WO 2005063115 A	14-07-2005	CA 2554232 A1	14-07-2005
		CN 1976627 A	06-06-2007
		US 2008027296 A1	31-01-2008

Form PCT/ISA/210 (patent family annex) (April 2005)

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(10) International Publication Number
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PCT/US2008/063110

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60/916,744	8 May 2007 (08.05.2007)	US
60/916,723	8 May 2007 (08.05.2007)	US
60/916,677	8 May 2007 (08.05.2007)	US

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(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **FENNELL, Martin, J.** [US/US]; 1274 Kestrel Court, Concord, CA 94521 (US). **HE, Lei** [CN/US]; 1419 Camino Peral, Moraga, CA 94556 (US). **SLOAN, Mark, K.** [US/US]; 246 Nice Court, Redwood City, CA 94065 (US). **HAYTER, Gary** [US/US]; 4409 Harbord Drive, Oakland, CA 94618 (US).

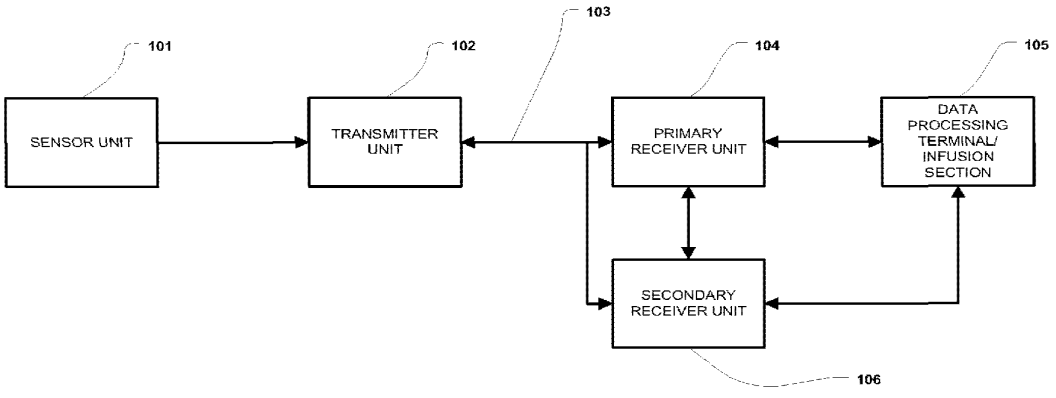
(74) Agent: **OH, Seong-Kun**; Jackson & Co., LLP, 6114 La Salle Ave., #507, Oakland, CA 94611 (US).

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Published:
— *without international search report and to be republished upon receipt of that report*

(54) Title: ANALYTE MONITORING SYSTEM AND METHODS



100

FIGURE 1

(57) Abstract: Methods and systems for providing data communication in medical systems are disclosed.

WO 2008/138006 A2

ANALYTE MONITORING SYSTEM AND METHODS

PRIORITY

The present application claims priority to U.S. provisional application no. 60/916,776 filed May 8, 2007, entitled "Analyte Monitoring System and Methods", U.S. provisional application no. 60/916,773 filed May 8, 2007, entitled "Analyte Monitoring System and Methods", U.S. provisional application no. 60/916,761 filed May 8, 2007, entitled "Analyte Monitoring System and Methods", U.S. provisional application no. 60/916,744 filed May 8, 2007, entitled "Analyte Monitoring System and Methods", U.S. provisional application no. 60/916,723 filed May 8, 2007, entitled "Analyte Monitoring System and Methods", and U.S. provisional application no. 60/916,677 filed May 8, 2007, entitled "Analyte Monitoring System and Methods", the disclosures of each of which are incorporated herein by reference for all purposes.

BACKGROUND

Analyte, e.g., glucose monitoring systems including continuous and discrete monitoring systems generally include a small, lightweight battery powered and microprocessor controlled system which is configured to detect signals proportional to the corresponding measured glucose levels using an electrometer. 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.

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.

Transmission of control or command data over wireless communication link is often constrained to occur within a substantially short time duration. In turn, the time constraint in data communication imposes limits on the type and size of data that may be transmitted during the transmission time period.

In view of the foregoing, it would be desirable to have a method and apparatus for optimizing the RF communication link between two or more communication devices, for example, in a medical communication system.

SUMMARY

Devices and methods for analyte monitoring, e.g., glucose monitoring, 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 and discrete analyte monitoring system.

In one embodiment, a method including 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, is disclosed, as well as devices and systems for the same.

In one embodiment, a method including detecting an electrical connection with an analyte sensor, and activating a data processing device to receive one or more analyte related signals from the analyte sensor, is disclosed, as well as devices and systems for the same.

In one embodiment, a method including receiving a command to initiate communication with an analyte sensor, retrieving an identification information, transmitting the retrieved identification information, and receiving a communication key associated with the transmitted identification information, is disclosed, as well as devices and systems for the same.

In one embodiment, a method including detecting a data transmission, incrementing a count associated with the detected data transmission, and storing the count, is disclosed, as well as devices and systems for the same.

In one embodiment, a method determining a communication status, receiving a communication related close proximity command, and modifying the communication status based on the received command, is disclosed, as well as devices and systems for the same.

In one embodiment, a method including periodically receiving data including a count information related to an analyte sensor associated with the received data, and comparing the count information in each data periodically received, and when it is determined that the count information of the periodically received data is different, generating one or more signals related to the status of the analyte sensor, is disclosed, as well as devices and systems for the same.

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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 invention;

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 invention;

FIG. 4 is a flowchart illustrating data packet procedure including rolling data for transmission in accordance with one embodiment of the present invention;

FIG. 5 is a flowchart illustrating data processing of the received data packet including the rolling data in accordance with one embodiment of the present invention;

FIG. 6 is a block diagram illustrating the sensor unit and the transmitter unit of the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention;

FIG. 7 is a flowchart illustrating data communication using close proximity commands in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention;

FIG. 8 is a flowchart illustrating sensor insertion detection routine in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention;

FIG. 9 is a flowchart illustrating sensor removal detection routine in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention;

FIG. 10 is a flowchart illustrating the pairing or synchronization routine in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention;

FIG. 11 is a flowchart illustrating the pairing or synchronization routine in the data monitoring and management system of FIG. 1 in accordance with another embodiment of the present invention;

FIG. 12 is a flowchart illustrating the power supply determination in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention;

FIG. 13 is a flowchart illustrating close proximity command for RF communication control in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention; and

FIG. 14 is a flowchart illustrating analyte sensor identification routine in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

As summarized above and as described in further detail below, in accordance with the various embodiments of the present invention, 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.

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 invention. 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.

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.

The analyte monitoring system 100 includes a sensor unit 101, a transmitter unit 102 coupleable to the sensor unit 101, and a primary receiver unit 104 which is configured to communicate with the 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 transmitter unit 102 via a communication link which may optionally be configured for bi-directional communication. Accordingly, transmitter unit 102 and/or receiver unit 104 may include a transceiver.

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 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 invention, 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.

In one aspect sensor unit 101 may include two or more sensors, each configured to communicate with transmitter unit 102. Furthermore, while only one, 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 invention, the analyte monitoring system 100 may be a continuous monitoring system, or semi-continuous, or a discrete monitoring system. In a multi-component environment, each device is configured to be uniquely identified by each of the other devices in the system so that communication conflict is readily resolved between the various components within the analyte monitoring system 100.

In one embodiment of the present invention, 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 transmitter unit 102. In certain embodiments, the 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 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 transmitter unit 102 transmits analyte information to the primary receiver unit 104 via the communication link 103.

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

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

In operation, upon completing the power-on procedure, the primary receiver unit 104 is configured to detect the presence of the transmitter unit 102 within its range based on, for example, the strength of the detected data signals received from the transmitter unit 102 and/or a predetermined transmitter identification information. Upon successful synchronization with the corresponding transmitter unit 102, the primary receiver unit 104 is configured to begin receiving from the transmitter unit 102 data signals corresponding to the user's detected analyte level. More specifically,

the primary receiver unit 104 in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized transmitter unit 102 via the communication link 103 to obtain the user's detected analyte level.

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

Within the scope of the present invention, 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 transmitter unit 102.

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

In this embodiment, the data processing terminal 105 which may include an insulin pump, may be configured to receive the analyte signals from the transmitter unit 102, and thus, incorporate the functions of the receiver 103 including data

processing for managing the patient's insulin therapy and analyte monitoring. In one embodiment, the communication link 103 may include one or more of an RF communication protocol, an infrared communication protocol, a Bluetooth enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPPA requirements) while avoiding potential data collision and interference.

FIG. 2 is a block diagram of the transmitter of the data monitoring and detection system shown in FIG. 1 in accordance with one embodiment of the present invention. Referring to the Figure, the 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 detection 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 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.

Further shown in FIG. 2 are a transmitter serial communication section 205 and an RF transmitter 206, each of which is also operatively coupled to the transmitter processor 204. Moreover, a power supply 207 such as a battery is also provided in the transmitter unit 102 to provide the necessary power for the transmitter unit 102. Additionally, as can be seen from the Figure, clock 208 is provided to, among others, supply real time information to the transmitter processor 204.

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

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

In certain embodiments, the transmitter unit 102 is also configured such that the power supply section 207 is capable of providing power to the transmitter for a minimum of about three months of continuous operation, e.g., after having been stored for about eighteen months such as stored in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor 204 operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μA of current. Indeed, in one embodiment, a step during the manufacturing process of the transmitter unit 102 may place the transmitter unit 102 in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter unit 102 may be significantly improved.

Moreover, as shown in FIG. 2, while the power supply unit 207 is shown as coupled to the processor 204, and as such, the processor 204 is configured to provide control of the power supply unit 207, it should be noted that within the scope of the present invention, the power supply unit 207 is configured to provide the necessary power to each of the components of the transmitter unit 102 shown in FIG. 2.

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

Referring yet again to FIG. 2, the temperature detection section 203 of the transmitter unit 102 is configured to monitor the temperature of the skin near the sensor insertion site. The temperature reading is used to adjust the analyte readings obtained from the analog interface 201. 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.

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 invention 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.

Describe sensor, calibration (single point), etc. 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.

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 invention. 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 detection section 304, and a clock 305, each of which is operatively coupled to a receiver processor 307. As can be further seen from the Figure, the primary receiver unit 104 also includes a power supply 306 operatively coupled to a power conversion and monitoring section 308. Further, the power conversion and monitoring section 308 is also coupled to the receiver processor 307. Moreover, also shown are a receiver serial communication section 309, and an output 310, each operatively coupled to the receiver processor 307.

In one embodiment, the test strip interface 301 includes a glucose level testing portion to receive a manual insertion of a glucose test strip, and thereby determine and display the glucose level of the test strip on the output 310 of the primary receiver unit 104. This manual testing of glucose 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 detection section 304 is configured to provide temperature information of the primary receiver unit 104 to the receiver processor 307, while the clock 305 provides, among others, real time information to the receiver processor 307.

Each of the various components of the primary receiver unit 104 shown in FIG. 3 is powered by the power supply 306 which, in one embodiment, includes a battery. Furthermore, the power conversion and monitoring section 308 is configured

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

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

Referring back to FIG. 3, the primary receiver unit 104 in one embodiment may also include a storage section such as a programmable, non-volatile memory device as part of the processor 307, or provided separately in the primary receiver unit 104, operatively coupled to the processor 307. The processor 307 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.

Additional description of the RF communication between the transmitter 102 and the primary receiver 104 (or with the secondary receiver 106) that may be employed in embodiments of the subject invention is disclosed in pending application no. 11/060,365 filed February 16, 2005 entitled "Method and System for Providing Data Communication in Continuous Glucose Monitoring and Management System" the disclosure of which is incorporated herein by reference for all purposes.

Referring to the Figures, in one embodiment, the transmitter 102 (FIG. 1) may be configured to generate data packets for periodic transmission to one ore more of the receiver units 104, 106, where each data packet includes in one embodiment two categories of data – urgent data and non-urgent data. For example, urgent data such as for example glucose data from the sensor and/or temperature data associated with the sensor may be packed in each data packet in addition to non-urgent data, where the non-urgent data is rolled or varied with each data packet transmission.

That is, the non-urgent data is transmitted at a timed interval so as to maintain the integrity of the analyte monitoring system without being transmitted over the RF communication link with each data transmission packet from the transmitter 102. In this manner, the non-urgent data, for example that are not time sensitive, may be periodically transmitted (and not with each data packet transmission) or broken up into predetermined number of segments and sent or transmitted over multiple packets, while the urgent data is transmitted substantially in its entirety with each data transmission.

Referring again to the Figures, upon receiving the data packets from the transmitter 102, the one or more receiver units 104, 106 may be configured to parse the received the data packet to separate the urgent data from the non-urgent data, and also, may be configured to store the urgent data and the non-urgent data, e.g., in a hierarchical manner. In accordance with the particular configuration of the data packet or the data transmission protocol, more or less data may be transmitted as part of the urgent data, or the non-urgent rolling data. That is, within the scope of the present disclosure, the specific data packet implementation such as the number of bits per packet, and the like, may vary based on, among others, the communication protocol, data transmission time window, and so on.

In an exemplary embodiment, different types of data packets may be identified accordingly. For example, identification in certain exemplary embodiments may include – (1) single sensor, one minute of data, (2) two or multiple sensors, (3) dual sensor, alternate one minute data, and (4) response packet. For single sensor one minute data packet, in one embodiment, the transmitter 102 may be configured to generate the data packet in the manner, or similar to the manner, shown in Table 1 below.

Table 1. Single sensor, one minute of data

Number of Bits	Data Field
8	Transmit Time
14	Sensor1 Current Data
14	Sensor1 Historic Data
8	Transmit Status
12	AUX Counter
12	AUX Thermistor 1
12	AUX Thermistor 2
8	Rolling-Data-1

As shown in Table 1 above, the transmitter data packet in one embodiment may include 8 bits of transmit time data, 14 bits of current sensor data, 14 bits of preceding sensor data, 8 bits of transmitter status data, 12 bits of auxiliary counter data, 12 bits of auxiliary thermistor 1 data, 12 bits of auxiliary thermistor 1 data and 8 bits of rolling data. In one embodiment of the present invention, the data packet generated by the transmitter for transmission over the RF communication link may include all or some of the data shown above in Table 1.

Referring back, the 14 bits of the current sensor data provides the real time or current sensor data associated with the detected analyte level, while the 14 bits of the sensor historic or preceding sensor data includes the sensor data associated with the detected analyte level one minute ago. In this manner, in the case where the receiver unit 104, 106 drops or fails to successfully receive the data packet from the transmitter 102 in the minute by minute transmission, the receiver unit 104, 106 may

be able to capture the sensor data of a prior minute transmission from a subsequent minute transmission.

Referring again to Table 1, the Auxiliary data in one embodiment may include one or more of the patient's skin temperature data, a temperature gradient data, reference data, and counter electrode voltage. The transmitter status field may include status data that is configured to indicate corrupt data for the current transmission (for example, if shown as BAD status (as opposed to GOOD status which indicates that the data in the current transmission is not corrupt)). Furthermore, the rolling data field is configured to include the non-urgent data, and in one embodiment, may be associated with the time-hop sequence number. In addition, the Transmitter Time field in one embodiment includes a protocol value that is configured to start at zero and is incremented by one with each data packet. In one aspect, the transmitter time data may be used to synchronize the data transmission window with the receiver unit 104, 106, and also, provide an index for the Rolling data field.

In a further embodiment, the transmitter data packet may be configured to provide or transmit analyte sensor data from two or more independent analyte sensors. The sensors may relate to the same or different analyte or property. In such a case, the data packet from the transmitter 102 may be configured to include 14 bits of the current sensor data from both sensors in the embodiment in which 2 sensors are employed. In this case, the data packet does not include the immediately preceding sensor data in the current data packet transmission. Instead, a second analyte sensor data is transmitted with a first analyte sensor data.

Table 2. Dual sensor data

Number of Bits	Data Field
8	Transmit Time
14	Sensor1 Current Data
14	Sensor2 Current Data
8	Transmit Status
12	AUX Counter
12	AUX Thermistor 1
12	AUX Thermistor 2
8	Rolling-Data-1

In a further embodiment, the transmitter data packet may be alternated with each transmission between two analyte sensors, for example, alternating between the data packet shown in Table 3 and Table 4 below.

Table 3. Sensor Data Packet Alternate 1

Number of Bits	Data Field
8	Transmitter Time
14	Sensor1 Current Data
14	Sensor1 Historic Data
8	Transmit Status
12	AUX Counter
12	AUX Thermistor 1
12	AUX Thermistor 2
8	Rolling-Data-1

Table 4. Sensor Data Packet Alternate 2

Number of Bits	Data Field
8	Transmitter Time
14	Sensor1 Current Data
14	Sensor2 Current Data
8	Transmit Status
12	AUX Counter
12	AUX Thermistor 1
12	AUX Thermistor 2
8	Rolling-Data-1

As shown above in reference to Tables 3 and 4, the minute by minute data packet transmission from the transmitter 102 (FIG. 1) in one embodiment may alternate between the data packet shown in Table 3 and the data packet shown in Table 4. More specifically, the transmitter 102 may be configured in one embodiment transmit the current sensor data of the first sensor and the preceding sensor data of the first sensor (Table 3), as well as the rolling data, and further, at the subsequent transmission, the transmitter 102 may be configured to transmit the current sensor data of the first and the second sensor in addition to the rolling data.

In one embodiment, the rolling data transmitted with each data packet may include a sequence of various predetermined types of data that are considered not-urgent or not time sensitive. That is, in one embodiment, the following list of data shown in Table 5 may be sequentially included in the 8 bits of transmitter data packet, and not transmitted with each data packet transmission of the transmitter (for example, with each 60 second data transmission from the transmitter 102).

Table 5. Rolling Data

Time Slot	Bits	Rolling-Data
0	8	Mode
1	8	Glucose1 Slope
2	8	Glucose2 Slope
3	8	Ref-R
4	8	Hobbs Counter, Ref-R
5	8	Hobbs Counter
6	8	Hobbs Counter
7	8	Sensor Count

As can be seen from Table 5 above, in one embodiment, a sequence of rolling data are appended or added to the transmitter data packet with each data transmission time slot. In one embodiment, there may be 256 time slots for data transmission by the transmitter 102 (FIG. 1), and where, each time slot is separately by approximately 60 second interval. For example, referring to the Table 5 above, the data packet in transmission time slot 0 (zero) may include operational mode data (Mode) as the rolling data that is appended to the transmitted data packet. At the subsequent data transmission time slot (for example, approximately 60 seconds after the initial time slot (0), the transmitted data packet may include the analyte sensor 1 calibration factor information (Glucose1 slope) as the rolling data. In this manner, with each data transmission, the rolling data may be updated over the 256 time slot cycle.

Referring again to Table 5, each rolling data field is described in further detail for various embodiments. For example, the Mode data may include information related to the different operating modes such as, but not limited to, the data packet type, the type of battery used, diagnostic routines, single sensor or multiple sensor input, type of data transmission (rf communication link or other data link such as

serial connection). Further, the Glucose1-slope data may include an 8-bit scaling factor or calibration data for first sensor (scaling factor for sensor 1 data) , while Glucose2-slope data may include an 8-bit scaling factor or calibration data for the second analyte sensor (in the embodiment including more than one analyte sensors).

In addition, the Ref-R data may include 12 bits of on-board reference resistor used to calibrate our temperature measurement in the thermister circuit (where 8 bits are transmitted in time slot 3, and the remaining 4 bits are transmitted in time slot 4), and the 20-bit Hobbs counter data may be separately transmitted in three time slots (for example, in time slot 4, time slot 5 and time slot 6) to add up to 20 bits. In one embodiment, the Hobbs counter may be configured to count each occurrence of the data transmission (for example, a packet transmission at approximately 60 second intervals) and may be incremented by a count of one (1).

In one aspect, the Hobbs counter is stored in a nonvolatile memory of the transmitter unit 102 (FIG. 1) and may be used to ascertain the power supply status information such as, for example, the estimated battery life remaining in the transmitter unit 102. That is, with each sensor replacement, the Hobbs counter is not reset, but rather, continues the count with each replacement of the sensor unit 101 to establish contact with the transmitter unit 102 such that, over an extended usage time period of the transmitter unit 102, it may be possible to determine, based on the Hobbs count information, the amount of consumed battery life in the transmitter unit 102, and also, an estimated remaining life of the battery in the transmitter unit 102.

That is, in one embodiment, the 20 bit Hobbs counter is incremented by one each time the transmitter unit 102 transmits a data packet (for example, approximately each 60 seconds), and based on the count information in the Hobbs counter, in one aspect, the battery life of the transmitter unit 102 may be estimated. In this manner, in configurations of the transmitter unit 620 (see FIG. 6) where the power supply is not a replaceable component but rather, embedded within the housing the transmitter unit 620, it is possible to estimate the remaining life of the embedded battery within the transmitter unit 620. Moreover, the Hobbs counter is configured to remain persistent in the memory device of the transmitter unit 620 such that, even when the transmitter unit power is turned off or powered down (for example, during the periodic sensor

unit replacement, RF transmission turned off period and the like), the Hobbs counter information is retained.

Referring to Table 5 above, the transmitted rolling data may also include 8 bits of sensor count information (for example, transmitted in time slot 7). The 8 bit sensor counter is incremented by one each time a new sensor unit is connected to the transmitter unit. The ASIC configuration of the transmitter unit (or a microprocessor based transmitter configuration or with discrete components) may be configured to store in a nonvolatile memory unit the sensor count information and transmit it to the primary receiver unit 104 (for example). In turn, the primary receiver unit 104 (and/or the secondary receiver unit 106) may be configured to determine whether it is receiving data from the transmitter unit that is associated with the same sensor unit (based on the sensor count information), or from a new or replaced sensor unit (which will have a sensor count incremented by one from the prior sensor count). In this manner, in one aspect, the receiver unit (primary or secondary) may be configured to prevent reuse of the same sensor unit by the user based on verifying the sensor count information associated with the data transmission received from the transmitter unit 102. In addition, in a further aspect, user notification may be associated with one or more of these parameters. Further, the receiver unit (primary or secondary) may be configured to detect when a new sensor has been inserted, and thus prevent erroneous application of one or more calibration parameters determined in conjunction with a prior sensor, that may potentially result in false or inaccurate analyte level determination based on the sensor data.

FIG. 4 is a flowchart illustrating a data packet procedure including rolling data for transmission in accordance with one embodiment of the present invention. Referring to FIG. 4, in one embodiment, a counter is initialized (for example, to T = 0) (410). Thereafter the associated rolling data is retrieved from memory device, for example (420), and also, the time sensitive or urgent data is retrieved (430). In one embodiment, the retrieval of the rolling data (420) and the retrieval of the time sensitive data (430) may be retrieved at substantially the same time.

Referring back to FIG. 4, with the rolling data and the time sensitive data, for example, the data packet for transmission is generated (440), an upon transmission, the counter is incremented by one and the routine returns to retrieval of the rolling

data (420). In this manner, in one embodiment, the urgent time sensitive data as well as the non-urgent data may be incorporated in the same data packet and transmitted by the transmitter 102 (FIG. 1) to a remote device such as one or more of the receivers 104, 106. Furthermore, as discussed above, the rolling data may be updated at a predetermined time interval which is longer than the time interval for each data packet transmission from the transmitter 102 (FIG. 1).

FIG. 5 is a flowchart illustrating data processing of the received data packet including the rolling data in accordance with one embodiment of the present invention. Referring to FIG. 5, when the data packet is received (510) (for example, by one or more of the receivers 104, 106, in one embodiment. the received data packet is parsed so that the urgent data may be separated from the not-urgent data (stored in, for example, the rolling data field in the data packet). Thereafter the parsed data is suitably stored in an appropriate memory or storage device (530).

In the manner described above, in accordance with one embodiment of the present invention, there is provided method and apparatus for separating non-urgent type data (for example, data associated with calibration) from urgent type data (for example, monitored analyte related data) to be transmitted over the communication link to minimize the potential burden or constraint on the available transmission time. More specifically, in one embodiment, non-urgent data may be separated from data that is required by the communication system to be transmitted immediately, and transmitted over the communication link together while maintaining a minimum transmission time window. In one embodiment, the non-urgent data may be parsed or broken up in to a number of data segments, and transmitted over multiple data packets. The time sensitive immediate data (for example, the analyte sensor data, temperature data etc), may be transmitted over the communication link substantially in its entirety with each data packet or transmission.

FIG. 6 is a block diagram illustrating the sensor unit and the transmitter unit of the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention. Referring to FIG. 6, in one aspect, a transmitter unit 620 is provided in a substantially water tight and sealed housing. The transmitter unit 620 includes respective contacts (wrk, Ref, Cntr, and gnd) for respectively establishing electrical contact with one or more of the working electrode, the

reference electrode, the counter electrode and the ground terminal (or guard trace) of the sensor unit 610. Also shown in FIG. 6 is a conductivity bar/trace 611 provided on the sensor unit 610. For example, in one embodiment, the conductivity bar/trace 611 may comprise a carbon trace on a substrate layer of the sensor unit 610. In this manner, in one embodiment, when the sensor unit 610 is coupled to the transmitter unit 610, electrical contact is established, for example, via the conductivity bar/trace 611 between the contact pads or points of the transmitter unit 620 (for example, at the counter electrode contact (cntr) and the ground terminal contact (gnd) such that the transmitter unit 620 may be powered for data communication.

That is, during manufacturing of the transmitter unit 620, in one aspect, the transmitter unit 620 is configured to include a power supply such as battery 621. Further, during the initial non-use period (e.g., post manufacturing sleep mode), the transmitter unit 620 is configured such that it is not used and thus drained by the components of the transmitter unit 620. During the sleep mode, and prior to establishing electrical contact with the sensor unit 610 via the conductivity bar/trace 611, the transmitter unit 620 is provided with a low power signal from, for example, a low power voltage comparator 622, via an electronic switch 623 to maintain the low power state of, for example, the transmitter unit 620 components. Thereafter, upon connection with the sensor unit 610, and establishing electrical contact via the conductivity bar/trace 611, the embedded power supply 621 of the transmitter unit 620 is activated or powered up so that some of all of the components of the transmitter unit 620 are configured to receive the necessary power signals for operations related to, for example, data communication, processing and/or storage.

In one aspect, since the transmitter unit 620 is configured to a sealed housing without a separate replaceable battery compartment, in this manner, the power supply of the battery 621 is preserved during the post manufacturing sleep mode prior to use.

In a further aspect, the transmitter unit 620 may be disposed or positioned on a separate on-body mounting unit that may include, for example, an adhesive layer (on its bottom surface) to firmly retain the mounting unit on the skin of the user, and which is configured to receive or firmly position the transmitter unit 620 on the mounting unit during use. In one aspect, the mounting unit may be configured to at least partially retain the position of the sensor unit 610 in a transcutaneous manner so

that at least a portion of the sensor unit is in fluid contact with the analyte of the user. Example embodiments of the mounting or base unit and its cooperation or coupling with the transmitter unit are provided, for example, in US Patent No. 6,175,752, incorporated herein by reference for all purposes.

In such a configuration, the power supply for the transmitter unit 620 may be provided within the housing of the mounting unit such that, the transmitter unit 620 may be configured to be powered on or activated upon placement of the transmitter unit 620 on the mounting unit and in electrical contact with the sensor unit 610. For example, the sensor unit 610 may be provided pre-configured or integrated with the mounting unit and the insertion device such that, the user may position the sensor unit 610 on the skin layer of the user using the insertion device coupled to the mounting unit. Thereafter, upon transcutaneous positioning of the sensor unit 610, the insertion device may be discarded or removed from the mounting unit, leaving behind the transcutaneously positioned sensor unit 610 and the mounting unit on the skin surface of the user.

Thereafter, when the transmitter unit 620 is positioned on, over or within the mounting unit, the battery or power supply provided within the mounting unit is configured to electrically couple to the transmitter unit 620 and/or the sensor unit 610. Given that the sensor unit 610 and the mounting unit are provided as replaceable components for replacement every 3, 5, 7 days or other predetermined time periods, the user is conveniently not burdened with verifying the status of the power supply providing power to the transmitter unit 620 during use. That is, with the power supply or battery replaced with each replacement of the sensor unit 610, a new power supply or battery will be provided with the new mounting unit for use with the transmitter unit 620.

Referring to FIG. 6 again, in one aspect, when the sensor unit 610 is removed from the transmitter unit 620 (or vice versa), the electrical contact is broken and the conductivity bar/trace 611 returns to an open circuit. In this case, the transmitter unit 620 may be configured, to detect such condition and generate a last gasp transmission sent to the primary receiver unit 104 (and/or the secondary receiver unit 106) indicating that the sensor unit 610 is disconnected from the transmitter unit 620, and that the transmitter unit 620 is entering a powered down (or low power off) state.

And the transmitter unit 620 is powered down into the sleep mode since the connection to the power supply (that is embedded within the transmitter unit 620 housing) is broken.

In this manner, in one aspect, the processor 624 of the transmitter unit 620 may be configured to generate the appropriate one or more data or signals associated with the detection of sensor unit 610 disconnection for transmission to the receiver unit 104 (FIG. 1), and also, to initiate the power down procedure of the transmitter unit 620. In one aspect, the components of the transmitter unit 620 may be configured to include application specific integrated circuit (ASIC) design with one or more state machines and one or more nonvolatile and/or volatile memory units such as, for example, EEPROMs and the like.

Referring again to FIGS. 1 and 6, in one embodiment, the communication between the transmitter unit 620 (or 102 of FIG. 1) and the primary receiver unit 104 (and/or the secondary receiver unit 106) may be based on close proximity communication where bi-directional (or uni-directional) wireless communication is established when the devices are physically located in close proximity to each other. That is, in one embodiment, the transmitter unit 620 may be configured to receive very short range commands from the primary receiver unit 104 (FIG. 1) and perform one or more specific operations based on the received commands from the receiver unit 104).

In one embodiment, to maintain secure communication between the transmitter unit and the data receiver unit, the transmitter unit ASIC may be configured to generate a unique close proximity key at power on or initialization. In one aspect, the 4 or 8 bit key may be generated based on, for example, the transmitter unit identification information, and which may be used to prevent undesirable or unintended communication. In a further aspect, the close proximity key may be generated by the receiver unit based on, for example, the transmitter identification information received by the transmitter unit during the initial synchronization or pairing procedure of the transmitter and the receiver units.

Referring again to FIGS. 1 and 6, in one embodiment, the transmitter unit ASIC configuration may include a 32KHz oscillator and a counter which may be configured to drive the state machine in the transmitter unit ASIC. The transmitter

ASIC configuration may include a plurality of close proximity communication commands including, for example, new sensor initiation, pairing with the receiver unit, and RF communication control, among others. For example, when a new sensor unit is positioned and coupled to the transmitter unit so that the transmitter unit is powered on, the transmitter unit is configured to detect or receive a command from the receiver unit positioned in close proximity to the transmitter unit. For example, the receiver unit may be positioned within a couple of inches from the on-body position of the transmitter unit, and when the user activates or initiates a command associated with the new sensor initiation from the receiver unit, the transmitter unit is configured to receive the command from the receiver and, in its response data packet, transmit, among others, its identification information back to the receiver unit.

In one embodiment, the initial sensor unit initiation command does not require the use of the close proximity key. However, other predefined or preconfigured close-proximity commands may be configured to require the use of the 8 bit key (or a key of a different number of bits). For example, in one embodiment, the receiver unit may be configured to transmit a RF on/off command to turn on/off the RF communication module or unit in the transmitter unit 102. Such RF on/off command in one embodiment includes the close proximity key as part of the transmitted command for reception by the transmitter unit.

During the period that the RF communication module or unit is turned off based on the received close proximity command, the transmitter unit does not transmit any data, including any glucose related data. In one embodiment, the glucose related data from the sensor unit which are not transmitted by the transmitter unit during the time period when the RF communication module or unit of the transmitter unit is turned off may be stored in a memory or storage unit of the transmitter unit for subsequent transmission to the receiver unit when the transmitter unit RF communication module or unit is turned back on based on the RF-on command from the receiver unit. In this manner, in one embodiment, the transmitter unit may be powered down (temporarily, for example, during air travel) without removing the transmitter unit from the on-body position.

FIG. 7 is a flowchart illustrating data communication using close proximity commands in the data monitoring and management system of FIG. 1 in accordance

with one embodiment of the present invention. Referring to FIG. 7, the primary receiver unit 104 (FIG. 1) in one aspect may be configured to retrieve or generate a close proximity command (710) for transmission to the transmitter unit 102. To establish the transmission range (720), the primary receiver unit 104 may be positioned physically close to (that is, within a predetermined distance from) the transmitter unit 102. For example, the transmission range for the close proximity communication may be established at approximately one foot distance or less between the transmitter unit 102 and the primary receiver unit 104. When the transmitter unit 102 and the primary receiver unit 104 are within the transmission range, the close proximity command, upon initiation from the receiver unit 104 may be transmitted to the transmitter unit 102 (730).

Referring back to FIG. 7, in response to the transmitted close proximity command, a response data packet or other responsive communication may be received (740). In one aspect, the response data packet or other responsive communication may include identification information of the transmitter unit 102 transmitting the response data packer or other response communication to the receiver unit 104. In one aspect, the receiver unit 104 may be configured to generate a key (for example, an 8 bit key or a key of a predetermined length) based on the transmitter identification information (750), and which may be used in subsequent close proximity communication between the transmitter unit 102 and the receiver unit 104.

In one aspect, the data communication including the generated key may allow the recipient of the data communication to recognize the sender of the data communication and confirm that the sender of the data communication is the intended data sending device, and thus, including data which is desired or anticipated by the recipient of the data communication. In this manner, in one embodiment, one or more close proximity commands may be configured to include the generated key as part of the transmitted data packet. Moreover, the generated key may be based on the transmitter ID or other suitable unique information so that the receiver unit 104 may use such information for purposes of generating the unique key for the bi-directional communication between the devices.

While the description above includes generating the key based on the transmitter unit 102 identification information, within the scope of the present

disclosure, the key may be generated based on one or more other information associated with the transmitter unit 102, and/or the receiver unit combination. In a further embodiment, the key may be encrypted and stored in a memory unit or storage device in the transmitter unit 102 for transmission to the receiver unit 104.

FIG. 8 is a flowchart illustrating sensor insertion detection routine in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention. Referring to FIG. 8, connection to an analyte sensor is detected (810, based on for example, a power up procedure where the sensor conduction trace 611 (FIG. 6) is configured to establish electrical contact with a predetermined one or more contact points on the transmitter unit 102. That is, when the sensor unit 101 (for example, the electrodes of the sensor) is correspondingly connected to the contact points on the transmitter unit 102, the transmitter unit 102 is configured to close the circuit connecting its power supply (for example, the battery 621 (FIG. 6)) to the components of the transmitter unit 102 and thereby exiting the power down or low power state into active or power up state.

In this manner, as discussed above, in one aspect, the transmitter unit 102 may be configured to include a power supply such as a battery 621 integrally provided within the sealed housing of the transmitter unit 102. When the transmitter unit 102 is connected or coupled to the respective electrodes of the analyte sensor that is positioned in a transcutaneous manner under the skin layer of the patient, the transmitter unit 102 is configured to wake up from its low power or sleep state (820), and power up the various components of the transmitter unit 102. In the active state, the transmitter unit 102 may be further configured to receive and process sensor signals received from the analyte sensor (FIG. 1) (830), and thereafter, transmit the processed sensor signals (840) to, for example, the receiver unit 104 (FIG. 1).

Accordingly, in one aspect, the sensor unit 610 (FIG. 6) may be provided with a conduction trace 611 which may be used to wake up or exit the transmitter unit from its post manufacturing sleep mode into an active state, by for example, establishing a closed circuit with the power supply provided within the transmitter unit 102.

FIG. 9 is a flowchart illustrating sensor removal detection routine in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention. Referring to FIG. 9, when the sensor removal is detected (910)

for example, based on detaching or removing the transmitter unit 102 that was in contact with the sensor unit 101, one or more status signal is generated (920), that includes, for example, an indication that the sensor removal state has been detected, and/or an indication that the transmitter unit 102 will enter a sleep mode or a powered down status. Thereafter, the generated status signal in one aspect is transmitted, for example, to the receiver unit 104 (930), and the transmitter unit 102 is configured to enter the power down mode or low power sleep mode (940).

In this manner, in one aspect, when the transmitter unit 102 is disconnected with an active sensor unit 101, the transmitter unit 102 is configured to notify the receiver unit 104 that the sensor unit 101 has been disconnected or otherwise, signals from the sensor unit 101 is no longer received by the transmitter unit 102. After transmitting the one or more signals to notify the receiver unit 104, the transmitter unit 102 in one embodiment is configured to enter sleep mode or low power state during which no data related to the monitored analyte level is transmitted to the receiver unit 104.

FIG. 10 is a flowchart illustrating the pairing or synchronization routine in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention. Referring to FIG. 10, in one embodiment, the transmitter unit 102 may be configured to receive a sensor initiate close proximity command (1010) from the receiver unit 104 positioned within the close transmission range. Based on the received sensor initiate command, the transmitter unit identification information may be retrieved (for example, from a nonvolatile memory) and transmitted (1020) to the receiver unit 104 or the sender of the sensor initiate command.

Referring back to FIG. 10, a communication key (1030) optionally encrypted is received in one embodiment, and thereafter, sensor related data is transmitted with the communication key on a periodic basis such as, every 60 seconds, five minutes, or any suitable predetermined time intervals.

Referring now to FIG. 11, a flowchart illustrating the pairing or synchronization routine in the data monitoring and management system of FIG. 1 in accordance with another embodiment of the present invention is shown. That is, in one aspect, FIG. 11 illustrates the pairing or synchronization routine from the receiver

unit 104. Referring back to FIG. 11, the sensor initiate command is transmitted to the transmitter unit 102 (1110) when the receiver unit 104 is positioned within a close transmission range. Thereafter, in one aspect, the transmitter identification information is received (1120) for example, from the transmitter unit that received the sensor initiate command. Thereafter, a communication key (optionally encrypted) may be generated and transmitted (1130) to the transmitter unit.

In the manner described above, in one embodiment, a simplified pairing or synchronization between the transmitter unit 102 and the receiver unit 104 may be established using, for example, close proximity commands between the devices. As described above, in one aspect, upon pairing or synchronization, the transmitter unit 102 may be configured to periodically transmit analyte level information to the receiver unit for further processing.

FIG. 12 is a flowchart illustrating the power supply determination in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention. That is, in one embodiment, using a counter, the receiver unit 104 may be configured to determine the power supply level of the transmitter unit 102 battery so as to determine a suitable time for replacement of the power supply or the transmitter unit 102 itself. Referring to FIG. 12, periodic data transmission is detected (1210), and a corresponding count in the counter is incremented for example, by one with each detected data transmission (1220). In particular, a Hobbs counter may be used in the rolling data configuration described above to provide a count that is associated with the transmitter unit data transmission occurrence.

Referring to FIG. 12, the updated or incremented count stored in the Hobbs counter is periodically transmitted in the data packet from the transmitter unit 102 to the receiver unit 104. Moreover, the incremented or updated count may be stored (1240) in a persistent nonvolatile memory unit of the transmitter unit 102. Accordingly, based on the number of data transmission occurrences, the battery power supply level may be estimated, and in turn, which may provide an indication as to when the battery (and thus the transmitter unit in the embodiment where the power supply is manufactured to be embedded within the transmitter unit housing) needs to be replaced.

Moreover, in one aspect, the incremented count in the Hobbs counter is stored in a persistent nonvolatile memory such that, the counter is not reset or otherwise restarted with each sensor unit replacement.

FIG. 13 is a flowchart illustrating close proximity command for RF communication control in the data monitoring and management system of FIG. 1 in accordance with one embodiment of the present invention. Referring to FIG. 13, a close proximity command associated with communication status, for example is received (1310). In one aspect, the command associated with the communication status may include, for example, a communication module turn on or turn off command for, for example, turning on or turning off the associated RF communication device of the transmitter unit 102. Referring to FIG. 13, the communication status is determined (1320), and thereafter, modified based on the received command (1330).

That is, in one aspect, using one or more close proximity commands, the receiver unit 104 may be configured to control the RF communication of the transmitter unit 102 to, for example, disable or turn off the RF communication functionality for a predetermined time period. This may be particularly useful when used in air travel or other locations such as hospital settings, where RF communication devices need to be disabled. In one aspect, the close proximity command may be used to either turn on or turn off the RF communication module of the transmitter unit 102, such that, when the receiver unit 104 is positioned in close proximity to the transmitter unit 102, and the RF command is transmitted, the transmitter unit 102 is configured, in one embodiment, to either turn off or turn on the RF communication capability of the transmitter unit 102.

FIG. 14 is a flowchart illustrating analyte sensor identification routine in accordance with one embodiment of the present invention. Referring to FIG. 14, periodically, sensor counter information is received (1410), for example included as rolling data discussed above. The received sensor counter information may be stored in one or more storage units such as a memory unit. When the sensor counter information is received, a stored sensor counter information is retrieved (1420), and the retrieved sensor counter information is compared with the received sensor counter information (1430). Based on the comparison between the retrieved sensor counter

information and the received sensor counter information, one or more signal is generated and output (1440).

That is, in one aspect, the sensor counter in the transmitter unit 102 may be configured to increment by one with each new sensor replacement. Thus, in one aspect, the sensor counter information may be associated with a particular sensor from which monitored analyte level information is generated and transmitted to the receiver unit 104. Accordingly, in one embodiment, based on the sensor counter information, the receiver unit 104 may be configured to ensure that the analyte related data is generated and received from the correct analyte sensor transmitted from the transmitter unit 102.

An analyte monitoring system in one aspect includes a data processing unit, and a control unit in wireless communication with the data processing unit, the control unit configured to transmit one or more predefined close proximity commands to the data processing unit, where the data processing unit is configured to perform one or more predefined functions in response to the received one or more predefined close proximity commands.

The data processing unit may include a close proximity receiver coupled to an antenna for receiving the one or more predefined close proximity commands from the control unit.

In one aspect, the data processing unit may be configured to transmit one or more signals related to a monitored analyte level in response to the received one or more predefined close proximity commands.

Further, the communication of the one or more predefined close proximity commands may be performed when the data processing unit and the control unit are within a predetermined distance from each other, where the predetermined distance may include a distance of less than one foot.

Also, there may be provided a memory unit, which may include an EEPROM or any other suitable type of nonvolatile or volatile memory, or combinations thereof.

In one embodiment, the control unit may include an application specific integrated circuit (ASIC) configuration.

The analyte sensor may be coupled to the data processing unit, where the data processing unit may receive one or more signals from the analyte sensor, and where

the control unit and the data processing unit may be in wireless communication using RF communication protocol.

A method in accordance with one embodiment includes 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.

The method may include generating a communication key associated with the response packet, where the communication key may be generated based on at least in part, a transmitter unit identification information, and further, where the transmitter unit identification information may be included in the response packet.

The transmission range in one embodiment may include a distance of less than one foot.

The method may also include storing one or more of the predefined close proximity commands or the response packet, where storing may include storing the commands or the response packet in a nonvolatile memory device.

The method may include receiving one or more signals from the analyte sensor, and further, where the transmitting and receiving include RF communication protocol.

An analyte sensor in one embodiment includes a substrate, a plurality of electrodes provided on the substrate, at least a portion of one of the plurality of electrodes positioned in fluid contact with an analyte of a user, and a conductive trace provided on the substrate and coupled to one of the plurality of electrodes.

The conductive trace may comprise carbon.

In one aspect, the conductive trace is connected to a ground terminal.

The plurality of electrodes may include one or more of a working electrode, a reference electrode and/or a counter electrode, and where the conductive trace may be connected to the counter electrode.

In one embodiment, the plurality of electrodes may be positioned in a stacked configuration.

The conductive trace in one aspect may be configured to establish electrical contact with a power supply to provide electrical signal to one or more of the plurality of electrodes.

Additionally, the conductive trace may be connected to a ground terminal, or alternatively, the conductive trace may be connected to a guard trace.

A system for powering a data processing device in accordance with another embodiment includes an analyte sensor, including a substrate, a plurality of electrodes provided on the substrate, at least a portion of one of the plurality of electrodes positioned in fluid contact with an analyte of a user, and a conductive trace provided on the substrate and coupled to one of the plurality of electrodes, a data processing device including a contact point for electrically connecting to one of the plurality of electrodes, the data processing device further including a power supply where when the contact point is in electrical connection with the one of the plurality of electrodes, the power supply is configured to transition the data processing device from a low power state to an active power state.

The power supply in one aspect includes a battery.

The one of the plurality of electrodes may include a counter electrode of the analyte sensor.

The conductive trace and the data processing device may be coupled to a ground terminal.

The sensor may include a guard trace disposed on the substrate, and further, where the data processing device may include a guard contact point for electrically coupling to the guard trace.

The data processing device may include a data communication unit to transmit one or more signals related to the monitored analyte level received from the analyte sensor, and further, where the data communication unit may include a close proximity receiver for receiving one or more close proximity commands.

The analyte sensor may include a glucose sensor.

Additionally, the analyte sensor may be transcutaneously positioned such that at least a portion of at least one of the plurality of electrodes is in fluid contact with an analyte of a user.

A method in accordance with still another embodiment includes detecting an electrical connection with an analyte sensor, and activating a data processing device to receive one or more analyte related signals from the analyte sensor.

The method may also include processing the one or more analyte related signals for wireless transmission.

An analyte monitoring device in one embodiment includes a data transmission section, a data receiving section, and a data processing section coupled to the data receiving section, where the data receiving section is configured to receive a predefined command, and further, where the data processing section is configured to control the data transmission section to transmit one or more data in response to the received predefined command.

The data receiving section may include a close proximity receiver.

The data transmission section may include an RF transmitter.

The device may include an antenna coupled to the data transmission section and the data receiving section for wireless data communication.

The data processing section may include a state machine.

The transmitted one or more data in one embodiment may include a device identification information.

In one aspect, the transmitted one or more data may include a response data packet, where the response data packet may include one or more of a communication mode information, a device status information, a device type information, a close proximity command information, or a sensor count information.

The device may include a memory unit for storing data.

A method in another embodiment includes receiving a command to initiate communication with an analyte sensor, retrieving an identification information, transmitting the retrieved identification information, and receiving a communication key associated with the transmitted identification information.

In one aspect, the received command may include a close proximity command.

Moreover, the retrieved identification information may be wirelessly transmitted over an RF communication link.

The identification information may include a data processing device identification information, where the data processing device identification information may include a transmitter identification information.

The communication key may include an 8 bit data associated with the identification information.

The method in another aspect may include transmitting a data packet including the communication key.

The method may also include storing the communication key.

In still another aspect, the analyte sensor may include a glucose sensor.

Moreover, the method may include receiving one or more signals related to a monitored analyte level, where the analyte level may include glucose level.

A method in one embodiment includes detecting a data transmission, incrementing a count associated with the detected data transmission, and storing the count.

The count may be incremented by one.

In a further aspect, the method may include associating a power supply level information with the stored count.

Moreover, the method may also include generating a signal associated with the stored count, and/or include outputting the generated signal, where outputting the generated signal may include one or more of visually displaying the generated signal, audibly outputting the generated signal, or vibratorily outputting the generated signal.

In yet another aspect, the method may include transmitting the count with the data transmission, where the count may be transmitted periodically with the data transmission.

In still another aspect, the method may include associating a power supply status with the count.

A data processing device in another embodiment may include a counter, a data communication unit, and a data processing section coupled to the data communication unit and the counter, the data processing section configured to increment a count stored in the counter based on data transmission by the data communication unit.

In one aspect, the counter may include a nonvolatile memory unit. The counter may include an EEPROM.

The data communication unit may include an RF transceiver.

The count stored in the counter may be incremented by one with each data transmission by the data communication unit.

The device may include a power supply coupled to the data processing unit, the data communication unit and the counter, where the count stored in the counter is not erased when the power supply is disabled or in low power state.

The data processing unit may be configured to estimate the power supply life based on the stored count in the counter.

The device in a further aspect may include an output section for outputting one or more signals associated with the count information, where the output section may include one or more of a display unit, an audible output section, or a vibratory output section.

An analyte monitoring system in one embodiment includes a data processing unit including a communication module, and a control unit in wireless communication with the data processing unit, the control unit configured to receive a predefined close proximity command associated with the wireless communication status of the data processing unit to the data processing unit, where in response to the received predefined close proximity command, the data processing unit changes the operational status of the communication module.

The predefined close proximity command may include one of an RF switch on command or an RF switch off command.

The data processing unit may modify the operational status of the communication module in response to the received predefined close proximity command, where the operational status may include one of an active status and an inactive status.

Additionally, when the communication module is in the inactive status, the data processing unit may be configured to not transmit any data to the control unit.

The control unit may include an output section to output information associated with the predefined close proximity command, where the output information may include one or more of a visual display output, an audible output, or a vibratory output.

In one aspect, the output information may include an icon, a visual display, a two or three dimensional image, video, or graphics, a audible output, an alarm, or combinations thereof.

A method in accordance with another embodiment includes determining a communication status, receiving a communication related close proximity command, and modifying the communication status based on the received command, where the communication status may include one of an RF communication module in active mode, or the RF communication module in inactive mode.

Also, modifying the communication status may include switching from the active mode to the inactive mode of the RF communication module, or from the inactive mode to the active mode of the RF communication module.

Additionally, modifying the communication status may include disabling wireless data transmission based on the received command.

The wireless data transmission may be disabled for a predetermined time period.

In another aspect, the method may include receiving a further communication related close proximity command, and further modifying the communication status based on the received further command, where further modifying may include activating the wireless data transmission based on the received further command.

The method in a further aspect may include transmitting data associated with monitored analyte level of a user, and further, also may include wirelessly transmitting the data associated with the monitored analyte level for further processing.

The method may include entering inactive operational mode based on the modified communication status.

In still another aspect, the method may include storing analyte related data received from an analyte sensor during the modified communication status period.

An analyte monitoring device in one embodiment includes a counter, and a data processing section coupled to the counter, the data processing section configured to increment a count stored in the counter based on a detection of an analyte sensor.

The counter may include a nonvolatile memory unit.

The data processing section may include a communication module to transmit data related to the count.

A control device for communicating with an analyte monitoring unit in one embodiment includes a data communication section configured to periodically receive data including a count information related to an analyte sensor associated with the received data, and a processing unit coupled to the data communication section to process the received data, the processing unit further configured to compare the count information in each data periodically received, and when it is determined that the count information of the periodically received data is different, the processing unit is configured to generate one or more signals related to the status of the analyte sensor.

In one aspect, the one or more signals generated may include a command to disable the data communication section.

The one or more signals generated may be provided to a user.

The device in a further aspect may include a display unit and where the one or more signals generated is displayed on the display unit.

In yet another aspect, the one or more signals output may include one or more of a visual indicator, an audible indicator or a vibratory indicator.

A method in accordance with yet another embodiment includes detecting an analyte sensor, updating a count associated with the detected analyte sensor, and transmitting the updated count.

The method may include storing the updated count.

Additionally, the method may include detecting a further analyte sensor, further updating the count associated with the detected further analyte sensor, and transmitting the further updated count.

A method in accordance with still another embodiment includes periodically receiving data including a count information related to an analyte sensor associated with the received data, and comparing the count information in each data periodically received, and when it is determined that the count information of the periodically received data is different, generating one or more signals related to the status of the analyte sensor.

The one or more signals generated may include a command to disable data communication.

The method may also include providing the one or more signals generated to a user, and also, include outputting the one or more signals generated.

In still a further aspect, the method may include storing the count information.

The status of the analyte sensor may include a new analyte sensor detection.

Additionally, the method may include prompting a user to replace the analyte sensor.

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 invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. An analyte monitoring system, comprising:

a data processing unit; and

a control unit in wireless communication with the data processing unit, the control unit configured to transmit one or more predefined close proximity commands to the data processing unit;

wherein the data processing unit is configured to perform one or more predefined functions in response to the received one or more predefined close proximity commands.

2. The system of claim 1 wherein the data processing unit includes a close proximity receiver coupled to an antenna for receiving the one or more predefined close proximity commands from the control unit.

3. The system of claim 1 wherein the data processing unit is configured to transmit one or more signals related to a monitored analyte level in response to the received one or more predefined close proximity commands.

4. The system of claim 3 wherein the communication of the one or more predefined close proximity commands is performed when the data processing unit and the control unit are within a predetermined distance from each other.

5. The system of claim 4 wherein the predetermined distance includes a distance of less than one foot.

6. The system of claim 1 including a memory unit.

7. The system of claim 6 wherein the memory unit includes an EEPROM.

8. The system of claim 1 wherein the control unit includes an application specific integrated circuit (ASIC) configuration.

9. The system of claim 1 including an analyte sensor coupled to the data processing unit, wherein the data processing unit receives one or more signals from the analyte sensor.

10. The system of claim 9 wherein the control unit and the data processing unit are in wireless communication using RF communication protocol.

11. A method, comprising:

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.

12. The method of claim 11 including generating a communication key associated with the response packet.

13. The method of claim 12, wherein the communication key is generated based on at least in part, a transmitter unit identification information.

14. The method of claim 13 wherein the transmitter unit identification information is included in the response packet.

15. The method of claim 11 wherein the transmission range includes a distance of less than one foot.

16. The method of claim 11 including storing one or more of the predefined close proximity commands or the response packet.

17. The method of claim 16 wherein storing includes storing the commands or the response packet in a nonvolatile memory device.

18. The method of claim 11 including receiving one or more signals from the analyte sensor.

19. The method of claim 11 wherein the transmitting and receiving include RF communication protocol.

20. An analyte sensor, comprising:

a substrate;

a plurality of electrodes provided on the substrate, at least a portion of one of the plurality of electrodes positioned in fluid contact with an analyte of a user; and

a conductive trace provided on the substrate and coupled to one of the plurality of electrodes.

21. The sensor of claim 20 wherein the conductive trace comprises carbon.

22. The sensor of claim 20 wherein the conductive trace is connected to a ground terminal.

23. The sensor of claim 20 wherein the plurality of electrodes includes a working electrode, a reference electrode and a counter electrode.

24. The sensor of claim 23 wherein the conductive trace is connected to the counter electrode.

25. The sensor of claim 20 wherein the plurality of electrodes are positioned in a stacked configuration.

26. The sensor of claim 20 wherein the conductive trace is configured to establish electrical contact with a power supply to provide electrical signal to one or more of the plurality of electrodes.

27. The sensor of claim 20 wherein the conductive trace is connected to a ground terminal.

28. The sensor of claim 20 wherein the conductive trace is connected to a guard trace.

29. A system for powering a data processing device, comprising:
an analyte sensor, including:
a substrate;
a plurality of electrodes provided on the substrate, at least a portion of one of the plurality of electrodes positioned in fluid contact with an analyte of a user; and
a conductive trace provided on the substrate and coupled to one of the plurality of electrodes; and
a data processing device including a contact point for electrically connecting to one of the plurality of electrodes, the data processing device further including a power supply wherein when the contact point is in electrical connection with the one of the plurality of electrodes, the power supply is configured to transition the data processing device from a low power state to an active power state.

30. The system of claim 29 wherein the power supply includes a battery.

31. The system of claim 29 wherein the one of the plurality of electrodes includes a counter electrode of the analyte sensor.

32. The system of claim 29 wherein the conductive trace and the data processing device are coupled to a ground terminal.

33. The system of claim 29 wherein the sensor includes a guard trace disposed on the substrate, and further, wherein the data processing device includes a guard contact point for electrically coupling to the guard trace.

34. The system of claim 29 wherein the data processing device includes a data communication unit to transmit one or more signals related to the monitored analyte level received from the analyte sensor.

35. The system of claim 34 wherein the data communication unit includes a close proximity receiver for receiving one or more close proximity commands.

36. The system of claim 29 wherein the analyte sensor includes a glucose sensor.

37. The system of claim 29 wherein the analyte sensor is transcutaneously positioned such that at least a portion of at least one of the plurality of electrodes is in fluid contact with an analyte of a user.

38. A method, comprising:

detecting an electrical connection with an analyte sensor; and

activating a data processing device to receive one or more analyte related signals from the analyte sensor.

39. The method of claim 38 including processing the one or more analyte related signals for wireless transmission.

40. An analyte monitoring device, comprising:

a data transmission section;

a data receiving section; and

a data processing section coupled to the data receiving section;

wherein the data receiving section is configured to receive a predefined command, and further, wherein the data processing section is configured to control the data transmission section to transmit one or more data in response to the received predefined command.

41. The device of claim 40 wherein the data receiving section includes a close proximity receiver.

42. The device of claim 40 wherein the data transmission section includes an RF transmitter.

43. The device of claim 40 including an antenna coupled to the data transmission section and the data receiving section for wireless data communication.

44. The device of claim 40 wherein the data processing section includes a state machine.

45. The device of claim 40 wherein the transmitted one or more data includes a device identification information.

46. The device of claim 40 wherein the transmitted one or more data includes a response data packet.

47. The device of claim 46 wherein the response data packet includes one or more of a communication mode information, a device status information, a device type information, a close proximity command information, or a sensor count information.

48. The device of claim 40 including a memory unit for storing data.

49. A method, comprising:
receiving a command to initiate communication with an analyte sensor;
retrieving an identification information;
transmitting the retrieved identification information; and
receiving a communication key associated with the transmitted identification information.

50. The method of claim 49 wherein the received command includes a close proximity command.

51. The method of claim 49 wherein the retrieved identification information is wirelessly transmitted over an RF communication link.

52. The method of claim 49 wherein the identification information includes a data processing device identification information.

53. The method of claim 52 wherein the data processing device identification information includes a transmitter identification information.

54. The method of claim 49 wherein the communication key includes an 8 bit data associated with the identification information.

55. The method of claim 49 including transmitting a data packet including the communication key.

56. The method of claim 49 including storing the communication key.

57. The method of claim 49 wherein the analyte sensor includes a glucose sensor.

58. The method of claim 49 including receiving one or more signals related to a monitored analyte level.

59. The method of claim 58 wherein the analyte level includes glucose level.

60. A method, comprising:
detecting a data transmission;
incrementing a count associated with the detected data transmission; and
storing the count.

61. The method of claim 60 wherein the count is incremented by one.

62. The method of claim 60 including associating a power supply level information with the stored count.

63. The method of claim 60 including generating a signal associated with the stored count.

64. The method of claim 63 including outputting the generated signal.

65. The method of claim 64 wherein outputting the generated signal includes one or more of visually displaying the generated signal, audibly outputting the generated signal, or vibratorily outputting the generated signal.

66. The method of claim 60 including transmitting the count with the data transmission.

67. The method of claim 66 wherein the count is transmitted periodically with the data transmission.

68. The method of claim 60 including associating a power supply status with the count.

69. A data processing device, comprising:

a counter;

a data communication unit; and

a data processing section coupled to the data communication unit and the counter, the data processing section configured to increment a count stored in the counter based on data transmission by the data communication unit.

70. The device of claim 69 wherein the counter includes a nonvolatile memory unit.

71. The device of claim 69 wherein the counter includes an EEPROM.

72. The device of claim 69 wherein the data communication unit includes an RF transceiver.

73. The device of claim 69 wherein the count stored in the counter is incremented by one with each data transmission by the data communication unit.

74. The device of claim 69 including a power supply coupled to the data processing unit, the data communication unit and the counter.

75. The device of claim 74 wherein the count stored in the counter is not erased when the power supply is disabled or in low power state.

76. The device of claim 74 wherein the data processing unit is configured to estimate the power supply life based on the stored count in the counter.

77. The device of claim 69 including an output section for outputting one or more signals associated with the count information.

78. The device of claim 77 wherein the output section includes one or more of a display unit, an audible output section, or a vibratory output section.

79. An analyte monitoring system, comprising:

a data processing unit including a communication module; and

a control unit in wireless communication with the data processing unit, the control unit configured to receive a predefined close proximity command associated with the wireless communication status of the data processing unit to the data processing unit;

wherein in response to the received predefined close proximity command, the data processing unit changes the operational status of the communication module.

80. The system of claim 79 wherein the predefined close proximity command includes one of an RF switch on command or an RF switch off command.

81. The system of claim 79 wherein the data processing unit modifies the operational status of the communication module in response to the received predefined close proximity command.

82. The system of claim 81 wherein the operational status includes one of an active status and an inactive status.

83. The system of claim 82 wherein when the communication module is in the inactive status, the data processing unit does not transmit any data to the control unit.

84. The system of claim 79 wherein the control unit includes an output section to output information associated with the predefined close proximity command.

85. The system of claim 84 wherein the output information includes one or more of a visual display output, an audible output, or a vibratory output.

86. The system of claim 84 wherein the output information includes an icon.

87. A method, comprising:
determining a communication status;
receiving a communication related close proximity command; and
modifying the communication status based on the received command.

88. The method of claim 87 wherein the communication status includes one of an RF communication module in active mode, or the RF communication module in inactive mode.

89. The method of claim 88 wherein modifying the communication status includes switching from the active mode to the inactive mode of the RF communication module, or from the inactive mode to the active mode of the RF communication module.

90. The method of claim 87 wherein modifying the communication status includes disabling wireless data transmission based on the received command.

91. The method of claim 90 wherein the wireless data transmission is disabled for a predetermined time period.

92. The method of claim 90 further including:
receiving a further communication related close proximity command; and
further modifying the communication status based on the received further command.

93. The method of claim 92 wherein further modifying includes activating the wireless data transmission based on the received further command.

94. The method of claim 88 including transmitting data associated with monitored analyte level of a user.

95. The method of claim 94 including wirelessly transmitting the data associated with the monitored analyte level for further processing.

96. The method of claim 88 including entering inactive operational mode based on the modified communication status.

97. The method of claim 88 including storing analyte related data received from an analyte sensor during the modified communication status period.

98. An analyte monitoring device, comprising:

a counter; and

a data processing section coupled to the counter, the data processing section configured to increment a count stored in the counter based on a detection of an analyte sensor.

99. The device of claim 98 wherein the counter includes a nonvolatile memory unit.

100. The device of claim 98 wherein the data processing section includes a communication module to transmit data related to the count.

101. A control device for communicating with an analyte monitoring unit, comprising:

a data communication section configured to periodically receive data including a count information related to an analyte sensor associated with the received data; and

a processing unit coupled to the data communication section to process the received data, the processing unit further configured to compare the count information in each data periodically received, and when it is determined that the count information of the periodically received data is different, the processing unit is configured to generate one or more signals related to the status of the analyte sensor.

102. The device of claim 101 wherein the one or more signals generated include a command to disable the data communication section.

103. The device of claim 101 wherein the one or more signals generated is provided to a user.

104. The device of claim 103 including a display unit and wherein the one or more signals generated is displayed on the display unit.

105. The device of claim 103 wherein the one or more signals output includes one or more of a visual indicator, an audible indicator or a vibratory indicator.

106. A method, comprising:
detecting an analyte sensor;
updating a count associated with the detected analyte sensor; and
transmitting the updated count.

107. The method of claim 106 including storing the updated count.

108. The method of claim 106 including:
detecting a further analyte sensor;
further updating the count associated with the detected further analyte sensor; and
transmitting the further updated count.

109. A method, comprising:
periodically receiving data including a count information related to an analyte sensor associated with the received data; and
comparing the count information in each data periodically received, and when it is determined that the count information of the periodically received data is different, generating one or more signals related to the status of the analyte sensor.

110. The method of claim 109 wherein the one or more signals generated includes a command to disable data communication.

111. The method of claim 109 including providing the one or more signals generated to a user.

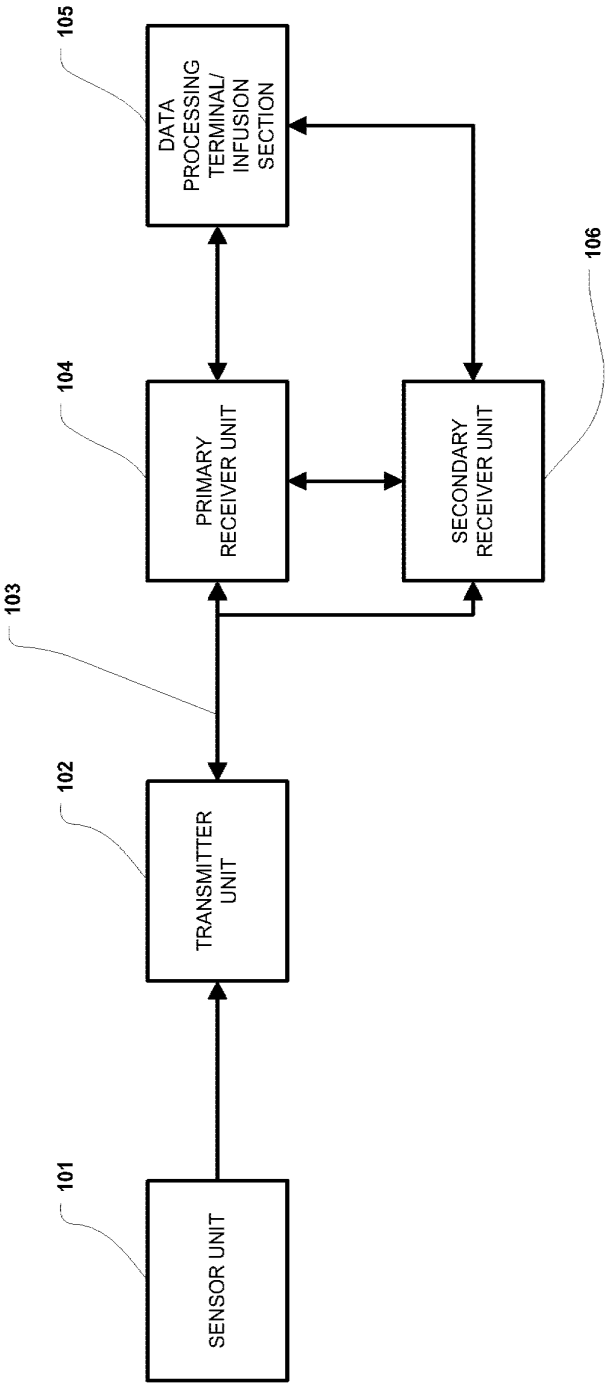
112. The method of claim 111 including outputting the one or more signals generated.

113. The method of claim 109 including storing the count information.

114. The method of claim 109 wherein the status of the analyte sensor includes a new analyte sensor detection.

5

115. The method of claim 109 including prompting a user to replace the analyte sensor.


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

100

FIGURE 1

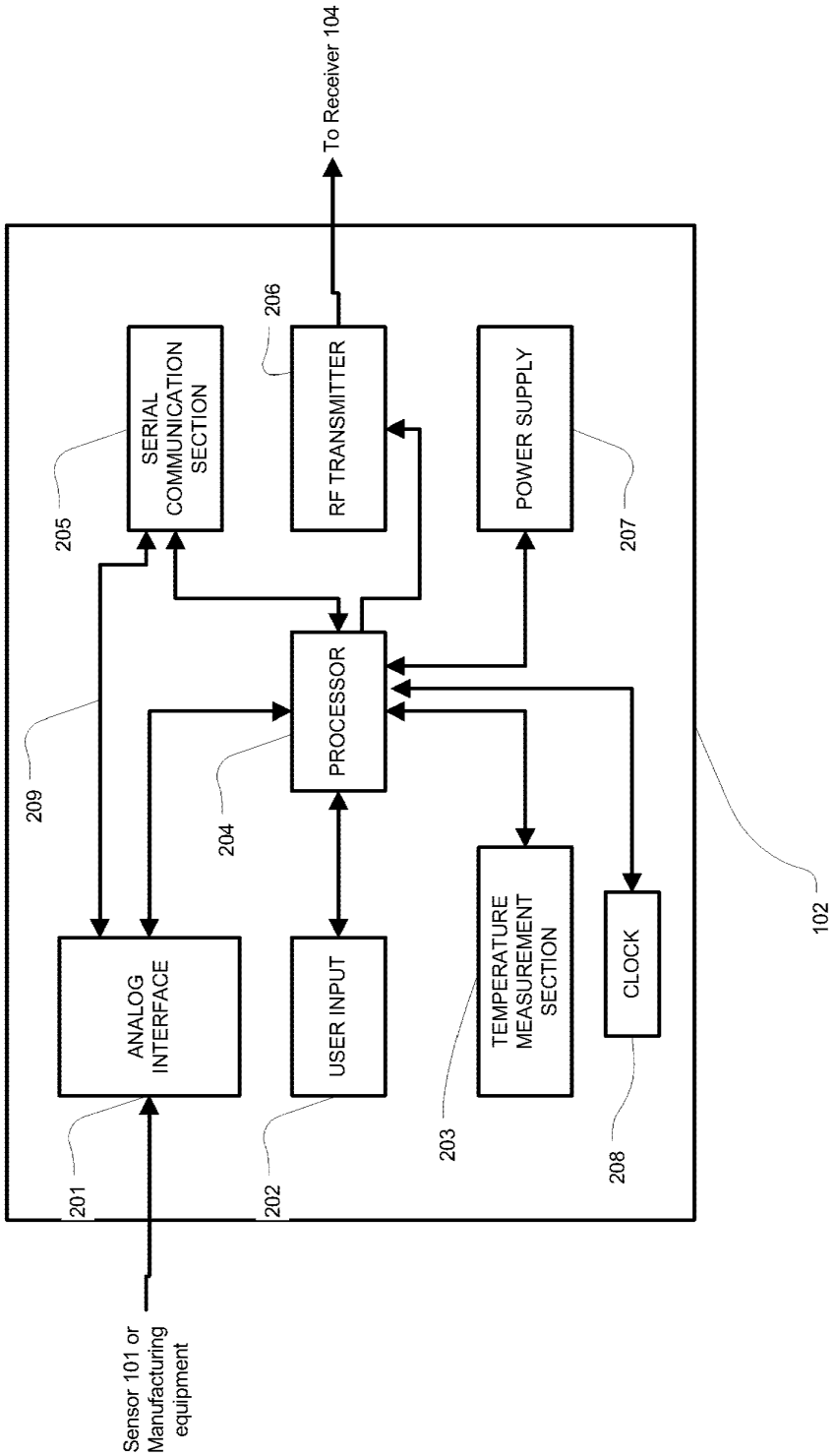

To Receiver 104
206
SERIAL COMMUNICATION SECTION
RF TRANSMITTER
POWER SUPPLY
205
207
PROCESSOR
209
204
ANALOG INTERFACE
USER INPUT
TEMPERATURE MEASUREMENT SECTION
CLOCK
102
201
202
203
208
Sensor 101 or Manufacturing equipment

FIGURE 2

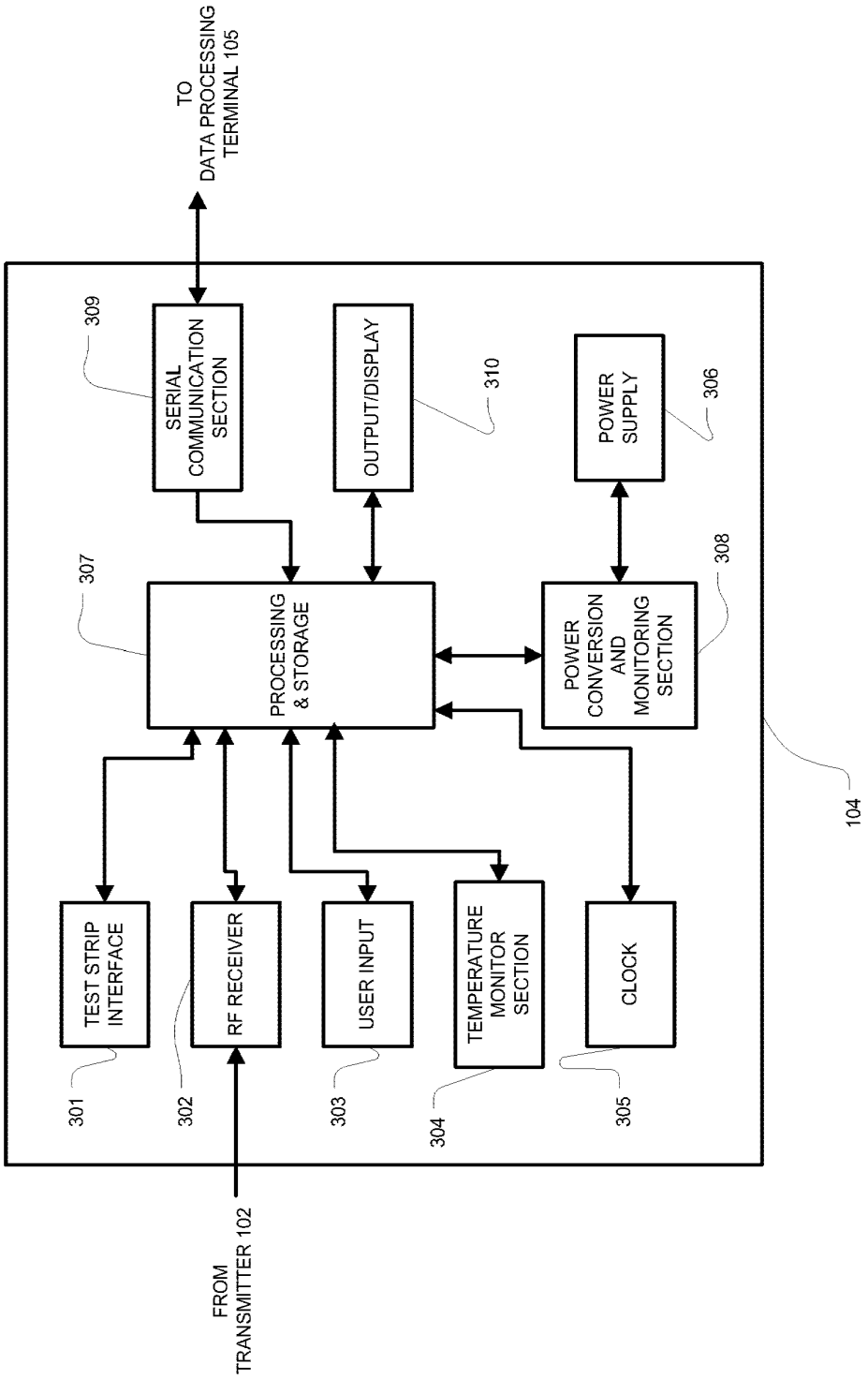

TO
DATA PROCESSING
TERMINAL 105
SERIAL
COMMUNICATION
SECTION
309
OUTPUT/DISPLAY
310
POWER
SUPPLY
306
PROCESSING
& STORAGE
307
POWER
CONVERSION
AND
MONITORING
SECTION
308
104
TEST STRIP
INTERFACE
301
RF RECEIVER
302
USER INPUT
303
TEMPERATURE
MONITOR
SECTION
304
CLOCK
305
FROM
TRANSMITTER 102

FIGURE 3

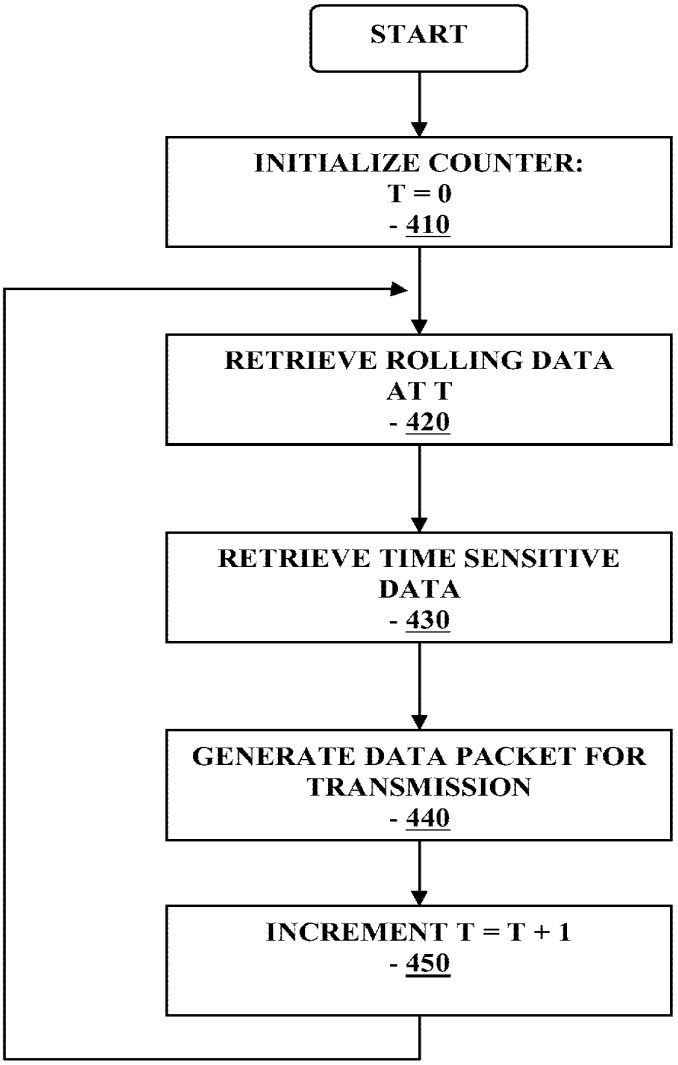

START
INITIALIZE COUNTER:
T = 0
- 410
RETRIEVE ROLLING DATA
AT T
- 420
RETRIEVE TIME SENSITIVE
DATA
- 430
GENERATE DATA PACKET FOR
TRANSMISSION
- 440
INCREMENT T = T + 1
- 450

FIGURE 4

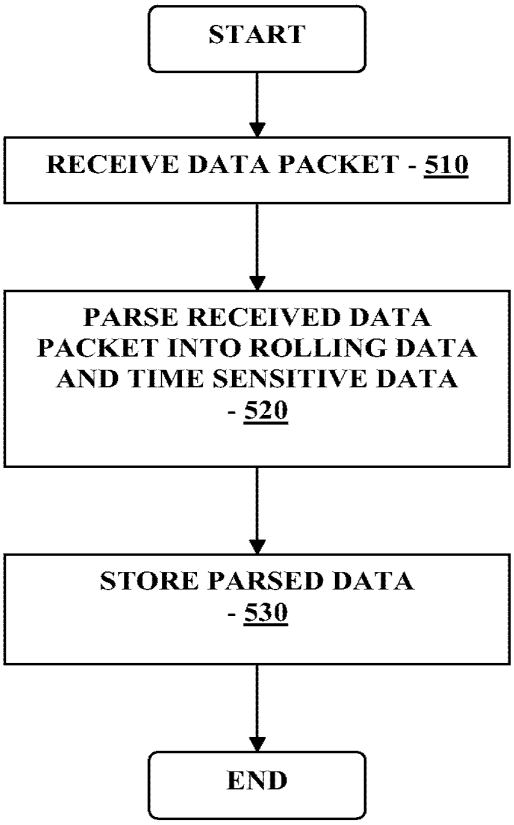

START
RECEIVE DATA PACKET - 510
PARSE RECEIVED DATA PACKET INTO ROLLING DATA AND TIME SENSITIVE DATA - 520
STORE PARSED DATA - 530
END

FIGURE 5

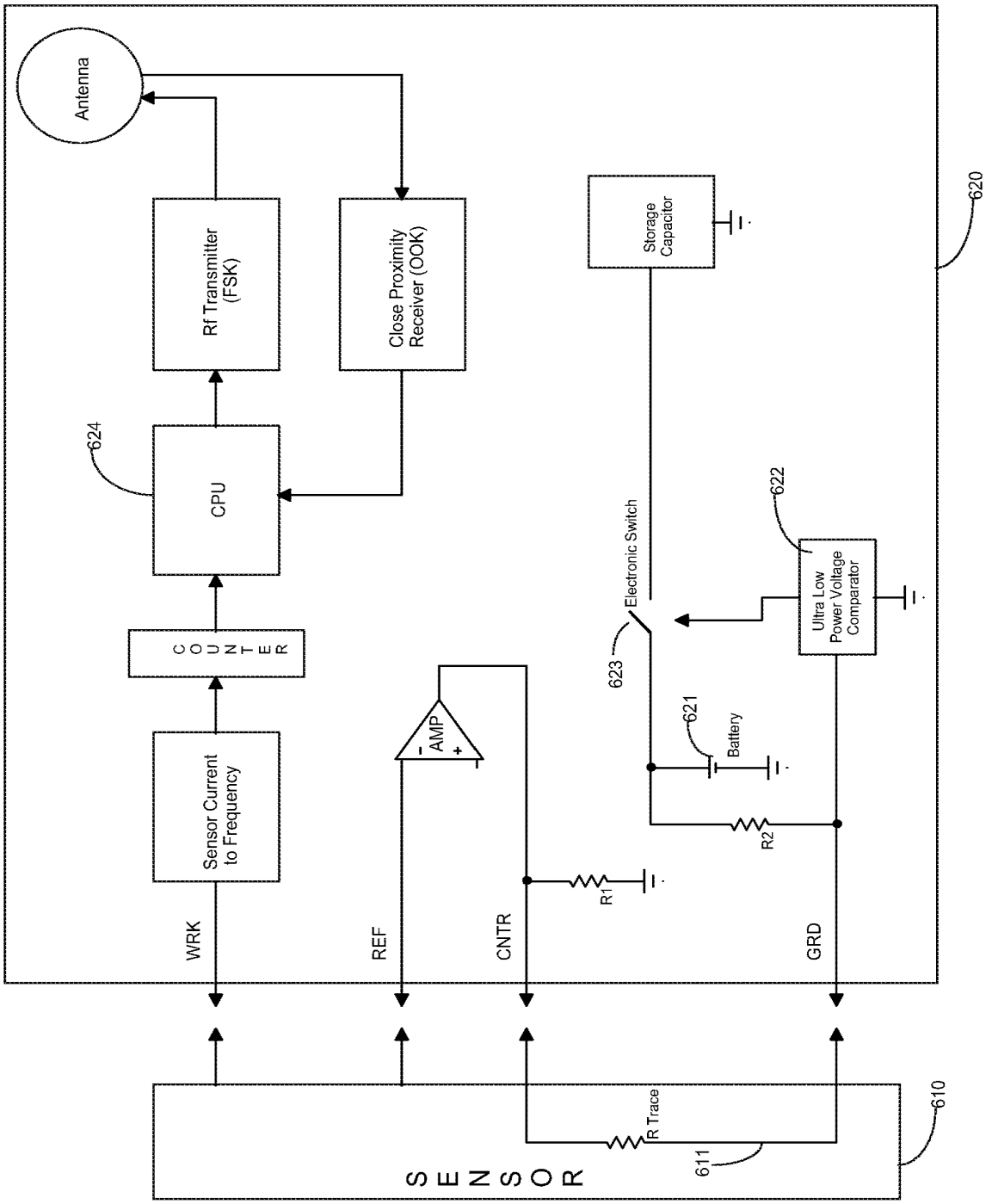

Antenna
Rf Transmitter (FSK)
Close Proximity Receiver (OOK)
Storage Capacitor
620
624
CPU
622
Ultra Low Power Voltage Comparator
Electronic Switch
COUNTER
623
621
Battery
AMP
Sensor Current to Frequency
R2
R1
WRK
REF
CNTR
GRD
R Trace
611
610
SENSOR

FIGURE 6

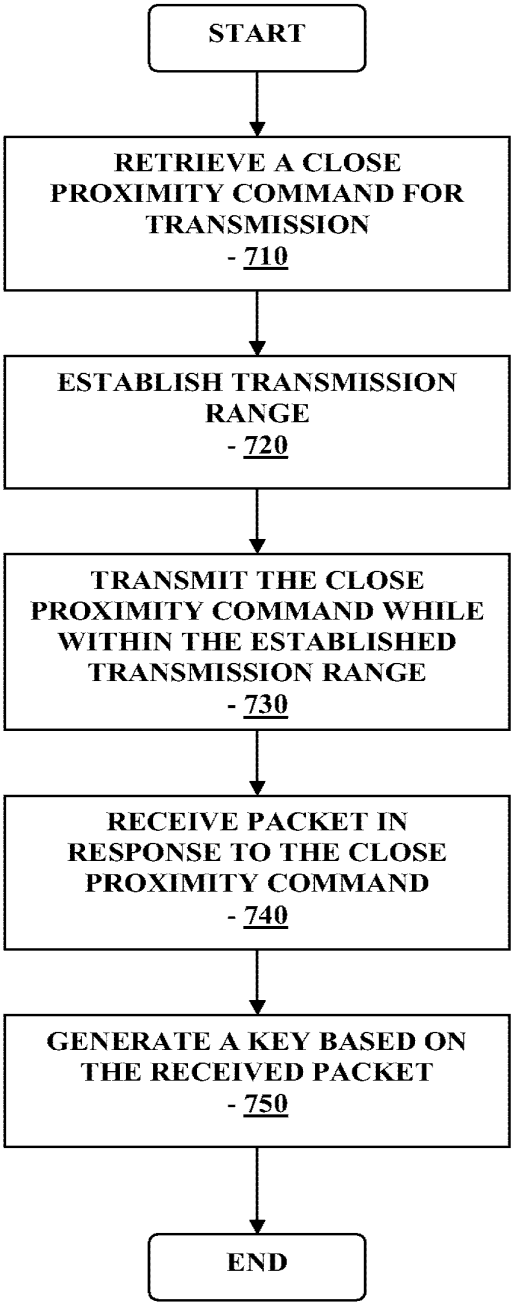

START
RETRIEVE A CLOSE PROXIMITY COMMAND FOR TRANSMISSION - 710
ESTABLISH TRANSMISSION RANGE - 720
TRANSMIT THE CLOSE PROXIMITY COMMAND WHILE WITHIN THE ESTABLISHED TRANSMISSION RANGE - 730
RECEIVE PACKET IN RESPONSE TO THE CLOSE PROXIMITY COMMAND - 740
GENERATE A KEY BASED ON THE RECEIVED PACKET - 750
END

FIGURE 7

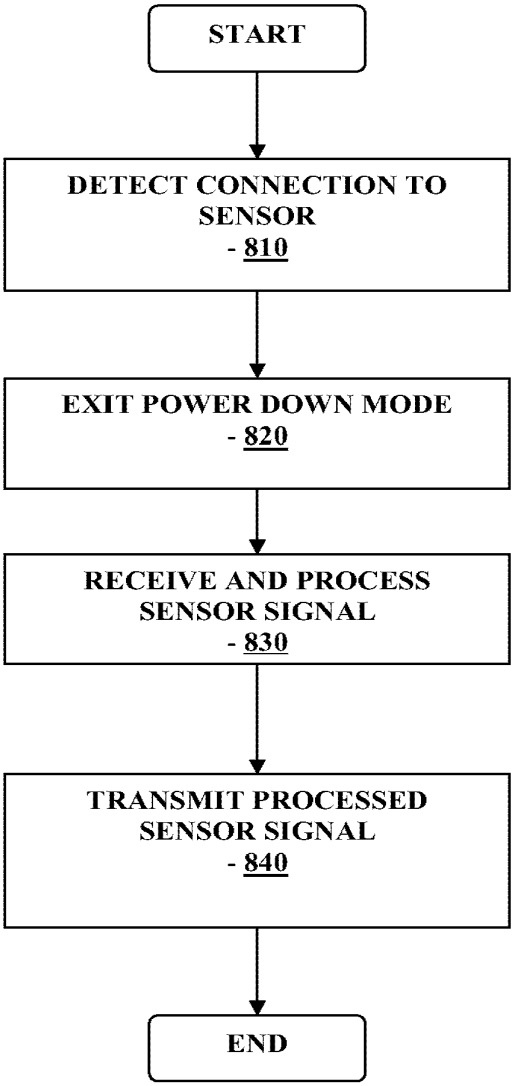

START
DETECT CONNECTION TO SENSOR - 810
EXIT POWER DOWN MODE - 820
RECEIVE AND PROCESS SENSOR SIGNAL - 830
TRANSMIT PROCESSED SENSOR SIGNAL - 840
END

FIGURE 8

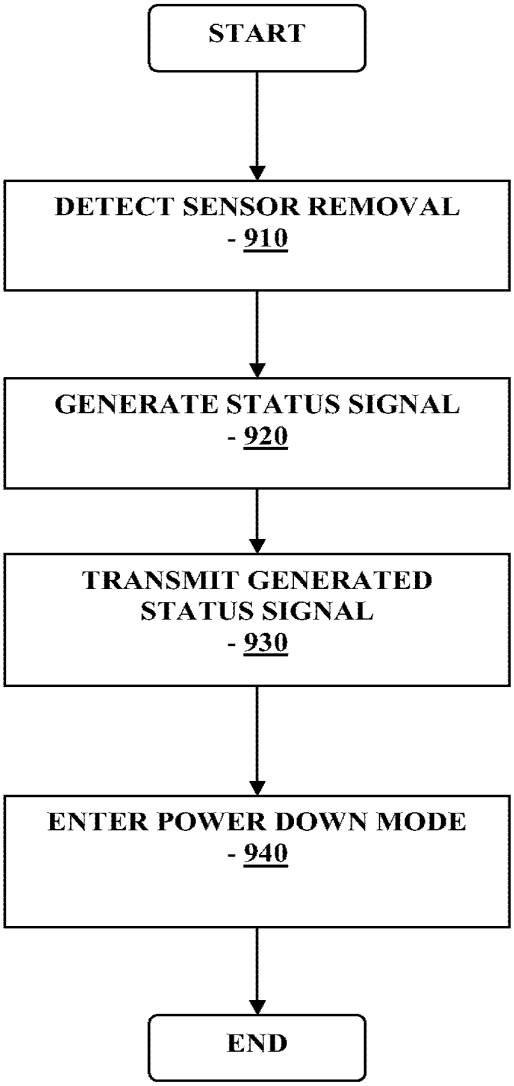

START
DETECT SENSOR REMOVAL - 910
GENERATE STATUS SIGNAL - 920
TRANSMIT GENERATED STATUS SIGNAL - 930
ENTER POWER DOWN MODE - 940
END

FIGURE 9

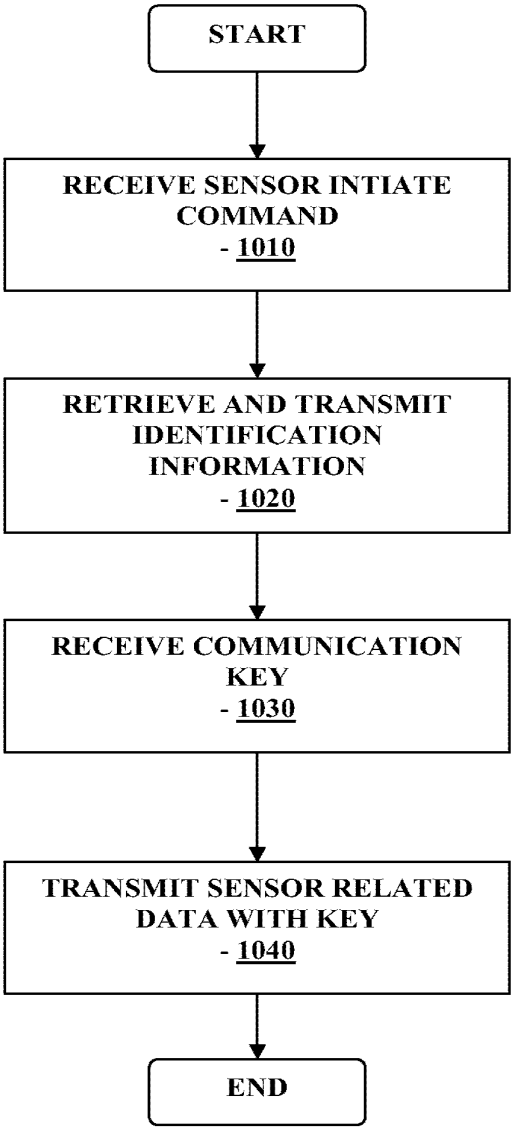

START
RECEIVE SENSOR INTIATE COMMAND - 1010
RETRIEVE AND TRANSMIT IDENTIFICATION INFORMATION - 1020
RECEIVE COMMUNICATION KEY - 1030
TRANSMIT SENSOR RELATED DATA WITH KEY - 1040
END

FIGURE 10

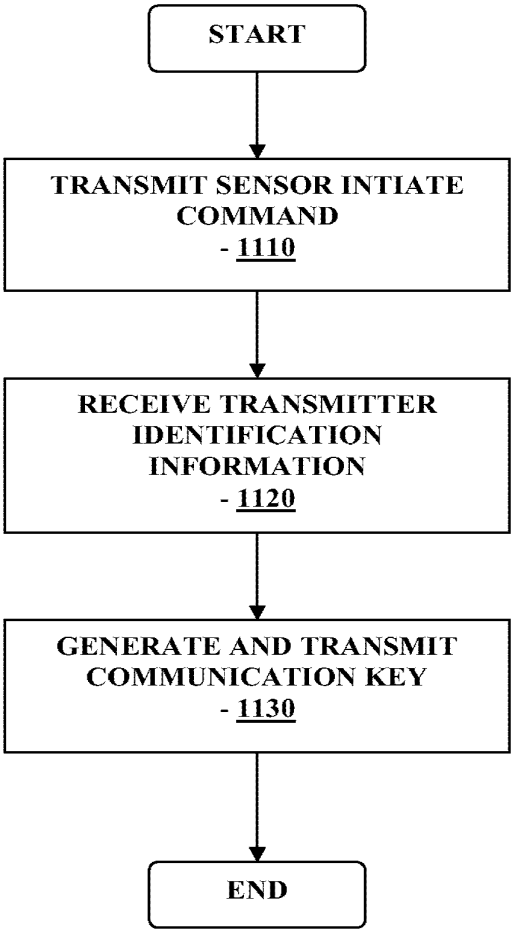

START
TRANSMIT SENSOR INTIATE COMMAND - 1110
RECEIVE TRANSMITTER IDENTIFICATION INFORMATION - 1120
GENERATE AND TRANSMIT COMMUNICATION KEY - 1130
END

FIGURE 11

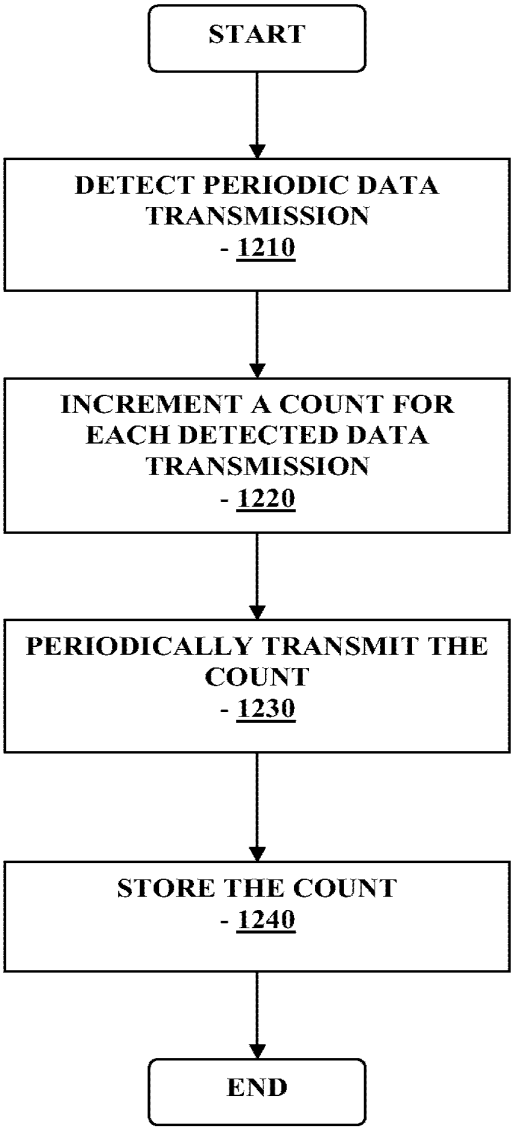

START
DETECT PERIODIC DATA TRANSMISSION - 1210
INCREMENT A COUNT FOR EACH DETECTED DATA TRANSMISSION - 1220
PERIODICALLY TRANSMIT THE COUNT - 1230
STORE THE COUNT - 1240
END

FIGURE 12

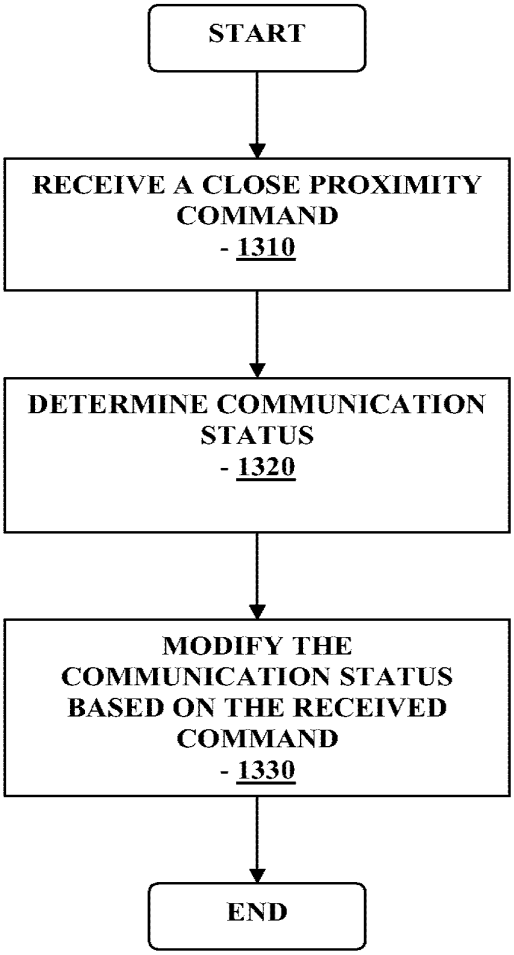

START
RECEIVE A CLOSE PROXIMITY COMMAND - 1310
DETERMINE COMMUNICATION STATUS - 1320
MODIFY THE COMMUNICATION STATUS BASED ON THE RECEIVED COMMAND - 1330
END

FIGURE 13

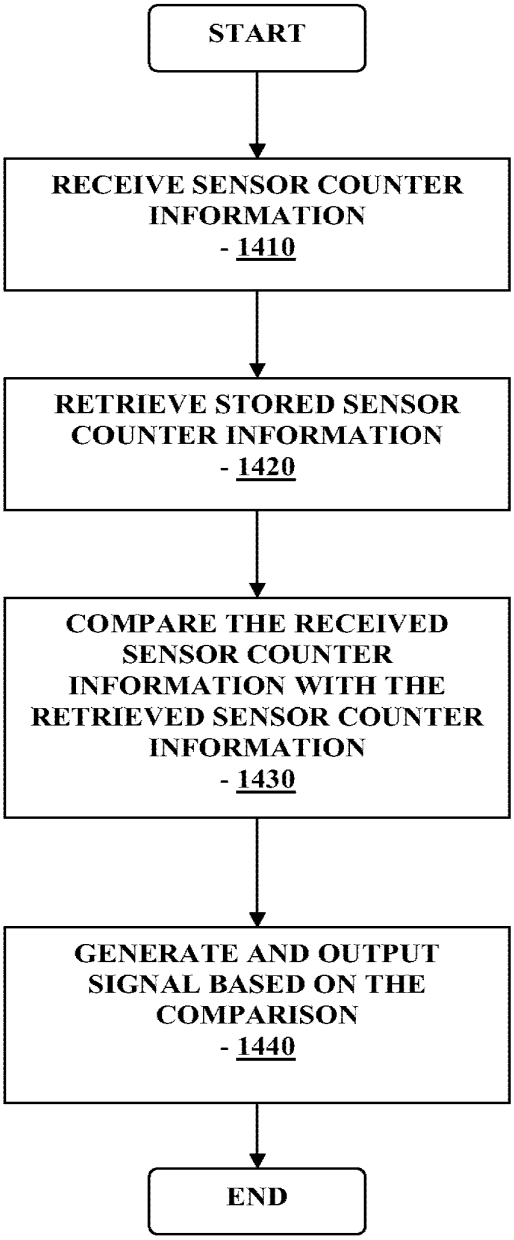

START
RECEIVE SENSOR COUNTER INFORMATION - 1410
RETRIEVE STORED SENSOR COUNTER INFORMATION - 1420
COMPARE THE RECEIVED SENSOR COUNTER INFORMATION WITH THE RETRIEVED SENSOR COUNTER INFORMATION - 1430
GENERATE AND OUTPUT SIGNAL BASED ON THE COMPARISON - 1440
END

FIGURE 14

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(54) **Title:** HEALTH MONITOR

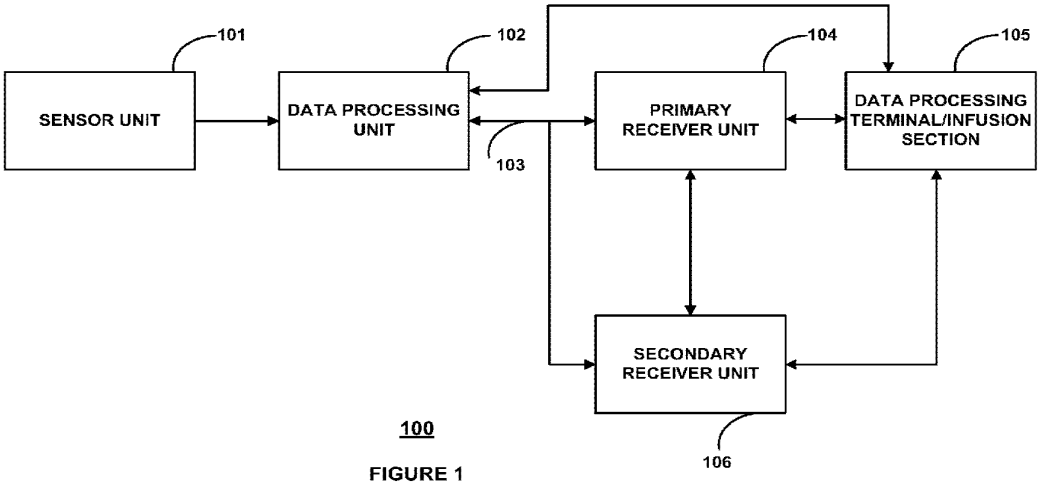


FIGURE 1

(57) **Abstract:** Methods and devices to detect analyte in body fluid are provided. Embodiments include enhanced analyte monitoring devices and systems.

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HEALTH MONITOR

PRIORITY

The present application claims priority to U.S. provisional application no. 60/945,581 filed June 21, 2007, entitled "Health Monitor," the disclosure of which is incorporated by reference for all purposes.

BACKGROUND

The detection of the level of analytes, such as glucose, lactate, oxygen, and the like, in certain individuals is vitally important to their health. For example, the monitoring of glucose is particularly important to individuals with diabetes. Diabetics may need to monitor glucose levels to determine when insulin is needed to reduce glucose levels in their bodies or when additional glucose is needed to raise the level of glucose in their bodies.

Accordingly, of interest are devices, system and methods that allow a user to test for one or more analytes.

SUMMARY

Embodiments include enhanced in vitro analyte meters and systems which are enhanced with in vivo continuous analyte monitoring functionality. The descriptions herein describe in vitro analyte glucose meters primarily as in vitro blood glucose ("BG") meters and in vivo continuous analyte system primarily as in vivo continuous glucose ("CG") monitoring devices and systems, for convenience only. Such descriptions are in no way intended to limit the scope of the disclosure in any way.

Accordingly, BG meters and systems having high levels of functionality are provided. Each BG or CG system may accept and process data from its own respective system and/or from another system, e.g., a BG system may accept and process CG system data, or vice versa. Embodiments enable CG data to be provided to a user by way of a BG meter.

Embodiments may be useful to users who may require conventional blood glucose BG data most of the time, but who may have a periodic need for CG data. One way this problem has been addressed in the past is to provide the user with both a

BG meter and a CG system. However, this has the disadvantage of cost because a CG system may be more expensive than a BG meter, and increased training as the user must learn how to use two meters – a BG meter for normal use and a CG meter for those times when CG data is required.

Embodiments herein may be appropriate for Type I and Type II diabetics, other patients experiencing diabetic conditions, or patients in post surgery recovery period.

Also provided are devices, methods and kits.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a block diagram of an embodiment of a data monitoring and management system according to the present disclosure;

FIG. 2 shows a block diagram of an embodiment of the transmitter unit of the data monitoring and management system of FIG. 1;

FIG. 3 shows a block diagram of an embodiment of the receiver/monitor unit of the data monitoring and management system of FIG. 1;

FIG. 4 shows a schematic diagram of an embodiment of an analyte sensor according to the present disclosure;

FIGS. 5A-5B show a perspective view and a cross sectional view, respectively of another embodiment an analyte sensor;

FIG. 6 shows an exemplary embodiment of a system that includes a CG Data Logger (for example, including a data storage device or memory) and an enhanced BG meter, in which the CG Data Logger is capable of transferring CG data obtained by a CG analyte sensor positioned at least partially beneath a skin surface of a user to the enhanced BG meter;

FIG. 7 shows an exemplary embodiment of a Modular System that includes a CG unit having a transmitter, data transfer module and enhanced BG meter, in which the CG unit is capable of wirelessly transferring data obtained by a CG analyte sensor positioned at least partially beneath a skin surface of a user to the enhanced BG meter by way of the data transfer module;

FIG. 8 shows an exemplary embodiment of an integrated system that includes an enhanced BG meter and a CG unit having a transmitter, in which the CG unit is

capable of transferring CG data obtained by a CG analyte sensor positioned at least partially beneath a skin surface of a user to the enhanced BG meter in real time;

FIG. 9 shows an exemplary embodiment of a system which includes a BG meter and a docking unit, herein shown configured as a belt holster;

FIGS. 10A-10C show exemplary embodiments of glucose test strips that may be used with the enhanced systems described herein; and

FIGS. 11A-11C show exemplary BG meters.

DETAILED DESCRIPTION

Before the present disclosure is described, 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.

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.

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.

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.

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

Embodiments include devices which allow diabetic patients to measure the blood (or other bodily fluid) glucose levels, e.g., hand-held electronic meters (blood glucose meters), e.g., such as Freestyle® or Precision® blood glucose monitoring systems available from Abbott Diabetes Care, Inc., of Alameda, California (and the like) which receives blood samples via enzyme-based test strips. Typically, a user inserts a test strip into a meter and lances a finger or alternate body site to obtain a blood sample. The drawn sample is applied to the test strip and the meter reads the strip and determines analyte concentration, which is then conveyed to the user. For example, the blood glucose meter converts a current generated by the enzymatic reaction in the test strip to a corresponding blood glucose value which is displayed or otherwise provided to the patient to show the level of glucose at the time of testing.

Such periodic discrete glucose testing helps diabetic patients to take any necessary corrective actions to better manage diabetic conditions.

Test strips may be adapted to measure the concentration of an analyte in any volume of sample, including but not limited to small volumes of sample, e.g., about 1 microliter or less sample, for example about 0.5 microliters or less, for example about 0.3 microliters or less, for example about 0.1 microliters or less. In some embodiments, the volume of sample may be as low as about 0.05 microliters or as low as about 0.03 microliters. Strips may be configures so that an accurate analyte measurement may be obtained using a volume of sample that wholly or partially fills a sample chamber of a strip. In certain embodiments, a test may only start when sufficient sample has been applied to a strip, e.g., as detected by a detector such as an electrode. A system may be programmed to allow re-application of additional sample if insufficient sample is firstly applied, e.g., the time to reapply sample may range from about 10 seconds to about 2 minutes, e.g., from about 30 seconds to about 60 seconds.

Strips may be side fill, front fill, top fill or corner fill, or any combination thereof. Test strips may be calibration-free, e.g., minimal input (if any) is required of a user to calibrate. In certain embodiments, no calibration test strips may be

employed. In such embodiments, the user need not take any action for calibration, i.e., calibration is invisible to a user.

As noted above, strips are used with meters. In certain embodiments, meters may be integrated meters, i.e., a device which has at least one strip and at least a second element, such as a meter and/or a skin piercing element such as a lancet or the like, in the device. In some embodiments, a strip may be integrated with both a meter and a lancet, e.g., in a single housing. Having multiple elements together in one device reduces the number of devices needed to obtain an analyte level and facilitates the sampling process. For example, embodiments may include a housing that includes one or more analyte test strips, a skin piercing element and a processor for determining the concentration of an analyte in a sample applied to the strip. A plurality of strips may be retained in a magazine in the housing interior and, upon actuation by a user, a single strip may be dispensed from the magazine so that at least a portion extends out of the housing for use.

Test strips may be short test time test strips. For example, test times may range from about 1 second to about 20 seconds, e.g., from about 3 seconds to about 10 seconds, e.g., from about 3 seconds to about 7 seconds, e.g., about 5 seconds or about 3 seconds.

Exemplary meters and test strips and using the same are shown in FIGS. 10A-10C and 11A-11C.

Embodiments include analyte monitoring devices and systems that include an analyte sensor- at least a portion of which is positionable beneath the skin of the user - for the *in vivo* detection, of at least one analyte, such as glucose, lactate, and the like, in a body fluid. Such in vivo sensors are generally referred to herein as in vivo sensors/systems and/or continuous sensors/systems, where such are used interchangeably unless indicated otherwise. Embodiments include wholly implantable analyte sensors and analyte sensors in which only a portion of the sensor is positioned under the skin and a portion of the sensor resides above the skin, e.g., for contact to a transmitter, receiver, transceiver, processor, etc. The sensor may be, for example, subcutaneously positionable in a patient for the continuous or periodic monitoring of a level of an analyte in a patient's interstitial fluid. For the purposes of this description, continuous monitoring and periodic monitoring will be used interchangeably, unless

noted otherwise. The sensor response may be correlated and/or converted to analyte levels in blood or other fluids. In certain embodiments, an analyte sensor may be positioned in contact with interstitial fluid to detect the level of glucose, which detected glucose may be used to infer the glucose level in the patient's bloodstream. Analyte sensors may be insertable into a vein, artery, or other portion of the body containing fluid. Embodiments of the analyte sensors of the subject disclosure may be configured for monitoring the level of the analyte over a time period which may range from minutes, hours, days, weeks, or longer. Analyte sensors that do not require contact with bodily fluid are also contemplated.

Of interest are analyte sensors, such as glucose sensors, that are capable of in vivo detection of an analyte for about one hour or more, e.g., about a few hours or more, e.g., about a few days of more, e.g., about three or more days, e.g., about five days or more, e.g., about seven days or more, e.g., about several weeks or at least one month. Future analyte levels may be predicted based on information obtained, e.g., the current analyte level at time t_0, the rate of change of the analyte, etc. Predictive alarms may notify the user of a predicted analyte levels that may be of concern in advance of the user's analyte level reaching the future level. This provides the user an opportunity to take corrective action.

FIG. 1 shows a data monitoring and management system such as, for example, an analyte (e.g., glucose) monitoring system 100 in accordance with certain embodiments. Embodiments of the subject disclosure are further described primarily with respect to glucose monitoring devices and systems, and methods of glucose detection, for convenience only and such description is in no way intended to limit the scope of the disclosure. It is to be understood that the analyte monitoring system may be configured to monitor a variety of analytes at the same time or at different times.

Analytes that may be monitored include, but are not limited to, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, creatinine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketone bodies, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be monitored. In those

embodiments that monitor more than one analyte, the analytes may be monitored at the same or different times.

The analyte monitoring system 100 includes a sensor 101, a data processing unit 102 connectable to the sensor 101, and a primary receiver unit 104 which is configured to communicate with the data processing unit 102 via a communication link 103. In certain embodiments, the primary receiver unit 104 may be further configured to transmit data to a data processing terminal 105 to evaluate or otherwise process or format data received by the primary receiver unit 104. The data processing terminal 105 may be configured to receive data directly from the data processing unit 102 via a communication link which may optionally be configured for bi-directional communication. Further, the data processing unit 102 may include a transmitter or a transceiver to transmit and/or receive data to and/or from the primary receiver unit 104 and/or the data processing terminal 105 and/or optionally the secondary receiver unit 106.

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 unit 102. The secondary receiver unit 106 may be configured to communicate with the primary receiver unit 104, as well as the data processing terminal 105. The secondary receiver unit 106 may be configured for bi-directional wireless communication with each of the primary receiver unit 104 and the data processing terminal 105. As discussed in further detail below, in certain embodiments the secondary receiver unit 106 may be a de-featured receiver as compared to the primary receiver, i.e., the secondary receiver may include a limited or minimal number of functions and features as compared with the primary receiver unit 104. As such, the secondary receiver unit 106 may include a smaller (in one or more, including all, dimensions), compact housing or embodied in a device such as a wrist watch, arm band, etc., for example. Alternatively, the secondary receiver unit 106 may be configured with the same or substantially similar functions and features as the primary receiver unit 104. The secondary receiver unit 106 may include a docking portion to be mated with a docking cradle unit for placement by, e.g., the bedside for night time monitoring, and/or a bi-directional communication device. A docking cradle may recharge a powers supply.

Only one sensor 101, data processing unit or control unit 102 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 more than one sensor 101 and/or more than one data processing unit 102, and/or more than one data processing terminal 105. Multiple sensors may be positioned in a patient for analyte monitoring at the same or different times. In certain embodiments, analyte information obtained by a first positioned sensor may be employed as a comparison to analyte information obtained by a second sensor. This may be useful to confirm or validate analyte information obtained from one or both of the sensors. Such redundancy may be useful if analyte information is contemplated in critical therapy-related decisions. In certain embodiments, a first sensor may be used to calibrate a second sensor.

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 component may be configured to be uniquely identified by one or more of the other components in the system so that communication conflict may be readily resolved between the various components within the analyte monitoring system 100. For example, unique IDs, communication channels, and the like, may be used.

In certain embodiments, the sensor 101 is physically positioned in or on the body of a user whose analyte level is being monitored. The sensor 101 may be configured to at least periodically sample the analyte level of the user and convert the sampled analyte level into a corresponding signal for transmission by the data processing unit 102. The data processing unit 102 is coupleable to the sensor 101 so that both devices are positioned in or on the user's body, with at least a portion of the analyte sensor 101 positioned transcutaneously. The data processing unit may include a fixation element such as adhesive or the like to secure it to the user's body. A mount (not shown) attachable to the user and mateable with the unit 102 may be used. For example, a mount may include an adhesive surface. The data processing unit 102 performs data processing functions, where such functions may include but are not limited to, amplification, filtering and encoding of data signals, each of which

corresponds to a sampled analyte level of the user, for transmission to the primary receiver unit 104 via the communication link 103. In one embodiment, the sensor 101 or the data processing unit 102 or a combined sensor/data processing unit may be wholly implantable under the skin layer of the user.

In certain embodiments, the primary receiver unit 104 may include an analog interface section including an RF receiver and an antenna that is configured to communicate with the data processing unit 102 via the communication link 103, and a data processing section for processing the received data from the data processing unit 102 such as data decoding, error detection and correction, data clock generation, data bit recovery, etc., or any combination thereof.

In operation, the primary receiver unit 104 in certain embodiments is configured to synchronize with the data processing unit 102 to uniquely identify the data processing unit 102, based on, for example, an identification information of the data processing unit 102, and thereafter, to periodically receive signals transmitted from the data processing unit 102 associated with the monitored analyte levels detected by the sensor 101.

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), telephone such as a cellular phone (e.g., a multimedia and Internet-enabled mobile phone such as an iPhone or similar phone), mp3 player, pager, and the like), drug delivery device, 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, updating, and/or analyzing data corresponding to the detected analyte level of the user.

The data processing terminal 105 may include an infusion device such as an insulin infusion pump or the like, which may be configured to administer insulin to patients, and which may be configured to communicate with the primary receiver unit 104 for receiving, among others, the measured analyte level. Alternatively, the primary receiver unit 104 may be configured to integrate an infusion device therein so that the primary receiver unit 104 is configured to administer insulin (or other appropriate drug) 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 unit 102. An infusion device may be an external device or an internal device (wholly implantable in a user).

In certain embodiments, the data processing terminal 105, which may include an insulin pump, may be configured to receive the analyte signals from the data processing unit 102, and thus, incorporate the functions of the primary receiver unit 104 including data processing for managing the patient's insulin therapy and analyte monitoring. In certain embodiments, the communication link 103 as well as one or more of the other communication interfaces shown in FIG. 1, may use one or more of: an RF communication protocol, an infrared communication protocol, a Bluetooth enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPPA requirements), while avoiding potential data collision and interference.

FIG. 2 shows a block diagram of an embodiment of a data processing unit of the data monitoring and detection system shown in FIG. 1. User input and/or interface components may be included or a data processing unit may be free of user input and/or interface components. In certain embodiments, one or more application-specific integrated circuits (ASIC) may be used to implement one or more functions or routines associated with the operations of the data processing unit (and/or receiver unit) using for example one or more state machines and buffers. The processor shown in FIG. 2 may be equipped with sufficient memory to store the data of interest (such as analyte data) for extended periods of time ranging from one to several samples to the number of samples obtained for an entire wear period of several days to weeks. In one aspect, the memory may be included as part of the processor 204. In another embodiment, a separate memory unit such as a memory chip, random access memory (RAM) or any other storage device for storing for subsequent retrieval data. For example, as shown, the data processing unit may include a storage unit 215 operative coupled to the processor 204, and configured to store the analyte data received, for example, from the sensor 101 (FIG. 1). In one aspect, the storage unit 215 may be configured to store a large volume of data received over a predetermined time period

from the sensor, and, the processor 204 may be configured to, for example, transmit the stored analyte sensor data in a batch mode, for example, after collecting and storing over a defined time period in a single or multiple data transmission. In another aspect, the processor 204 may be configured such that the received analyte sensor data is e transmitted in real time, when received from the analyte sensor.

Also, the processor 204 may be configured to anticipate or wait for a receipt confirmation signal from the recipient of the data transmission (for example, the receiver unit 104 FIG. 1), where when the signal receipt confirmation signal is not received, the processor 204 of the data processing unit 102 may be configured to retrieve the stored analyte sensor data and retransmit it to the receiver unit 104, for example.

As can be seen in the embodiment of FIG. 2, the sensor unit 101 (FIG. 1) includes four contacts, three of which are electrodes - work electrode (W) 210, reference electrode (R) 212, and counter electrode (C) 213, each operatively coupled to the analog interface 201 of the data processing unit 102. This embodiment also shows optional guard contact (G) 211. Fewer or greater electrodes may be employed. For example, the counter and reference electrode functions may be served by a single counter/reference electrode, there may be more than one working electrode and/or reference electrode and/or counter electrode, etc.

FIG. 3 is a block diagram of an embodiment of a receiver/monitor unit such as the primary receiver unit 104 of the data monitoring and management system shown in FIG. 1. The primary receiver unit 104 includes one or more of: a blood glucose test strip interface 301, an RF receiver 302, an input 303, a temperature detection section 304, and a clock 305, each of which is operatively coupled to a processing and storage section 307. 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 processing and storage unit 307. The receiver may include user input and/or interface components or may be free of user input and/or interface components.

In certain embodiments, the test strip interface 301 includes a glucose level testing portion to receive a blood (or other body fluid sample) glucose test or information related thereto. For example, the interface may include a test strip port to receive a glucose test strip. The device may determine the glucose level of the test strip, and optionally display (or otherwise notice) the glucose level on the output 310 of the primary receiver unit 104. Any suitable test strip may be employed, e.g., test strips that only require a very small amount (e.g., one microliter or less, e.g., 0.5 microliter or less, e.g., 0.1 microliter or less), of applied sample to the strip in order to obtain accurate glucose information, e.g. FreeStyle® blood glucose test strips from Abbott Diabetes Care, Inc. Glucose information obtained by the *in vitro* glucose testing device may be used for a variety of purposes, computations, etc. For example, the information may be used to calibrate sensor 101, confirm results of the sensor 101 to increase the confidence thereof (e.g., in instances in which information obtained by sensor 101 is employed in therapy related decisions), etc.

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

Additional detailed description of embodiments of test strips, blood glucose (BG) meters and continuous monitoring systems and data management systems that may be employed are provided in but not limited to: US Patent No. 6,175,752; US Patent No. 6,560,471; US Patent No. US Patent No. 5,262,035; US Patent No. 6,881,551; US Patent No. 6,121,009; US Patent No. 7,167,818; US Patent No. 6,270,455; US Patent No. 6,161,095; US Patent No. 5,918,603; US Patent No. 6,144,837; US Patent No. 5,601,435; US Patent No. 5,822,715; US Patent No. 5,899,855; US Patent No. 6,071,391; US Patent No. 6,120,676; US Patent No.

6,143,164; US Patent No. 6,299,757; US Patent No. 6,338,790; US Patent No. 6,377,894; US Patent No. 6,600,997; US Patent No. 6,773,671; US Patent No. 6,514,460; US Patent No. 6,592,745; US Patent No. 5,628,890; US Patent No. 5,820,551; US Patent No. 6,736,957; US Patent No. 4,545,382; US Patent No. 4,711,245; US Patent No. 5,509,410; US Patent No. 6,540,891; US Patent No. 6,730,200; US Patent No. 6,764,581; US Patent No. 6,299,757; US Patent No. 6,461,496; US Patent No. 6,503,381; US Patent No. 6,591,125; US Patent No. 6,616,819; US Patent No. 6,618,934; US Patent No. 6,676,816; US Patent No. 6,749,740; US Patent No. 6,893,545; US Patent No. 6,942,518; US Patent No. 6,514,718; US Patent application no. 10/745,878 filed December 26, 2003 entitled "Continuous Glucose Monitoring System and Methods of Use", and elsewhere, the disclosures of each which are incorporated herein by reference for all purposes.

FIG. 4 schematically shows an embodiment of an analyte sensor in accordance with the present disclosure. This sensor embodiment includes electrodes 401, 402 and 403 on a base 404. Electrodes (and/or other features) may be applied or otherwise processed using any suitable technology, e.g., chemical vapor deposition (CVD), physical vapor deposition, sputtering, reactive sputtering, printing, coating, ablating (e.g., laser ablation), painting, dip coating, etching, and the like. Materials include but are not limited to aluminum, carbon (such as graphite), cobalt, copper, gallium, gold, indium, iridium, iron, lead, magnesium, mercury (as an amalgam), nickel, niobium, osmium, palladium, platinum, rhenium, rhodium, selenium, silicon (e.g., doped polycrystalline silicon), silver, tantalum, tin, titanium, tungsten, uranium, vanadium, zinc, zirconium, mixtures thereof, and alloys, oxides, or metallic compounds of these elements.

The sensor may be wholly implantable in a user or may be configured so that only a portion is positioned within (internal) a user and another portion outside (external) a user. For example, the sensor 400 may include a portion positionable above a surface of the skin 410, and a portion positioned below the skin. In such embodiments, the external portion may include contacts (connected to respective electrodes of the second portion by traces) to connect to another device also external to the user such as a transmitter unit. While the embodiment of FIG. 4 shows three electrodes side-by-side on the same surface of base 404, other configurations are

contemplated, e.g., fewer or greater electrodes, some or all electrodes on different surfaces of the base or present on another base, some or all electrodes stacked together, electrodes of differing materials and dimensions, etc.

FIG. 5A shows a perspective view of an embodiment of an electrochemical analyte sensor 500 having a first portion (which in this embodiment may be characterized as a major portion) positionable above a surface of the skin 510, and a second portion (which in this embodiment may be characterized as a minor portion) that includes an insertion tip 530 positionable below the skin, e.g., penetrating through the skin and into, e.g., the subcutaneous space 520, in contact with the user's biofluid such as interstitial fluid. Contact portions of a working electrode 501, a reference electrode 502, and a counter electrode 503 are positioned on the portion of the sensor 500 situated above the skin surface 510. Working electrode 501, a reference electrode 502, and a counter electrode 503 are shown at the second section and particularly at the insertion tip 530. Traces may be provided from the electrode at the tip to the contact, as shown in FIG. 5A. It is to be understood that greater or fewer electrodes may be provided on a sensor. For example, a sensor may include more than one working electrode and/or the counter and reference electrodes may be a single counter/reference electrode, etc.

FIG. 5B shows a cross sectional view of a portion of the sensor 500 of FIG. 5A. The electrodes 510, 502 and 503, of the sensor 500 as well as the substrate and the dielectric layers are provided in a layered configuration or construction. For example, as shown in FIG. 5B, in one aspect, the sensor 500 (such as the sensor unit 101 FIG. 1), includes a substrate layer 504, and a first conducting layer 501 such as carbon, gold, etc., disposed on at least a portion of the substrate layer 504, and which may provide the working electrode. Also shown disposed on at least a portion of the first conducting layer 501 is a sensing layer 508.

A first insulation layer such as a first dielectric layer 505 is disposed or layered on at least a portion of the first conducting layer 501, and further, a second conducting layer 509 may be disposed or stacked on top of at least a portion of the first insulation layer (or dielectric layer) 505. As shown in FIG. 5B, the second conducting layer 509 may provide the reference electrode 502, and in one aspect, may include a layer of silver/silver chloride (Ag/AgCl), gold, etc.

A second insulation layer 506 such as a dielectric layer in one embodiment may be disposed or layered on at least a portion of the second conducting layer 509. Further, a third conducting layer 503 may provide the counter electrode 503. It may be disposed on at least a portion of the second insulation layer 506. Finally, a third insulation layer may be disposed or layered on at least a portion of the third conducting layer 503. In this manner, the sensor 500 may be layered such that at least a portion of each of the conducting layers is separated by a respective insulation layer (for example, a dielectric layer). The embodiment of FIGS. 5A and 5B show the layers having different lengths. Some or all of the layers may have the same or different lengths and/or widths.

In certain embodiments, some or all of the electrodes 501, 502, 503 may be provided on the same side of the substrate 504 in the layered construction as described above, or alternatively, may be provided in a co-planar manner such that two or more electrodes may be positioned on the same plane (e.g., side-by side (e.g., parallel) or angled relative to each other) on the substrate 504. For example, co-planar electrodes may include a suitable spacing there between and/or include dielectric material or insulation material disposed between the conducting layers/electrodes. Furthermore, in certain embodiments one or more of the electrodes 501, 502, 503 may be disposed on opposing sides of the substrate 504. In such embodiments, contact pads may be one the same or different sides of the substrate. For example, an electrode may be on a first side and its respective contact may be on a second side, e.g., a trace connecting the electrode and the contact may traverse through the substrate.

As noted above, analyte sensors may include an analyte-responsive enzyme to provide a sensing component or sensing layer. Some analytes, such as oxygen, can be directly electrooxidized or electroreduced on a sensor, and more specifically at least on a working electrode of a sensor. Other analytes, such as glucose and lactate, require the presence of at least one electron transfer agent and/or at least one catalyst to facilitate the electrooxidation or electroreduction of the analyte. Catalysts may also be used for those analyte, such as oxygen, that can be directly electrooxidized or electroreduced on the working electrode. For these analytes, each working electrode includes a sensing layer (see for example sensing layer 408 of FIG. 5B) proximate to or on a surface of a working electrode. In many embodiments, a sensing layer is

formed near or on only a small portion of at least a working electrode.

The sensing layer includes one or more components designed to facilitate the electrochemical oxidation or reduction of the analyte. The sensing layer may include, for example, a catalyst to catalyze a reaction of the analyte and produce a response at the working electrode, an electron transfer agent to transfer electrons between the analyte and the working electrode (or other component), or both.

A variety of different sensing layer configurations may be used. In certain embodiments, the sensing layer is deposited on the conductive material of a working electrode. The sensing layer may extend beyond the conductive material of the working electrode. In some cases, the sensing layer may also extend over other electrodes, e.g., over the counter electrode and/or reference electrode (or counter/reference is provided).

A sensing layer that is in direct contact with the working electrode may contain an electron transfer agent to transfer electrons directly or indirectly between the analyte and the working electrode, and/or a catalyst to facilitate a reaction of the analyte. For example, a glucose, lactate, or oxygen electrode may be formed having a sensing layer which contains a catalyst, such as glucose oxidase, lactate oxidase, or laccase, respectively, and an electron transfer agent that facilitates the electrooxidation of the glucose, lactate, or oxygen, respectively.

In other embodiments the sensing layer is not deposited directly on the working electrode. Instead, the sensing layer 64 may be spaced apart from the working electrode, and separated from the working electrode, e.g., by a separation layer. A separation layer may include one or more membranes or films or a physical distance. In addition to separating the working electrode from the sensing layer the separation layer may also act as a mass transport limiting layer and/or an interferent eliminating layer and/or a biocompatible layer.

In certain embodiments which include more than one working electrode, one or more of the working electrodes may not have a corresponding sensing layer, or may have a sensing layer which does not contain one or more components (e.g., an electron transfer agent and/or catalyst) needed to electrolyze the analyte. Thus, the signal at this working electrode may correspond to background signal which may be removed from the analyte signal obtained from one or more other working electrodes

that are associated with fully-functional sensing layers by, for example, subtracting the signal.

In certain embodiments, the sensing layer includes one or more electron transfer agents. Electron transfer agents that may be employed are electroreducible and electrooxidizable ions or molecules having redox potentials that are a few hundred millivolts above or below the redox potential of the standard calomel electrode (SCE). The electron transfer agent may be organic, organometallic, or inorganic. Examples of organic redox species are quinones and species that in their oxidized state have quinoid structures, such as Nile blue and indophenol. Examples of organometallic redox species are metallocenes such as ferrocene. Examples of inorganic redox species are hexacyanoferrate (III), ruthenium hexamine etc.

In certain embodiments, electron transfer agents have structures or charges which prevent or substantially reduce the diffusional loss of the electron transfer agent during the period of time that the sample is being analyzed. For example, electron transfer agents include but are not limited to a redox species, e.g., bound to a polymer which can in turn be disposed on or near the working electrode. The bond between the redox species and the polymer may be covalent, coordinative, or ionic. Although any organic, organometallic or inorganic redox species may be bound to a polymer and used as an electron transfer agent, in certain embodiments the redox species is a transition metal compound or complex, e.g., osmium, ruthenium, iron, and cobalt compounds or complexes. It will be recognized that many redox species described for use with a polymeric component may also be used, without a polymeric component.

One type of polymeric electron transfer agent contains a redox species covalently bound in a polymeric composition. An example of this type of mediator is poly(vinylferrocene). Another type of electron transfer agent contains an ionically-bound redox species. This type of mediator may include a charged polymer coupled to an oppositely charged redox species. Examples of this type of mediator include a negatively charged polymer coupled to a positively charged redox species such as an osmium or ruthenium polypyridyl cation. Another example of an ionically-bound mediator is a positively charged polymer such as quaternized poly(4-vinyl pyridine) or poly(1-vinyl imidazole) coupled to a negatively charged redox species such as ferricyanide or ferrocyanide. In other embodiments, electron transfer agents include a

redox species coordinatively bound to a polymer. For example, the mediator may be formed by coordination of an osmium or cobalt 2,2'-bipyridyl complex to poly(1-vinyl imidazole) or poly(4-vinyl pyridine).

Suitable electron transfer agents are osmium transition metal complexes with one or more ligands, each ligand having a nitrogen-containing heterocycle such as 2,2'-bipyridine, 1,10-phenanthroline, 1-methyl, 2-pyridyl biimidazole, or derivatives thereof. The electron transfer agents may also have one or more ligands covalently bound in a polymer, each ligand having at least one nitrogen-containing heterocycle, such as pyridine, imidazole, or derivatives thereof. One example of an electron transfer agent includes (a) a polymer or copolymer having pyridine or imidazole functional groups and (b) osmium cations complexed with two ligands, each ligand containing 2,2'-bipyridine, 1,10-phenanthroline, or derivatives thereof, the two ligands not necessarily being the same. Some derivatives of 2,2'-bipyridine for complexation with the osmium cation include but are not limited to 4,4'-dimethyl-2,2'-bipyridine and mono-, di-, and polyalkoxy-2,2'-bipyridines, such as 4,4'-dimethoxy-2,2'-bipyridine. Derivatives of 1,10-phenanthroline for complexation with the osmium cation include but are not limited to 4,7-dimethyl-1,10-phenanthroline and mono, di-, and polyalkoxy-1,10-phenanthrolines, such as 4,7-dimethoxy-1,10-phenanthroline. Polymers for complexation with the osmium cation include but are not limited to polymers and copolymers of poly(1-vinyl imidazole) (referred to as "PVI") and poly(4-vinyl pyridine) (referred to as "PVP"). Suitable copolymer substituents of poly(1-vinyl imidazole) include acrylonitrile, acrylamide, and substituted or quaternized N-vinyl imidazole, e.g., electron transfer agents with osmium complexed to a polymer or copolymer of poly(1-vinyl imidazole).

Embodiments may employ electron transfer agents having a redox potential ranging from about -200 mV to about +200 mV versus the standard calomel electrode (SCE). The sensing layer may also include a catalyst which is capable of catalyzing a reaction of the analyte. The catalyst may also, in some embodiments, act as an electron transfer agent. One example of a suitable catalyst is an enzyme which catalyzes a reaction of the analyte. For example, a catalyst, such as a glucose oxidase, glucose dehydrogenase (e.g., pyrroloquinoline quinone (PQQ), dependent glucose dehydrogenase, flavine adenine dinucleotide (FAD) dependent glucose

dehydrogenase, or nicotinamide adenine dinucleotide (NAD) dependent glucose dehydrogenase), may be used when the analyte of interest is glucose. A lactate oxidase or lactate dehydrogenase may be used when the analyte of interest is lactate. Laccase may be used when the analyte of interest is oxygen or when oxygen is generated or consumed in response to a reaction of the analyte.

The sensing layer may also include a catalyst which is capable of catalyzing a reaction of the analyte. The catalyst may also, in some embodiments, act as an electron transfer agent. One example of a suitable catalyst is an enzyme which catalyzes a reaction of the analyte. For example, a catalyst, such as a glucose oxidase, glucose dehydrogenase (e.g., pyrroloquinoline quinone (PQQ), dependent glucose dehydrogenase or oligosaccharide dehydrogenase, flavine adenine dinucleotide (FAD) dependent glucose dehydrogenase, nicotinamide adenine dinucleotide (NAD) dependent glucose dehydrogenase), may be used when the analyte of interest is glucose. A lactate oxidase or lactate dehydrogenase may be used when the analyte of interest is lactate. Laccase may be used when the analyte of interest is oxygen or when oxygen is generated or consumed in response to a reaction of the analyte.

In certain embodiments, a catalyst may be attached to a polymer, cross linking the catalyst with another electron transfer agent (which, as described above, may be polymeric. A second catalyst may also be used in certain embodiments. This second catalyst may be used to catalyze a reaction of a product compound resulting from the catalyzed reaction of the analyte. The second catalyst may operate with an electron transfer agent to electrolyze the product compound to generate a signal at the working electrode. Alternatively, a second catalyst may be provided in an interferent-eliminating layer to catalyze reactions that remove interferents.

Certain embodiments include a Wired Enzyme™ sensing layer (Abbott Diabetes Care, Inc.) that works at a gentle oxidizing potential, e.g., a potential of about +40 mV. This sensing layer uses an osmium (Os) -based mediator designed for low potential operation and is stably anchored in a polymeric layer. Accordingly, in certain embodiments the sensing element is redox active component that includes (1) Osmium-based mediator molecules attached by stable (bidente) ligands anchored to a polymeric backbone, and (2) glucose oxidase enzyme molecules. These two constituents are crosslinked together.

A mass transport limiting layer (not shown), e.g., an analyte flux modulating layer, may be included with the sensor to act as a diffusion-limiting barrier to reduce the rate of mass transport of the analyte, for example, glucose or lactate, into the region around the working electrodes. The mass transport limiting layers are useful in limiting the flux of an analyte to a working electrode in an electrochemical sensor so that the sensor is linearly responsive over a large range of analyte concentrations and is easily calibrated. Mass transport limiting layers may include polymers and may be biocompatible. A mass transport limiting layer may provide many functions, e.g., biocompatibility and/or interferent-eliminating, etc.

In certain embodiments, a mass transport limiting layer is a membrane composed of crosslinked polymers containing heterocyclic nitrogen groups, such as polymers of polyvinylpyridine and polyvinylimidazole. Embodiments also include membranes that are made of a polyurethane, or polyether urethane, or chemically related material, or membranes that are made of silicone, and the like.

A membrane may be formed by crosslinking in situ a polymer, modified with a zwitterionic moiety, a non-pyridine copolymer component, and optionally another moiety that is either hydrophilic or hydrophobic, and/or has other desirable properties, in an alcohol-buffer solution. The modified polymer may be made from a precursor polymer containing heterocyclic nitrogen groups. For example, a precursor polymer may be polyvinylpyridine or polyvinylimidazole. Optionally, hydrophilic or hydrophobic modifiers may be used to "fine-tune" the permeability of the resulting membrane to an analyte of interest. Optional hydrophilic modifiers, such as poly(ethylene glycol), hydroxyl or polyhydroxyl modifiers, may be used to enhance the biocompatibility of the polymer or the resulting membrane.

A membrane may be formed in situ by applying an alcohol-buffer solution of a crosslinker and a modified polymer over an enzyme-containing sensing layer and allowing the solution to cure for about one to two days or other appropriate time period. The crosslinker-polymer solution may be applied to the sensing layer by placing a droplet or droplets of the solution on the sensor, by dipping the sensor into the solution, or the like. Generally, the thickness of the membrane is controlled by the concentration of the solution, by the number of droplets of the solution applied, by the number of times the sensor is dipped in the solution, or by any combination of these

factors. A membrane applied in this manner may have any combination of the following functions: (1) mass transport limitation, i.e. reduction of the flux of analyte that can reach the sensing layer, (2) biocompatibility enhancement, or (3) interferent reduction.

The description herein is directed primarily to electrochemical sensors for convenience only and is in no way intended to limit the scope of the disclosure. Other sensors and sensor systems are contemplated. Such include, but are not limited to, optical sensors, colorimetric sensors, potentiometric sensors, coulometric sensors and sensors that detect hydrogen peroxide to infer glucose levels, for example. For example, a hydrogen peroxide-detecting sensor may be constructed in which a sensing layer includes enzyme such as glucose oxides, glucose dehydrogensae, or the like, and is positioned proximate to the working electrode. The sending layer may be covered by a membrane that is selectively permeable to glucose. Once the glucose passes through the membrane, it is oxidized by the enzyme and reduced glucose oxidase can then be oxidized by reacting with molecular oxygen to produce hydrogen peroxide.

Certain embodiments include a hydrogen peroxide-detecting sensor constructed from a sensing layer prepared by crosslinking two components together, for example: (1) a redox compound such as a redox polymer containing pendent Os polypyridyl complexes with oxidation potentials of about +200 mV vs. SCE, and (2) periodate oxidized horseradish peroxidase (HRP). Such a sensor functions in a reductive mode; the working electrode is controlled at a potential negative to that of the Os complex, resulting in mediated reduction of hydrogen peroxide through the HRP catalyst.

In another example, a potentiometric sensor can be constructed as follows. A glucose-sensing layer is constructed by crosslinking together (1) a redox polymer containing pendent Os polypyridyl complexes with oxidation potentials from about -200 mV to +200 mV vs. SCE, and (2) glucose oxidase. This sensor can then be used in a potentiometric mode, by exposing the sensor to a glucose containing solution, under conditions of zero current flow, and allowing the ratio of reduced/oxidized Os to reach an equilibrium value. The reduced/oxidized Os ratio varies in a reproducible way with the glucose concentration, and will cause the electrode's potential to vary in a similar way.

A sensor may also include an active agent such as an anticlotting and/or antiglycolytic agent(s) disposed on at least a portion a sensor that is positioned in a user. An anticlotting agent may reduce or eliminate the clotting of blood or other body fluid around the sensor, particularly after insertion of the sensor. Examples of useful anticlotting agents include heparin and tissue plasminogen activator (TPA), as well as other known anticlotting agents. Embodiments may include an antiglycolytic agent or precursor thereof. Examples of antiglycolytic agents are glyceraldehyde, fluoride ion, and mannose.

Sensors may be configured to require no system calibration or no user calibration. For example, a sensor may be factory calibrated and need not require further calibrating. In certain embodiments, calibration may be required, but may be done without user intervention, i.e., may be automatic. In those embodiments in which calibration by the user is required, the calibration may be according to a predetermined schedule or may be dynamic, i.e., the time for which may be determined by the system on a real-time basis according to various factors, such as but not limited to glucose concentration and/or temperature and/or rate of change of glucose, etc.

Calibration may be accomplished using an in vitro test strip (or other reference), e.g., a small sample test strip such as a test strip that requires less than about 1 microliter of sample (for example FreeStyle® blood glucose monitoring test strips from Abbott Diabetes Care). For example, test strips that require less than about 1 nanoliter of sample may be used. In certain embodiments, a sensor may be calibrated using only one sample of body fluid per calibration event. For example, a user need only lance a body part one time to obtain sample for a calibration event (e.g., for a test strip), or may lance more than one time within a short period of time if an insufficient volume of sample is firstly obtained. Embodiments include obtaining and using multiple samples of body fluid for a given calibration event, where glucose values of each sample are substantially similar. Data obtained from a given calibration event may be used independently to calibrate or combined with data obtained from previous calibration events, e.g., averaged including weighted averaged, etc., to calibrate. In certain embodiments, a system need only be calibrated once by a user, where recalibration of the system is not required.

Analyte systems may include an optional alarm system that, e.g., based on information from a processor, warns the patient of a potentially detrimental condition of the analyte. For example, if glucose is the analyte, an alarm system may warn a user of conditions such as hypoglycemia and/or hyperglycemia and/or impending hypoglycemia, and/or impending hyperglycemia. An alarm system may be triggered when analyte levels approach, reach or exceed a threshold value. An alarm system may also, or alternatively, be activated when the rate of change, or acceleration of the rate of change, in analyte level increase or decrease approaches, reaches or exceeds a threshold rate or acceleration. A system may also include system alarms that notify a user of system information such as battery condition, calibration, sensor dislodgment, sensor malfunction, etc. Alarms may be, for example, auditory and/or visual. Other sensory-stimulating alarm systems may be used including alarm systems which heat, cool, vibrate, or produce a mild electrical shock when activated.

The subject disclosure also includes sensors used in sensor-based drug delivery systems. The system may provide a drug to counteract the high or low level of the analyte in response to the signals from one or more sensors. Alternatively, the system may monitor the drug concentration to ensure that the drug remains within a desired therapeutic range. The drug delivery system may include one or more (e.g., two or more) sensors, a processing unit such as a transmitter, a receiver/display unit, and a drug administration system. In some cases, some or all components may be integrated in a single unit. A sensor-based drug delivery system may use data from the one or more sensors to provide necessary input for a control algorithm/mechanism to adjust the administration of drugs, e.g., automatically or semi-automatically. As an example, a glucose sensor may be used to control and adjust the administration of insulin from an external or implanted insulin pump.

As discussed above, embodiments of the present disclosure relate to methods and devices for detecting at least one analyte such as glucose in body fluid. Embodiments relate to the continuous and/or automatic in vivo monitoring of the level of one or more analytes using a continuous analyte monitoring system that includes an analyte sensor at least a portion of which is to be positioned beneath a skin surface of a user for a period of time and/or the discrete monitoring of one or more analytes using an in vitro blood glucose ("BG") meter in conjunction with an

analyte test strip. Embodiments include combined or combinable devices, systems and methods and/or transferring data between an in vivo continuous system and a BG meter system, and include integrated systems.

Embodiments include "Data Logger" systems which include a continuous glucose monitoring system (at least an analyte sensor and control unit (e.g., an on body unit)). The continuous glucose monitoring ("CG") system may have limited real-time connectivity with a BG meter. For example, real time connectivity may be limited to communicating calibration data (e.g., a BG value) to the CG system or it may have the ability to receive data from the CG system on demand (as compared to a CG system continuously broadcasting such data). In one embodiment, the data processing unit (102) may be an on-body unit that is configured to operate in several transmission modes. In a fist mode, analyte related data may be transmitted when a new data value (e.g., sensor data) is available (for example, when received from the analyte sensor). This mode of operation may result in "lost data" because the data processing unit 102 does not get confirmation that the data was successfully received by the receiver unit 104, and in some embodiments, this data may not be resent.

In a second transmission mode, data may be transmitted when the new data is available and the data processing unit 102 may receive an acknowledgement that such data has been successfully received, or if the transmission was unsuccessful the data would be stored ("buffered") for another attempt. This mode reduces the likelihood of "lost data". In a third mode ("data logging mode"), the data processing unit 102 may be configured to retain or store all data (i.e.; not attempt to transmit it when it becomes available) until the receiver unit (104) requests the data, or based upon a scheduled data transmission.

CG data obtained by the CG Data Logger may be processed by the Data Logger system or by the BG meter and/or by a data management system ("DMS") which may includes a computer such as a PC and an optional server. For example, the CoPilot™ data management system from Abbott Diabetes Care, Inc., or the like, may be employed. In certain embodiments neither the CG system nor the BG meter are capable of (or have such capability, but the capability is selectively turned off) supporting continuous real time CG data communication, thereby substantially reducing power requirements. Such embodiments are CG Data Loggers in which CG

data resides (i.e., is logged) in a CG control unit (e.g., on-body unit) until it is retrieved by a BG meter. In other words, a CG Data Logger buffers the CG data and stores it in memory until the CG data is downloaded or transferred to the BG meter, e.g., a user initiates data transfer or transfer may occur at set times. The CG component logs continuous glucose data, but only gives up this data to the on-request to a BG meter. Retrieval may be by any suitable methodology, including but not limited to wireless communication protocols such as for example RF, optical means (such as an IR link), Bluetooth, or a direct connection (such as a USB, or the like), etc. A given BG meter and CG data Logger may be synchronized, e.g., by one or more unique identifiers, thereby ensuring preventing inadvertent data exchange between devices.

FIG. 6 shows an exemplary embodiment of a system that includes a CG Data Logger and an enhanced BG meter. As shown, the enhanced BG meter may communicate with the CG Data Logger by a wired connection and/or by IR or RF. Referring to the Figure, in one aspect, the CG data logger may be configured to collect and store monitored analyte data over a predetermined time period (for example, from a transcutaneous, subcutaneous or implanted analyte sensor), and transmit the collected and stored analyte data to the BG meter either continuously in real time, or periodically (for example, when the CG data logger is in signal communication with the BG meter (either cabled or wireless), or in a single data transfer mode, for example, at the end of the predetermined time period.

"Modular" embodiments are also provided. Modular systems may be used in conjunction with the Data Logger system in certain embodiments. For example, a separable CG data transfer module may be configured for wireless communication with the CG data logger and further configured to removably mate with a BG meter to transfer CG information to the BG meter (see for example FIG. 7). Modular embodiments include all the necessary hardware (and software) to support either (or both) continuous (real time) or "batched" (data logged) CG data collection in a snap-on or otherwise mateable module that provides CG data to a BG meter. Alarm functionality may be included in the BG meter, as well as features to support CG data processing and communication to a user, e.g., hardware and software to process CG data and/or calibrate CG data, enhanced user interface to communicate CG

information to a user (in addition to BG information), e.g., may include CG calibration information, CG trend information, rate of change indicators to indicate the rate of change of glucose, and the like.

Modules may be re-usable by a plurality of users. User privacy features may be included, e.g., a module may not permanently store patient data (user data may be automatically deleted or expunged after a certain time period), data may be encrypted, password protected, or otherwise provided with one or more security features that will limit access to only the intended users. In one aspect, the CG data logger may be configured to collect and store the monitored analyte data received from an analyte sensor, and upon establishing data communication with the BG meter via the data transfer module, communicate the received analyte data in one or more batch transfer, or continuously in real time as the analyte sensor data is received from the sensor.

FIG. 7 shows an exemplary embodiment of a modular system that includes a CG control unit/transmitter, a mateable module and an enhanced BG meter. In this embodiment, the CG data logger/transmitter is shown communicating with the module via RF where the module is mateably coupled to the BG meter. However, other suitable data communication approaches may be used including IR, Bluetooth, Zigbee communication, and the like.

FIG. 8 shows an integrated or continuous system that includes an enhanced BG meter and a CG data logger/transmitter, where the CG data logger is capable of transferring CG data to the enhanced BG meter directly and in real time, in this embodiment shown via a wireless protocol. For example, as shown, the enhanced BG meter may include an RF communication module or chipset that allows for wireless communication with the CG data logger. Accordingly, as the continuous analyte sensor data is received by the CG data logger, the data is substantially contemporaneously transferred or communicated in real time to the enhanced BG meter over the RF communication link.

FIG. 9 shows an exemplary embodiment of a system which includes a BG meter and a docking unit, herein shown configured as a belt holster. The BG meter couples to the holster via contacts of the holster, which correspond to contacts of the BG meter. The BG meter displays information to the user when electronically coupled to the holster, i.e., when docked or when in wireless signal communication with the

belt holster (for example, when removed from the holster). The holster may include some or all functionality of a primary receiver unit as described below for CG monitoring. For example, the holster may contain some or all of a FreeStyle Navigator® system, e.g., the receiver functionality as described above. In one aspect, the belt holster may integrate the CG data logger such that the collected and stored analyte data may be transferred to the BG meter when docked in the holster (or when wirelessly synchronized with the belt holster).

The CG system may be calibrated using the BG meter, e.g., when the BG meter is docked. Such as system may be useful in a variety of instances, e.g., for gestational diabetes, assessing/diagnosing diabetes, and the like.

In certain embodiments, the CG system (whether it be modular or includes a data logger) may be configured with reduced set of functionalities. For example, it may not include alarms (audible and/or vibratory and/or visual) and/or glucose rate of change indicators and/or a visual or user interface display such as a dot matrix display and/or additional processing power and/or miniaturized, or it may not include a test strip port. For example, FIG. 10 illustrates features which may be included in an exemplary full-featured CG system, and exemplary integrated real time system and an exemplary Data Logger system.

In certain embodiments, synchronization between a BG and CG systems is provided to calibrate the CG sensor using a BG strip measurement as a reference data point.

In certain applications, the enhanced BG meters may be used by those who require more intensive (i.e., continuous) glucose monitoring, by temporarily or periodically allowing a user's BG meter to capture CG data without the user having to obtain another meter. Likewise, the added value to a health care provider ("HCP") is gained by patients periodically obtaining more detailed blood glucose information (e.g., prior to regular check up), thus allowing the HCP to make more informed and suited therapy adjustments for the patient.

Various embodiments have extensive applicability. For example, indwelling or external sensors other than CG sensors may be included. Data from indwelling or external sensors other than a CG sensor may be captured by the systems described herein (such as temperature data, ketone data, and the like). Furthermore, functions

such as weigh management, enhanced data management or insulin pump control may also be added to a BG meter via the modular approach to further enhance the meter. In certain embodiments, a Data Logger includes providing molded electrical contacts that allow for electrical connections thru the on-body case without compromising the watertight seal of the case.

Embodiments herein may provide increased value of a BG meter to the patient by adding CG functionality to a base BG meter, a low learning curve such that the user does not need to become familiar with two different user interfaces (one for the BG unit and another for the CG system), reduction in cost of the overall system, and substantial immunity to environments where continuous wireless communication may be prohibited such as during flight on an airplane, within hospital or other settings that have sensitive instrumentation that may interfere with RF or other wireless signals.

Accordingly, an analyte monitoring system in one embodiment includes an analyte sensor for transcutaneous positioning under a skin layer of a subject, a data processing device operatively coupled to the analyte sensor, the device comprising: a control unit, a memory operatively coupled to the control unit and configured to store a plurality of data associated with the monitored analyte level received from the sensor, and a communication unit operatively coupled to the control unit; and a blood glucose meter configured for signal communication with the data processing device, where when the control unit of the data processing device detects a communication link with the blood glucose meter, the control unit is further configured to retrieve the stored plurality of data from the memory and to transmit the retrieved data to the blood glucose meter.

The blood glucose meter includes a strip port for receiving a blood glucose test strip.

The communication unit may be configured to communicate with the blood glucose meter using one or more of a wired connection, a USB cable connection, a serial cable connection, an RF communication protocol, an infrared communication protocol, a Bluetooth communication protocol, or an 802.11x communication protocol.

In one embodiment, data processing device does not include a user output component, where the user output component includes a display.

The control unit may detect the communication link with the blood glucose meter based on detection of a wired connection to the meter.

The retrieved stored plurality of data may correspond to glucose data of the subject collected over a predetermined time period.

The glucose data may be uncalibrated or calibrated.

The analyte sensor may be a glucose sensor.

In one aspect, the blood glucose meter may include an output unit configured to output one or more of the received retrieved data.

The output unit may include a display unit operatively coupled to a housing of the blood glucose meter.

The output of one or more received data may include a graphical output, a numerical output, or a text output.

The blood glucose meter may be configured to calibrate the received data.

The blood glucose meter may include a storage unit configured to store the calibrated data.

The blood glucose meter may include a storage unit configured to store the received data.

In another aspect, the system may include a holster device for receiving the blood glucose meter, and the data processing unit may be integrated in the holster device.

The control unit may be configured to detect the communication link with the blood glucose meter when the meter is coupled to the holster.

The holster device may include a belt clip.

A method in another embodiment may include transcutaneously positioning an analyte sensor under a skin layer of a subject, coupling a data processing device to the analyte sensor, storing in a memory of the data processing device a plurality of data associated with the monitored analyte level received from the sensor, operatively coupling a communication unit to the control unit, detecting a communication link with the blood glucose meter, retrieving the stored plurality of data from the memory, and commanding the communication unit to transmit the retrieved data to the blood glucose meter.

The communication link may be established based on one or more of a wired connection, a USB cable connection, a serial cable connection, an RF communication protocol, an infrared communication protocol, a Bluetooth communication protocol, or an 802.11x communication protocol.

The method may include displaying on the blood glucose meter the received analyte data.

The retrieved data may correspond to glucose data of the subject collected over a predetermined time period.

The method may include calibrating the received data.

In another aspect, the method may include storing the received data in a memory of the blood glucose meter.

In still a further aspect, the method may include encrypting the retrieved data prior to transmitting to the blood glucose meter.

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

WHAT IS CLAIMED IS:

1. An analyte monitoring system, comprising:

an analyte sensor for transcutaneous positioning under a skin layer of a subject;

a data processing device operatively coupled to the analyte sensor, the device comprising:

a control unit;

a memory operatively coupled to the control unit and configured to store a plurality of data associated with the monitored analyte level received from the sensor; and

a communication unit operatively coupled to the control unit; and

a blood glucose meter configured for signal communication with the data processing device;

wherein when the control unit of the data processing device detects a communication link with the blood glucose meter, the control unit is further configured to retrieve the stored plurality of data from the memory and to transmit the retrieved data to the blood glucose meter.

2. The system of claim 1 wherein the blood glucose meter includes a strip port for receiving a blood glucose test strip.

3. The system of claim 1 wherein the communication unit is configured to communicate with the blood glucose meter using one or more of a wired connection, a USB cable connection, a serial cable connection, an RF communication protocol, an infrared communication protocol, a Bluetooth communication protocol, or an 802.11x communication protocol.

4. The system of claim 1 wherein the data processing device does not includes a user output component.

5. The system of claim 4 wherein the user output component includes a display.

6. The system of claim 1 wherein the control unit detects the communication link with the blood glucose meter based on detection of a wired connection to the meter.

7. The system of claim 1, wherein the retrieved stored plurality of data correspond to glucose data of the subject collected over a predetermined time period.

8. The system of claim 7 wherein the glucose data is uncalibrated.

9. The system of claim 7 wherein the glucose data is calibrated.

10. The system of claim 1 wherein the analyte sensor is a glucose sensor.

11. The system of claim 1 wherein the blood glucose meter includes an output unit configured to output one or more of the received retrieved data.

12. The system of claim 11 wherein the output unit includes a display unit operatively coupled to a housing of the blood glucose meter.

13. The system of claim 11 wherein the output of one or more received data includes
a graphical output, a numerical output, or a text output.

14. The system of claim 1 wherein the blood glucose meter is configured to calibrate the received data.

15. The system of claim 14 wherein the blood glucose meter includes a storage unit configured to store the calibrated data.

16. The system of claim 1 wherein the blood glucose meter includes a storage unit configured to store the received data.

17. The system of claim 1 including a holster device for receiving the blood glucose meter.

18. The system of claim 17 wherein the data processing unit is integrated in the holster device.

19. The system of claim 17 wherein the control unit is configured to detect the communication link with the blood glucose meter when the meter is coupled to the holster.

20. The system of claim 17 wherein the holster device includes a belt clip.

21. A method, comprising:

transcutaneously positioning an analyte sensor under a skin layer of a subject;

coupling a data processing device to the analyte sensor;

storing in a memory of the data processing device a plurality of data associated with the monitored analyte level received from the sensor;

operatively coupling a communication unit to the control unit;

detecting a communication link with the blood glucose meter;

retrieving the stored plurality of data from the memory; and

commanding the communication unit to transmit the retrieved data to the blood glucose meter.

22. The method of claim 21 wherein the communication link is established based on one or more of a wired connection, a USB cable connection, a serial cable connection, an RF communication protocol, an infrared communication protocol, a Bluetooth communication protocol, or an 802.11x communication protocol.

23. The method of claim 21 including displaying on the blood glucose meter the received analyte data.

24. The method of claim 21 wherein the retrieved data corresponds to glucose data of the subject collected over a predetermined time period.

25. The method of claim 24 wherein the glucose data is uncalibrated.

26. The method of claim 24 wherein the glucose data is calibrated.

27. The method of claim 21 wherein the analyte sensor is a glucose sensor.

28. The method of claim 21 including calibrating the received data.

29. The method of claim 21 including storing the received data in a memory of the blood glucose meter.

30. The method of claim 21 including encrypting the retrieved data prior to transmitting to the blood glucose meter.

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

FIGURE 1

201
210
W
211
G
212
R
213
C
ANALOG INTERFACE
209
205
SERIAL COMMUNICATION SECTION
204
206
LEAK DETECTION CIRCUIT
214
PROCESSOR
RF TRANSMITTER/ RECEIVER
TO PRIMARY RECEIVER UNIT
104
202
USER INPUT
207
203
TEMPERATURE MEASUREMENT SECTION
POWER SUPPLY
208
CLOCK
STORAGE UNIT
215
102

FIGURE 2

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

FIGURE 3

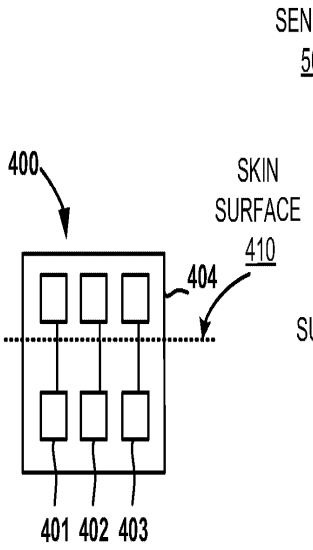


FIGURE 4

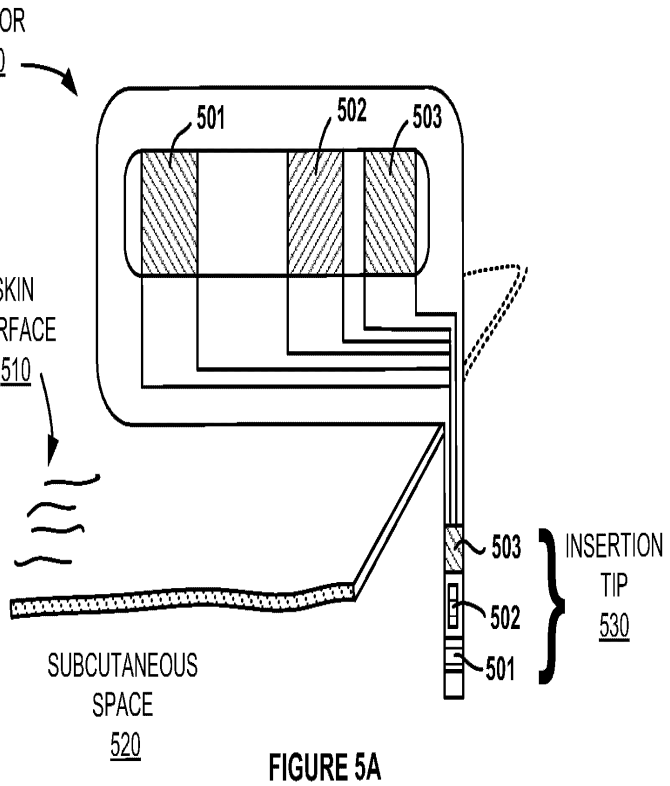


FIGURE 5A

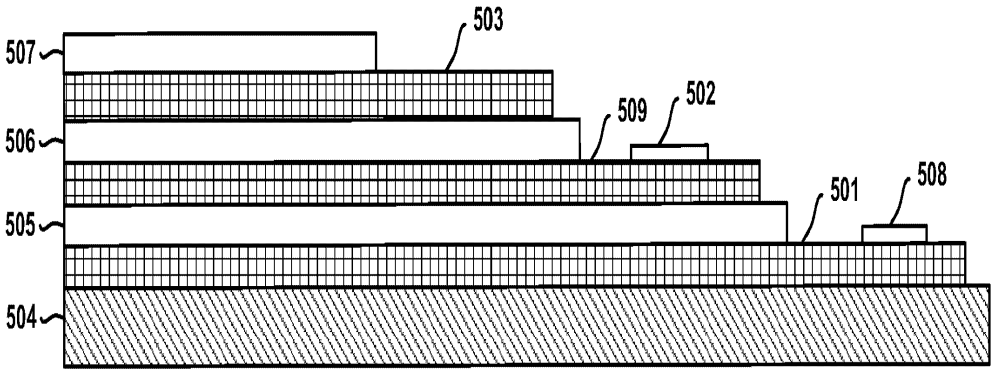


FIGURE 5B

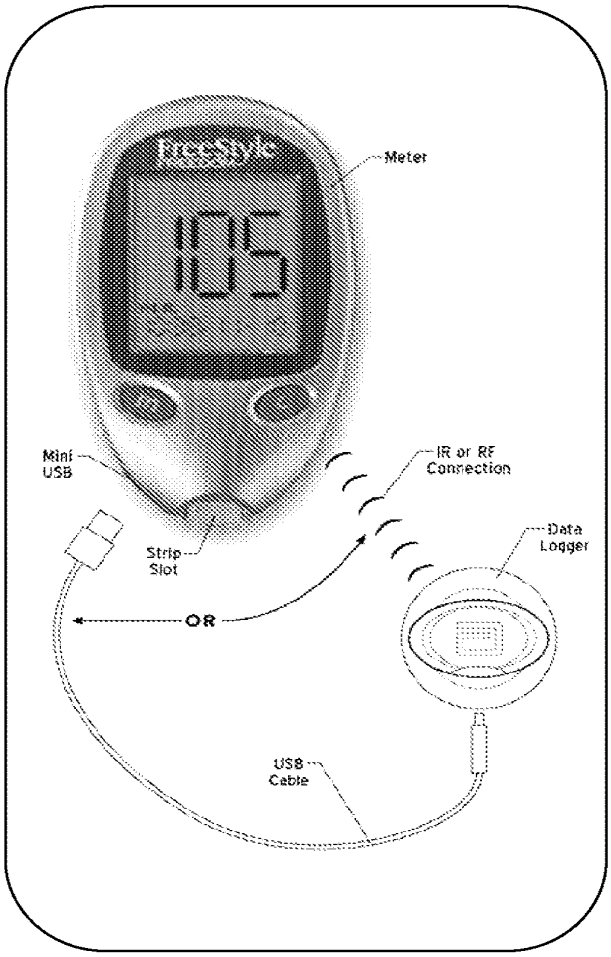

Meter
Mini USB
IR or RF Connection
Strip Slot
Data Logger
OR
USB Cable

FIGURE 6

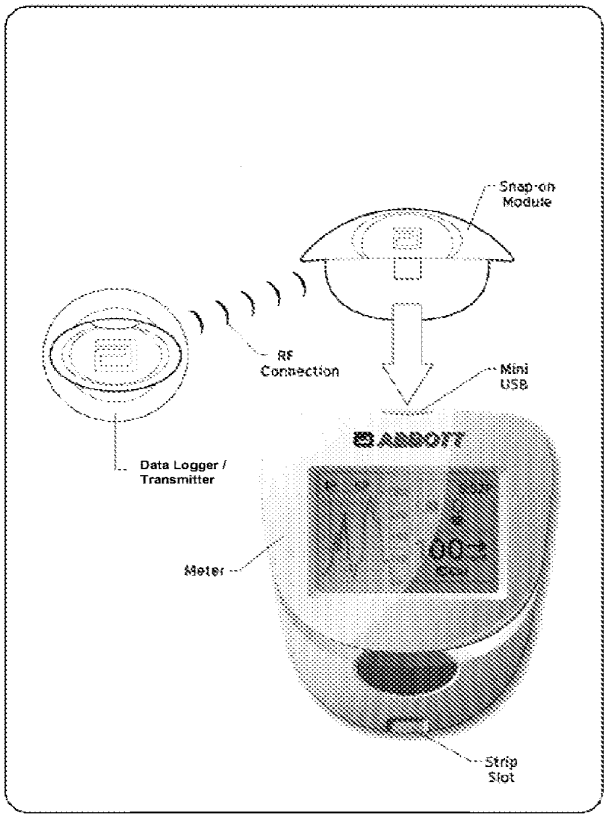


FIGURE 7

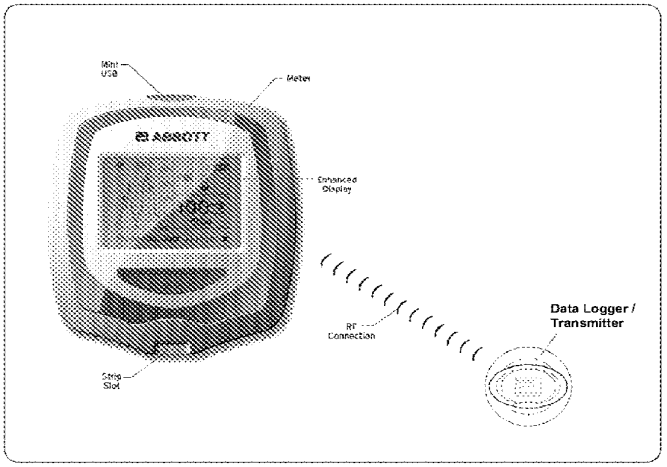


FIGURE 8

removable clip
belt
connector contacts
mini USB
reciever/dock
speaker
slides into dock
meter

FIGURE 9

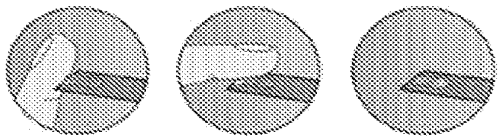


FIGURE 10A

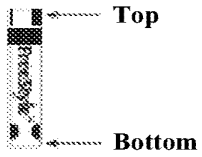


FIGURE 10B



FIGURE 10C

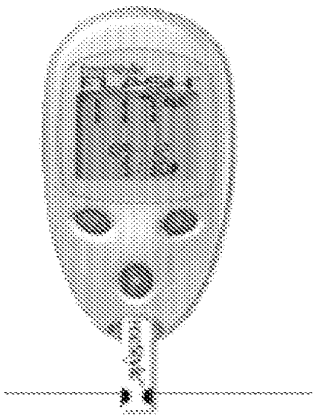


FIGURE 11A

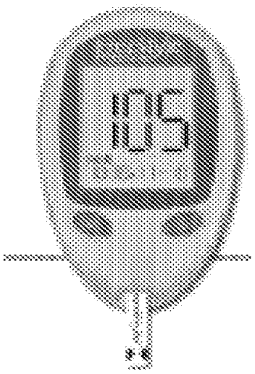


FIGURE 11B

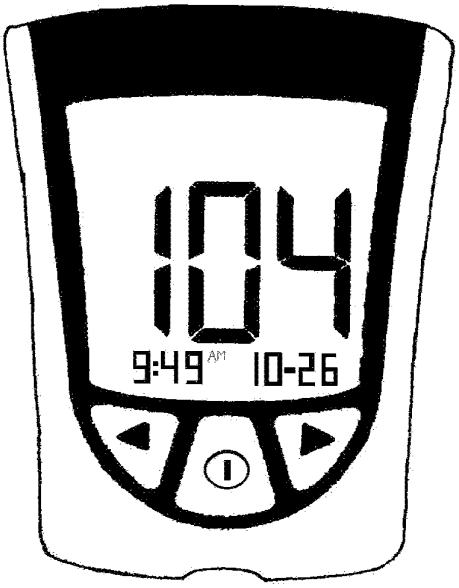


FIGURE 11C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/67793

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/00 (2008.04)
USPC - 600/309
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 (2008.04)
USPC: 600/309

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8): A61B 5/05, 5/05 (2008.01)
USPC: 600/316, 319, 345, 347, 523

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

PubEAST(USPT,PGPB,EPAB,JPAB); GoogleScholar
Search glucose analyte sensor, transcutaneous, insulin pump, computer, logic, data storage, memory, calibration, holder, holster, clip, test strips

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2007/0059196 A1 (BRISTER et al.) 15 March 2007 (15.03.2007) para[0218], para[0304], para[0472], para[0480], para[0584] and para[0585]	1, 3-13 and 16-29 ---- 2, 14-15 and 30
Y	US 2006/0064035 A1 (WANG et al.) 23 March 2006 (23.03.2006) para[0064]	2
Y	US 2007/0032706 A1 (KAMATH et al.) 8 February 2007 (08.02.2007) para[0152]	14-15
Y	US 2007/0038044 A1 (DOBBLES et al.) 15 February 2007 (15.02.2007) para[0514]	30

☐ 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	Date of mailing of the international search report
20 August 2008 (20.08.2008)	08 SEP 2008
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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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(54) **Title**: METHOD AND SYSTEM FOR UPDATING A MEDICAL DEVICE

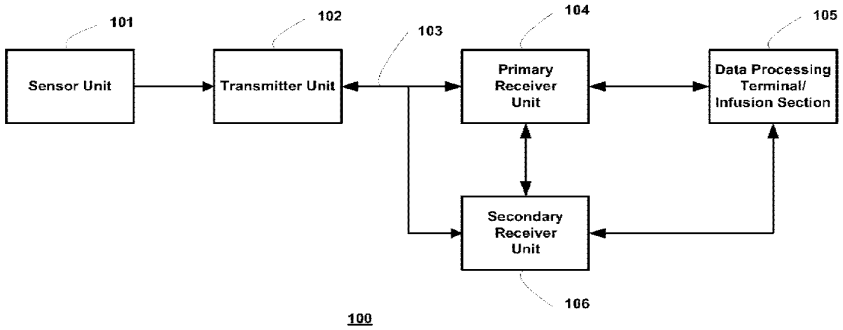


FIG. 1

(57) **Abstract**: Embodiments described herein include methods, devices and systems for updating a medical device and recovering from a failure to upgrade the medical device. One method comprising: establishing a connection between a medical device and a computing device; receiving an upgrade command at the medical device; storing a current version of persistent data executable code in a first storage area of the medical device; transmitting the persistent data to the computing device, the computing device converts the current version of the persistent data from a first format to a second format; receiving the second format of the persistent data and an upgraded version of executable code at the medical device; storing the second format persistent data and the upgraded executable code in a second storage area of the medical device; and executing the upgraded version of the executable code with the second format of the current version of the persistent data.

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METHOD AND SYSTEM FOR UPDATING A MEDICAL DEVICE

PRIORITY

[0001] The present application claims priority to U.S. Provisional Patent Application No. 61/184,234, entitled "Failure Recovery Methods of Corrupted Device Or During Software Downloads and Preservation of User Data and Manufacturing Data", filed on June 4, 2009, the disclosure of which is incorporated herein by reference in its entirety for all purposes.

BACKGROUND

[0002] In diabetes management, devices are available for diabetic patients to measure their blood glucose levels. One such type of device is a continuous glucose monitoring device that periodically receives and processes analyte related data from a transcutaneous sensor. The received and processed data may then be output on a display of the continuous blood glucose monitoring device or otherwise provided to the patient to enable the patient to continuously track measured glucose levels.

[0003] One challenge of currently available continuous glucose monitoring devices is upgrading software or firmware of the continuous glucose monitoring devices and the components of the continuous glucose monitoring devices. Further, if a patient experiences a problem with a continuous glucose monitoring device, such as, for example, the continuous glucose monitoring device ceases to function or data in the continuous glucose monitoring device becomes corrupt, the settings and/or the analyte related data stored on the on the continuous glucose monitoring device may be lost. Further, if a patient switches from using one continuous glucose monitoring device to another continuous glucose monitoring device, the user may need to manually change factory default settings of the new continuous glucose monitoring device to match the settings of the old continuous glucose monitoring device, which can be a time consuming process.

SUMMARY

[0004] Embodiments described herein include methods and/or systems for updating a medical device and recovering from a failure to upgrade the medical device. In

certain embodiments, a connection is established between a medical device and a remote computing device. An upgrade command is received at the medical device and in response to the upgrade command the medical device stores a current version of persistent data and a current version of executable code in a first storage area of the medical device. The medical device then transmits at least the current version of the persistent data to the remote computing device. The remote computing device is configured to convert the current version of the persistent data from a first format to a second format, with the first format of the current version of the persistent data corresponding to the current version of executable code and the second format of the current version of the persistent data corresponding to an upgraded version of executable code. The medical device receives the second format of the current version of the persistent data and the upgraded version of the executable code, stores the second format of the current version of the persistent data and the upgraded version of the executable code in a second storage area, and executes the upgraded version of the executable code and the second format of the current version of the persistent data in place of the current version of the executable code and the first format of the current version of the persistent data.

[0005] 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.

INCORPORATED BY REFERENCE

[0006] 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; 5,356,786; 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;

7,041,468; 7,167,818; and 7,299,082; U.S. Published Application Nos. 2004/0186365; 2005/0182306; 2006/0025662; 2006/0091006; 2007/0056858; 2007/0068807; 2007/0095661; 2007/0108048; 2007/0199818; 2007/0227911; 2007/0233013; 2008/0066305; 2008/0081977; 2008/0102441; 2008/0148873; 2008/0161666; 2008/0267823; and 2009/0054748; U.S. Patent Application Serial Nos. 11/461,725; 12/131,012; 12/242,823; 12/363,712; 12/495,709; and 12/698,124; and 12/714,439 and U.S. Provisional Application Serial Nos. 61/184,234; 61/230,686; 61/227,967; 61/347,754; and 61/347,813.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 illustrates a block diagram of a data monitoring and management system according to embodiments of the present disclosure;

[0008] FIG. 2 illustrates a block diagram of an upgrade and recovery system according to embodiments of the present disclosure;

[0009] FIG. 3 is a flowchart illustrating a method for updating a medical device according to embodiments of the present disclosure;

[0010] FIG. 4 is a flowchart illustrating a method for recovering non-user configurable data according to embodiments of the present disclosure;

[0011] FIG. 5 is a flowchart illustrating a method for transferring user configurable data from a first device to a second device according to embodiments of the present disclosure;

[0012] FIG. 6 illustrates an exemplary compatibility table according to embodiments of the present disclosure;

[0013] FIG. 7 is a flow chart illustrating a method for selectively upgrading a device based on a compatibility table according to embodiments of the present disclosure; and

[0014] FIG. 8 is a flow chart illustrating a method for reverting to a previous version of software for a device according to embodiments of the present disclosure.

DETAILED DESCRIPTION

[0015] 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.

[0016] 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.

[0017] 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.

[0018] 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.

[0019] 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.

[0020] 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.

[0021] The figures shown herein are not necessarily drawn to scale, with some components and features being exaggerated for clarity.

[0022] Embodiments described herein relate to upgrading, updating, adding, or modifying a medical device such as, for example, a continuous glucose monitoring device, and/or components of an analyte monitoring system. In certain aspects of the present disclosure, the device is upgraded and provided with updated software and/or data to assist users in better managing their health. In the manner described, in aspects of the present disclosure, patients with Type-1 or Type-2 diabetic conditions may improve their diabetes management, and further, the patients, users or healthcare providers may be provided with tools to improve the treatment of such conditions.

[0023] Software and firmware upgrades and the methods described herein may be used with various components of a data monitoring and management system such as the data monitoring and management system 100 illustrated in FIG. 1. In certain embodiments, the data management and monitoring system 100 is an analyte monitoring and management system, such as a continuous glucose monitoring management system. Although a continuous glucose monitoring system is specifically mentioned, it is contemplated that features described herein may also be applicable to other medical monitoring device such as drug or medication delivery devices and the like.

[0024] Referring back to FIG. 1, the analyte monitoring system 100 includes a sensor unit 101, a data processing and/or communication unit such as, for example, a transmitter unit 102 coupleable to the sensor unit 101, and a primary receiver unit 104 which is configured to communicate with the transmitter unit 102 via a bi-directional communication link 103. In certain embodiments, the communication link 103 may include 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.

[0025] Although not shown, it is contemplated that the sensor unit 101 and the transmitter unit 102 may be configured as a single integrated unit such as an on body patch device. In such embodiments, the integrated unit may wirelessly communicate with other components of the system 100 such as described herein.

[0026] 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 transmitter unit 102 via a communication link which may optionally be configured for bi-directional communication. Accordingly, transmitter unit 102 and/or receiver unit 104 may include a transceiver.

[0027] 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 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 bidirectional wireless communication with each or one of the transmitter unit 102, the primary receiver unit 104 and the data processing terminal 105. 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. In certain embodiments, the secondary receiver unit 106 may be configured with the same or substantially similar functionality as the primary receiver unit 104. Each 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 bidirectional communication device.

[0028] In one aspect, sensor unit 101 may include two or more sensors, each configured to communicate with transmitter unit 102. Furthermore, while only one, transmitter unit 102, communication link 103, and data processing terminal

105 are shown in the embodiment of the 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.

[0029] 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 transmitter unit 102. In certain embodiments, the 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 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 transmitter unit 102 transmits analyte information to the primary receiver unit 104 via the communication link 103. Additional detailed description of the continuous analyte monitoring system and its various components are provided in but not limited to: U.S. Patent Nos. 6,134,461, 6,175,752, 6,121,611, 6,560,471, 6,746,582, and U.S. Patent Publication No. 2008/0278332 filed May 8, 2008 and elsewhere, the disclosure of each of which are incorporated by reference for all purposes.

[0030] FIG. 2 illustrates a block diagram of an upgrade and recovery system 200 according to embodiments of the present disclosure. In certain embodiments, the upgrade and recovery system 200 includes, but is not limited to, a device 201, a computing device 202, and a server 203. As will be appreciated by one of ordinary skill in the art, the upgrade recovery system 200 may be used with the various components of the data monitoring and management system 100 (FIG. 1).

As such, as used herein, the term device, such as device 201 for example, may refer to a medical device, the transmitter unit 102, the primary receiver unit 104, and/or the secondary receiver unit 106.

[0031] In certain embodiments, the device 201 includes a plurality of microprocessors. Non-limiting examples include an ARM9 microprocessor, a MSP430 microprocessor, and a CC2510 microprocessor. In one aspect, at least one microprocessor of the device 201, such as, for example, an ARM9 microprocessor, is configured to handle user interface functionalities of the device 201, store persistent data (e.g. manufacturing setting and user-configurable settings) corresponding to the device 201, and store and manage the software and software upgrades for the other microprocessors (e.g., the MSP430 microprocessor and the CC2510 microprocessor) of the device 401. For example, when software corresponding to the MSP430 microprocessor is upgraded, the upgraded version of the software for the MSP430 microprocessor is stored in the ARM9 microprocessor. Thus, when the device 201 boots, a bootloader of the ARM9 microprocessor loads the software for the ARM9 microprocessor, the software for the CC2510 microprocessor and the upgraded version of the software for the MSP430 microprocessor.

[0032] In certain embodiments, a second microprocessor of the device 201, such as, for example, a MSP430 microprocessor, is configured to process glucose readings from a test strip inserted into the device 201 and/or manage continuous glucose data received from a sensor, such as, for example sensor unit 101 (FIG. 1). In another embodiment, a third microprocessor of the device, such as, for example a CC2510 microprocessor, is configured to interface with various peripheral devices, such as, for example, a wireless pump. Thus, using the third microprocessor of the device 201 a user may control the peripheral device directly from the device 201. Although specific microprocessors have been discussed, it is contemplated that various other microprocessors may be used by the device 201.

[0033] In certain embodiments, the computing device 202 may be a user's personal computer or laptop. The computing device 202 may also be a personal digital assistant, smart phone, tablet computer or other portable computing device that may receive data from the device 201 or transfer data to the device 201. The

computing device 202 may be configured to store and/or further analyze data, such as, for example, blood glucose data and/or continuously monitored glucose data from the device 201 that was transferred to the computing device 202 via a wireless or wired connection. In certain embodiments, a web-based application or other client application may be stored in a memory of the computing device 202 and may be executed by one or more processors of the computing device 202. Such applications may enable a user to view analyte related data on the computing device 202 as well as viewing and downloading available software and firmware upgrades for the device 201.

[0034] In certain embodiments, server 203 is configured to provide upgrades for the device 201 and/or the computing device 202. The upgrades for the device 201 and the computing device 202 include software upgrades, data upgrades, and firmware upgrades. The server 203 is further configured to store and/or analyze and process data obtained from device 201 and computing device 202 and transmit the received data to another computing device (not shown) such as, for example, a computing device of a healthcare provider.

[0035] In certain embodiments, the server 203 includes a database or other such data structure that stores serial numbers corresponding to a plurality of devices. The database also stores a compatibility table that corresponds to each device. As will be explained in greater detail below, the compatibility table associated with each device is used to store and track versions of software and firmware that have been downloaded and installed on the device 201 as well as user-configurable data associated with each version of software installed on the device 201. In one aspect, the compatibility table also stores information corresponding to the hardware versions of each of the microprocessors of the device 201 as well as software/firmware versions for each of the microprocessors of the device 201.

[0036] Referring back to FIG. 2, in certain embodiments, communication links 210, 220, and 230 connect the device 201 and computing device 202; the device 201 and the server 203; and the computing device 202 and the server 203. The communication links 210, 220, and 230 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, a Zigbee communication protocol, and the like.

[0037] One or more components of the upgrade and recovery system 200 may function to perform various and multiple upgrade and recovery operations related to software and data upgrades, data recovery, and/or data preservation. In certain embodiments, the upgrade and recovery system 200 may perform one or more routines for downloading data to a device, such as device 201 as described below in conjunction with the method 300 of FIG. 3.

[0038] Referring to FIG. 3, communication between a device, such as device 201 (FIG. 2), and at least one remote computing device, such as computing device 202 or server 203, is established (301). In certain embodiments, communication between the device 201 and the remote computing device is established through communication links 210 or 220. In one aspect, the communication between the device 201 and the remote computing device is established using a wireless connection. In another aspect, the communication between the device 201 and the remote computing device is established using a wired connection such as, for example, by connecting the device 201 to the remote computing device using a USB cable.

[0039] In certain embodiments, the device 201 includes a first memory for storing instructions for execution by the one or more microprocessors of the device 201 to upgrade, for example, software algorithms, computer executable routines and/or any other types of executable code stored on the device 201. The executable code may be written in one or more machine readable languages for retrieval and execution by one or more microprocessor driven or microprocessor controlled components of the device 201. For example, the upgrades may correspond to upgrades for an operating system being executed on the device 201, an application (e.g., bolus calculator application) being executed on the device 201 that enhances the functionality of the device 201, an application programming interface (API) (e.g., applications for communicating with and/or controlling peripheral devices that have been connected to the device 201) being executed on the device 201, and the like. Further, in certain embodiments, the instructions for execution by the one or more microprocessors of the device 201 are configured to verify the integrity of the upgraded version of the software algorithms, computer executable routines and/or the other executable code for the device 201. In another embodiment, the instructions for execution by the one or

more microprocessors of the device 201 are configured to verify the integrity of user-configurable data and manufacturing data that will be used by the upgraded version of the software algorithms, computer executable routines and/or other executable code for the device 201. In certain embodiments, the user-configurable data corresponds to user settings of the device 201 such as, for example, glucose threshold values, alarm settings, reminder settings, and language settings. In certain embodiments, the manufacturing data may include data that is used to identify the device 201 such as, for example, a serial number of the device 201. Additionally, the manufacturing data may also include default settings for the device 201 (e.g. unit of measure, an analog to digital converter (ADC) count etc.) and/or a current version of software that is being executed by the device 201.

[0040] The device 201 further includes a second memory with a plurality of segregated areas for storage of various types data (e.g., user-configurable data and upgraded versions of the user-configurable data) or upgraded versions of the software for the device 201. In certain embodiments, the first and/or second memory is random access memory. In another embodiment, the first memory is volatile memory. In yet another embodiment, the second memory is non-volatile memory, which may be flash memory. In certain embodiments, the first memory and the second memory are non-volatile or flash memory.

[0041] In certain embodiments, software that is executed by a microprocessor of the device 201 (e.g., a current version of the software or a current version of executable code), as well as the user-configurable and manufacturing data utilized by the software that is executed by the microprocessor of the device 201, is stored in a first storage area of the second memory of the device 201. For example, the software that is executed by a microprocessor of the device 201 may be an operating system of the device 201, an application utilized by the operating system to enhance the functionality of the device 201, or an application programming interface of the device 201. In one aspect, the user-configurable data and the manufacturing data is stored in a memory of the device 201 so that the user-configurable data and the manufacturing data may be used to restore the settings of the device 201 should any problems occur with the device 201, such as, for example, the device 201 becoming disconnected from the server 203 or the

computing device 202 during the upgrade process, by upgrade not being fully installed on the device 201, or if the upgrade installed on the device 201 is corrupt or is not compatible with the device 201. If a problem occurs when upgrading the device 201, the user-configurable data and manufacturing data may be used to restore the stored settings of the device 201.

[0042] Referring still to FIG. 3, in certain embodiments, the device 201 (FIG. 2) receives a command from a remote computing device regarding the download of an upgrade that is to be processed at the device 201 (302). In certain embodiments, the upgrade for the device 201 may be an upgrade to software currently being executed on the device 201, a new application programming interface (API) for the device 201, an upgrade to firmware for the device 201, or a new software application for the device 201. In certain embodiments, the upgrade command is initiated by the remote computing device and communicated by the remote computing device, such as, for example, the computing device 202, to the device 201. In certain embodiments, a microprocessor of the device 201 automatically initiates installation or downloading of the upgrade directly from the remote computing device when the command is received from the remote computing device. In another embodiment, the download of the upgrade for the device 201 will not be initiated until a user confirms that the available upgrade for the device 201 is desired.

[0043] When the download of the upgrade is initiated, the existing user-configurable data and manufacturing data (e.g., persistent data) utilized by the version of the software being executed by the device 201 (e.g., the user-configurable data and manufacturing data stored in the first memory area of the second memory of the device 201) is packed and copied along with the version of the software being executed on the device 201, to a second storage area of the second memory of the device 201 (303). In certain embodiments, the persistent data is packed or compressed using an encoding scheme (e.g., lossy or lossless encoding scheme) so that the persistent data may be represented using fewer bits than if the persistent data was not packed or compressed. Because the data is compressed, memory space of the device 201 may be conserved. Further, because the packed persistent data (e.g., user-configurable data and manufacturing data) is represented by a fewer number of bits, bandwidth requirements for transferring

the packed persistent data from the device 201 to the remote computing device may also be reduced (e.g., the amount of bandwidth required to transmit the packed persistent data is less than the amount of bandwidth required to transmit persistent data that has not been packed). Once the persistent data is packed, the persistent data may then be uploaded to the remote computing device, such as, for example a computing device 202 executing a software upgrade module. The persistent data may then be uploaded from the computing device 202 to the server 203. In one aspect, the packed persistent data may be uploaded directly from the device 201 to the server 203.

[0044] Once the packed persistent data has been uploaded to the server 203, the server 203 unpacks the persistent data and converts the persistent data to a new version of persistent data that can be utilized by the upgraded version of the software for the device 201 that is to be downloaded to the device 201 during the upgrade process. Once the persistent data has been converted by the server 203, the new version of persistent data is packed (e.g. compressed) by the server 203 and downloaded to the device 201, along with the upgraded version of the software, and is stored in the first memory of the device 201 (304).

[0045] In certain embodiments, when the conversion of the persistent data is performed by the server 203, the persistent data is mapped to a new version of persistent data so that the settings utilized by the user in the previous software version (e.g., the version of the software that was executed on the device 201 prior to the upgrade) are maintained by the upgraded version of the software that is to be installed on the device 201. Mapping of the persistent data will be described in more detail below with respect to FIG. 5.

[0046] In certain embodiments, the server 203 performs the upload, conversion, and download through client software being executed on the server 203. In another embodiment, the upload, conversion and download of the persistent data and upgraded version of the software for the device 201 is performed through an upgrade module being executed on an intervening device, such as, for example, the computing device 202. In another embodiment, the conversion may be performed directly on the device 201.

[0047] Once the new version of the persistent data and the upgraded version of the software have been downloaded to the device 201 and stored in the first memory

of the device 201, the integrity of the new version of the persistent data as well as the integrity of the upgraded version of the software for the device 201, is verified (305). In certain embodiments, verification of the new version of the persistent data and verification of the upgraded version of the software for the device 201 includes confirmation that the new version of the persistent data and the upgraded version of the software for the device 201 are not corrupt (e.g., no errors occurred in the transmission of the new version of the persistent data or the upgraded version of the software for the device 201 from the server to the second device) or that the new version of the persistent data and the upgraded version of the software may be used by the device 201. In certain embodiments, the integrity verification is performed by cyclic redundancy check (CRC). Thus, as the data is sent from the server 203 to the device 201, a CRC code is generated for each block of data. The CRC code is sent with each block of data and received by the device 201. When the block of data is received and/or read by a microprocessor of the device 201, the device 201 generates a CRC code for each received block of data and compares the generated CRC code with the received CRC code. If the CRC codes match, the data is verified. If however, the CRC codes do not match, a data error is detected. Although a cyclic redundancy check is specifically mentioned, it is contemplated that other error detection methods may be used including using parity bits, checksums, cryptographic hash functions and the like.

[0048] If the verification of the new version of the persistent data and the upgraded version of the software is satisfactory (e.g., no errors were detected by the cyclic redundancy check), the new version of the persistent data and the upgraded version of the software for the device 201 are copied from the first memory of the device 201 to a third storage area of the second memory of the device 201 (306).

[0049] In certain embodiments, if the new version of the persistent data and the upgraded version of the software for the device 201 are not verified by the cyclic redundancy check (e.g., the data is corrupt) (305) the method 300 ends and the user is notified that the upgrade was not completed. In certain embodiments, the user may be notified by a display screen output on a display of the device 201 that the upgrade to the software of the device 201 was not successful. Such errors maybe caused by the device 201 becoming disconnected from the remote

computing device or by a data transmission error (e.g. dropped data packets) between the server 203 and the device 201. In certain embodiments, if the new version of the persistent data and the upgraded version of the software for the device 201 is not verified, the new version of the persistent data and the upgraded version of the software for the device 201 is neither stored in the first memory of the device 201 or the second memory of the device 201.

[0050] In certain embodiments, if the integrity of the new version of the persistent data and the upgraded version of the software for the device 201 is not verified (305) the new version of persistent data, along with the upgraded version of the software for the device is downloaded from the server 203 to the device 201 a second time and stored in the first memory of the device 201 (304). In one aspect, if one portion of the data is verified, but another portion of the data is not verified, the unverified portion of the data is downloaded from the server 203 a second time while the verified portion of the data from the first download is stored in the first memory of the device 201.

[0051] For example, if the new version of the persistent data is verified by the cyclic redundancy check but the upgraded version of the software for the device 201 is not verified by the cyclic redundancy check, only the upgraded version of the software for the device 201 is downloaded a second time. Once the upgraded version of the software for the device 201 has been downloaded the second time, the integrity of the upgraded version of the software for the device 201 is verified (305). When both the new version of the persistent data and the upgraded version of the software for the device 201 have been verified, the new version of the persistent data and the upgraded version of the software for the device 201 are copied from the first memory of the device 201 to a third storage area of the second memory of the device 201 (306).

[0052] When the new version of the persistent data and the upgraded version of the software for the device 201 have been copied from the first memory of the device 201 to the third storage area of the second memory of the device 201, in certain embodiments, a microprocessor of the device 201 initiates a reset command to reset the device 201. Once the reset is complete, the microprocessor of the device 201 attempts to execute the upgraded version of the software for the device 201 and utilize the new version of the persistent data (307). As the microprocessor of

the device 201 is executing the upgraded version of the software for the device 201 and utilizing the new version of the persistent data, the packed new version of the persistent data and the upgraded version of the software for the device 201 that is stored in the third storage area of the second memory of the device 201 is unpacked and stored in the first storage area of the second memory of the device 201 (308). In certain embodiments, the new version of the persistent data and/or upgraded version of the software for the device 201 is unpacked or decompressed such that the data is reconstructed in a form, or in a substantially similar form, as it was prior to the data being packed or compressed. For example, if a language setting of the persistent data was represented by 4 bits prior to being compressed, and was represented by 2 bits after being compressed, when the persistent data is subsequently decompressed, the language setting of the persistent data is once again represented by 4 bits.

[0053] If a failure occurs while copying the new version of the persistent data and the upgraded version of the software for the device 201 from the third storage area of the second memory to the first storage area of the second memory, the copying process stops and the microprocessor of the device 201 initiates a reset command. When the device 201 recovers from the reset, a bootloader of the device 201 loads the persistent data and the version of the software (e.g., the version of the software of the device 201 prior to the upgraded version of the software for the device 201) that is stored in the second storage area of the second memory of the device 201 (309) and the microprocessor of the device executes the loaded version of the software. When the device 201 boots executing the software version that was stored on the second storage area of the second memory of the device 201, the microprocessor of the device 201 re-initiates the upgrade process. In one aspect, when the device 201 boots executing the software version that was stored on the second storage area of the second memory of the device 201, the user may be prompted, via a display screen on the device 201, to re-initiate installation of the upgraded version of the software for the device 201.

[0054] In certain embodiments, upon successful installation of the upgraded version of the software for the device 201, the new version of the persistent data and the upgraded version of the software for the device 201 are copied from the third

storage area of the second memory of the device 201 to the second storage area of the second memory of the device 201. Thus, the device 201 will have a backup copy of the upgraded version of the software for the device 201 and a copy of the new version of the persistent data stored in memory should the device 201 need to recover from a system failure.

[0055] In other embodiments, the new version of the persistent data and the upgraded version of the software for the device 201 may be copied from the first memory of the device 201 directly to the first storage area of the second memory of the device 201. The new version of the persistent data and the upgraded version of the software for the device 201 is executed and installed on the device 201 and upon successful installation, the new version of the persistent data and the upgraded version of the software for the device 201 may be copied to the second storage area of the second memory of the device 201 to serve as a backup copy of the upgraded version of the software for the device 201 and the new version of the persistent data.

[0056] In some embodiments of the present disclosure, method 300 may be applied as an upgrade method for various types of upgrades including, but not limited to, firmware upgrades, software patches, protocol updates, and any other executable code upgrades, patches or new versions.

[0057] In certain embodiments, the upgraded version of the software for the device 201 may correspond to a critical update for the device 201. In one aspect, if the critical update is not installed on the device 201, the device 201 may not function properly. For example, the critical update may correspond to a bolus calculation function or bolus delivery function of peripheral pump connected to the device 201. If the critical update is not installed on the device 201, an incorrect bolus dosage may be calculated and/or the pump may not deliver the expected amount of insulin based on the calculation.

[0058] In certain aspects, if a failure occurs during the installation of the critical update on the device 201, the microprocessor of the device 201 initiates a reset command and the device 201 resets. When the device 201 recovers from the reset, the microprocessor of the device 201 may cause the download and/or installation of the critical update to automatically restart. In certain embodiments, when the device 201 recovers from the reset, the user of the device

201 may be prompted to reinitiate the download and/or installation of the critical update. The prompt may be a message screen output on a display of the device 201, an audible alert, a tactile alert or a combination thereof.

[0059] In certain embodiments, when the device 201 recovers from the reset, the bootloader of the device 201 loads the persistent data and the version of the software (e.g., the version of the software of the device 201 prior to the upgraded version of the software for the device 201) that is stored in the second storage area of the second memory of the device 201 as was described above. However, in one aspect, the functionality or feature of the device 201 that corresponds to the critical update will not be accessible by the user until the critical update is installed. For example, if the critical update corresponds to a bolus calculation function, the user may not use the bolus calculation function until the critical update corresponding to the bolus calculation function is installed on the device 201. Although the particular functionality of the device 201 corresponding to the critical update is not operational, other features and functionalities of the device 201 are not affected. For example, although a bolus calculation function is not accessible by the user, a test strip port and blood glucose calculation function may be operational on the device 201.

[0060] It is also contemplated that although the critical update may correspond to a particular feature of the device 201, all functionalities and features of the device 201 may be non-functional until the critical update is installed on the device 201. In such cases, a message or alert screen may be output on the display of the device 201 indicating that all features and functionalities of the device 201 are non-functional and will remain non-functional until the critical update has been installed on the device 201. The user may then be prompted to reinitiate the download and/or installation of the critical update.

[0061] In yet another aspect, the functionality of the device 201 that corresponds to the critical update may have limited operational capabilities for a predetermined amount of time. For example, if the critical update corresponds to medication delivery of a peripheral pump, the microprocessor of the device 201 may instruct the peripheral pump to deliver a predetermined amount of insulin for the predetermined amount of time. When the predetermined amount of time expires,

the user may be prompted to re-initiate the download and/or installation of the critical update.

[0062] FIG. 4 is a flow chart illustrating a method 400 for use in one or more embodiments of the present disclosure, for recovering non-user configurable data (e.g., manufacturing data) used by a device, such as, for example device 201 (FIG. 2), in which the non-user configurable data has been corrupted or is no longer stored on the device 201. Referring to FIG. 4, the non-user configurable data, which is specific to the device 201, is stored in a database on a remote computing device, such as, for example, a server 203, a data storage terminal, or other computing device, such as, for example, computing device 202 (401). In certain embodiments, the non-user configurable data may be uploaded and stored on the remote computing device at predetermined times (e.g., every 3 months) or each time the device 201 is connected either directly or indirectly to the remote computing device. In another embodiment, the non-user configurable data is uploaded and stored on the remote computing device prior to a user initiated software upgrade. As discussed above, the non-user configurable data is associated with a serial number that identifies the device 201, a version of software being executed on the device 201 and/or default settings of the device 201.

[0063] Still referring to FIG. 4, electronic communication between the remote computing device and the device 201 is established (402) and the serial number for the device 201 is transmitted to the remote computing device (403). Such transmission may be initiated by a user of the device 201 upon experiencing, for example, a malfunction or problem with the device 201. In certain embodiments, the user provides the serial number through a user interface of the device 201 or through a user interface on a computing device that is in communication with the device 201. In certain embodiments, the microprocessor of the device 201 causes the serial number of the device 201 to be automatically transmitted to the remote computing device when a connection between the device 201 and the remote computing device is established. Further, the microprocessor of the device 201 may be configured to transmit the serial number to the remote computing device when a connection between the remote computing device and the device 201 is established if various performance indicators (e.g., a failure or partial failure of

the device 201 or components of the device 201) are detected by the microprocessor of the device 201.

[0064] Upon receipt of the serial number, remote computing device transmits the stored non-user configurable data to the device 201 (404). As will be described in detail below, the non-user configurable data may be stored in a compatibility table, such as, for example compatibility table 600 (FIG. 6). The transmission of the non-user configurable data from the remote computing device to the device 201 may be automatically performed in response to the receipt of the serial number, as receipt of the serial number at the remote computing device, for example, may indicate that the device 201 experienced a malfunction and requires the non-user configurable data to restore functionality of the device 201. In certain embodiments, transmission of the stored non-user configurable data may be transmitted from the remote computing device when the serial number is received in conjunction with a request from the user to transmit the non-user configurable data from the sever 203 to the device 201.

[0065] In certain embodiments, the non-user configurable data may identify the device 201 and include default settings for the device 201 or the settings for the device 201 based on the version of the software that was last installed on the device 201. When the non-user configurable data for the identified device 201 have been transmitted to the device 201, the device 201 may use the non-user configurable data to restore the device settings of the device 201 to the settings that were used prior to the operational problems of the device 201. In certain embodiments, when the non-user configurable data is transmitted to the device 201 from the remote computing device, the non-user configurable data is stored in a memory of the device 201.

[0066] FIG. 5 illustrates a method 500 for transferring user-configurable data from a first device to a second device according to embodiments of the present disclosure. The method 500 described herein may be used when the first device ceases to function or when use of another device is desired (e.g., when a physician prescribes use of a different device). In certain embodiments, the method 500 may be used to transfer data from the first device to the second device even if the devices are not related or have different functionality. For example, if the user is switching from a blood glucose monitoring device to a

continuous glucose monitoring device, various settings from the blood glucose monitoring device may be transferred to the continuous glucose monitoring device. In another embodiment, the method 500 may be used to ensure that settings corresponding to user-configurable data and manufacturing data remain constant between various versions of software being executed on the device 201.

[0067] Referring to FIG. 5, electronic communication is established between the first device such as, for example, device 201 (FIG. 2) and a remote computing device (501). In certain embodiments, the connection may be a wired or wireless connection such as described above. In certain embodiments, when the communication link is established between the first device and the remote computing device, the first device may transmit an identifier, such as, for example, a serial number, to the remote computing device to identify the type of the first device, a manufacturer of the first device and/or a current software version being executed on the first device. In certain embodiments, a compatibility table, such as, for example compatibility table 600 (FIG. 6) may be used to identify the type of the first device, the manufacturer of the first device, and/or the software version being executed on the first device. In certain embodiments, a microprocessor of the first device causes this data to be sent automatically when the communication link between the first device and the remote computing device is established or in response to a request from the remote computing device.

[0068] When the first device has been identified, user-configurable data is packed (e.g. compressed) and uploaded from the first device to the remote computing device (502). In certain embodiments, the remote computing device is a server, such as, for example, server 203 (FIG. 2). In another embodiment, the remote computing device may be a personal computer, laptop, personal digital assistant, smart phone, tablet computer, or other such computing device.

[0069] In certain embodiments, the user-configurable data is uploaded from the first device to the remote computing device based on the user-configurable data that was most recently uploaded. For example, if some of the user-configurable data to be uploaded was recently uploaded to the server 203 (e.g. within a predetermined number of days in the past) and the user-configurable data has not been changed (e.g., the language setting of the first device has not been changed

by the user), the user-configurable data is not be uploaded again as it is duplicate data. In certain embodiments, if some of the data to be uploaded was received and/or stored on the first device prior to a threshold time limit (e.g., 6 months in the past) the data is not uploaded to the remote computing device.

[0070] Still referring to FIG. 5, once the user-configurable data from the first device has been uploaded to the remote computing device, electronic communication is established between the second device and the remote computing device (503). As discussed above, the electronic communication may be a wired or wireless connection. Further, the established communication between the second device and the remote server need not be direct but may be routed through other servers and/or various other devices. In certain embodiments, when a connection is established between the second device and the remote computing device, the second device may send either automatically, or in response to a request from the remote computing device, an identifier that may be used to identify the device and/or a current software version running on the device such as was described above.

[0071] When the second device has been identified (e.g. by a serial number of the second device), the data that was uploaded from the first device is converted for use on the second device (504). In certain embodiments, the user-configurable data is mapped by the remote computing device for use with the second device. Although a second device is specifically mentioned, it is contemplated that the data mapping described herein may also be used to map user-configurable data as well as non-user configurable data from a device that is transitioning from a first software version to a second software version.

[0072] In certain embodiments, the remote computing device maps the user-configurable data by changing the format of the user-configurable data from a first format that is compatible with the first device to a second format that is compatible with the second device, or from a format that is compatible with one software version to a second software version that is to be executed on the first device. For example, the user configurable data from the first device may correspond to threshold values, alarm settings, reminder settings, and language settings. The length of the data corresponding to the threshold values may be 2 bits, the length of the data corresponding to the alarm settings may be 2 bits, the

length of the data for the reminder settings may be 4 bits and the length of the data for the language settings may be 4 bits.

[0073] As the data is mapped from the first device to the second device, the length of the data for each data element of the user-configurable data listed above may be changed by the remote computing device so the user-configurable data is compatible with the second device. Continuing with the above example, the length of the data for the threshold values may be changed to 4 bits, the length of the alarm settings may remain at 2 bits, the length of the data for the reminder settings may be 6 bits, and the length of the language settings may be 2 bits. Although the length of data element of the user-configurable data has been changed to be compatible with second device, the actual setting represented by the data element remains unchanged. For example, if the language setting of the first device (represented by 4 bits) is English, when the length of the data corresponding to the language setting is changed from the first format (e.g., 4 bits in length) to the second format (e.g., 2 bits in length) the language setting represented by the second format is English.

[0074] If some of the user-configurable data from the first device is not used in the second device, the remote computing device disregards that particular data element of the user-configurable data. For example, if the first device has a data element corresponding to units of measure, and the second device does not have an equivalent setting, the data element of the user-configurable data corresponding to units of measure is disregarded during the mapping process.

[0075] Further, the second device may have user-configurable data corresponding to settings that were not supported by the first device. Thus, when the remote computing device maps the user-configurable data from the first device to the second device, the particular setting corresponding to the data element that is not supported by the first device will not have mapped user-configurable data. In such cases, the setting that does not have a corresponding data element is set as the factory default setting. The factory default setting may then be changed by the user. For example, the second device may have a unit of measure setting that allows the user to change the unit of measure from mg/dL to mMol/L while the first device did not have this setting. Thus, when user-configurable data is

mapped, there is no data that corresponds to the unit of measure setting. As a result, the unit of measure setting will be set to default setting (e.g., mg/dL).

[0076] When the user-configurable data has been converted from the first format to the second format, the converted user-configurable data is downloaded and stored on the second device (505).

[0077] In certain embodiments, the converted user-configurable data is packed prior to being downloaded and stored on the second device and is stored in a first memory of the second device. In certain embodiments, the download operation may be performed by a software upgrade tool running on a computing device connected to the second device. In another embodiment, the remote computing device performs the download through client software running on a computing device that connects to the second device. In yet another embodiment, the software upgrade tool may be incorporated directly into the second device.

[0078] Referring back to FIG. 5, once the converted user-configurable data has been stored on the second device, the integrity of the converted user-configurable data is verified (506). The verification may be used to confirm that the converted user-configurable data is not corrupt and/or that if the user-configurable data was converted, the converted user-configurable data may be used by the second device. In certain embodiments, the verification is performed by cyclic redundancy check (CRC) such as described above. In another embodiment, the verification is performed by other error detection methods such as, for example, parity bits, checksums, cryptographic hash functions and the like.

[0079] In certain embodiments, when the converted user-configurable data stored on second device has been verified, the converted user-configurable data is copied from the first memory of the second device to a second memory of the second device (507). In certain embodiments, the first and/or second memory of the second device is random access memory. In another embodiment, the first memory of the second device is volatile memory and the second memory of the second device is non-volatile memory, which may be flash memory. In certain embodiments, the first memory and the second memory of the second device are non-volatile or flash memory.

[0080] In certain embodiments, the remote computing device may direct a computing device connected to the second device to perform the copying

operation through client software running on the connected computing device. In other embodiments, the data copying may be performed on the second device itself without the need for further instructions from another computing device. When the converted user-configurable data has been copied to the second memory of the second device, the settings of the second device are based on the converted user-configurable data. Thus, when a user transitions from the first device to the second device, the user may immediately use the second device without having to manually adjust all of the settings in the second device. In certain embodiments, the second device continues to operate based on its previously-stored user-configurable data until further operations/instructions are performed in which the converted user-configurable data is needed by the second device.

[0081] Referring back to FIG. 5, if the converted user-configurable data is not verified (506), the user-configurable data that was uploaded from the first device is remapped for use with the second device (504). In certain embodiments, the remote computing device tracks the mapping of the user-configurable data and only remaps the user-configurable data that was not verified by the cyclic redundancy check. For example, if data corresponding to the language setting was correctly mapped but data corresponding to the threshold values was not correctly mapped, the server remaps the data corresponding to the threshold values. Once the user-configurable data has been mapped, the converted user-configurable data is downloaded to the first memory of the second device (505). The newly downloaded converted user-configurable data is then verified (506) and stored in the second memory of the second device if the converted user-configurable data is verified (507).

[0082] Although data mapping has been specifically described for mapping user-configurable data from a first device to a second device, it is contemplated that data mapping may be used to preserve user-configurable data from a first version of software being executed on the first device to a second version of the software (e.g. software upgrade) that is downloaded and installed on the first device.

[0083] According to the above-described embodiments, a user is advantageously able to recover device functionality from a remote computing device rather than replacing the device and/or manually inputting each user setting into the device.

Further, the recovery may conveniently be done from the user's home or other preferred location. Moreover, recovery of the medical device provides a user access to a functioning medical device even if the software upgrade is unsuccessful.

[0084] FIG. 6 illustrates an exemplary compatibility table 600 according to embodiments of the present disclosure. In certain embodiments, the compatibility table is stored on a remote computing device, such as, for example, sever 203 (FIG. 2). The remote computing device stores a compatibility table for each unique device, such as, for example, device 201 (FIG. 2). As discussed above, the compatibility table 600 for each device is identified by a serial number of the device 201, a partial serial number of the device 201 or other such identifier.

[0085] As shown in FIG. 6, the compatibility table 600 includes a history for each revision of software 610 for the device 201 as well as software/firmware revisions for the first microprocessor 620, the second microprocessor 630 and the third microprocessor 640 of the device 201. In certain embodiments, when an upgrade to the device 201 is performed, the details of the upgrade are stored in the compatibility table 600. Thus, as shown in FIG. 6, when the software of the device 201 was upgraded from Release 10 to Release 14, the software of the first microprocessor 620 of the device 201 was upgraded from Release 10 to Release 12, the software of the second microprocessor 630 was not upgraded and the software for the third microprocessor 640 was upgraded from Release 6 to Release 7.

[0086] In certain embodiments, the compatibility table 600 also includes information corresponding to persistent data (e.g., user-configurable data and manufacturing data) associated with each revision of the software of the device 610. Thus, although the user-configurable data may be mapped as described above with respect to FIG. 5, when the software of the device 201 is upgraded from Release 10 to Release 14, the user-configurable data associated with Release 10 of the software for the device 201 is stored on the remote computing device.

[0087] Referring back to FIG. 6, the compatibility table 600 also shows that the software 610 of device 201 was subsequently upgraded from Release 14 to

Release 15. Although the software 610 of the device was upgraded, the software for each of the microprocessors 620, 630, and 640 were not upgraded.

[0088] In certain embodiments, the compatibility table 600 also stores information corresponding to a hardware version (not shown) of each of the microprocessors 620, 630 and 640 of the device 201. As will be explained below, when a software upgrade to the device 201 and/or one of the microprocessors 620, 630, or 640 is requested, the version of the hardware for the microprocessors is checked to determine if the desired software upgrade may be executed on hardware versions of the microprocessors 620, 630 and 640. If the microprocessors 620, 630 and 640 are not able to support the release required by the desired software version, the software upgrade will not be installed on the device 201.

[0089] FIG. 7 is a flow chart illustrating a method 700 for selectively upgrading a device based on a compatibility table according to embodiments of the present disclosure. The routine for selectively upgrading the device, such as, for example device 201 (FIG. 2) begins when a communication link is established between the device 201 and a remote computing device (701). In certain embodiments, the communication link between the device 201 and the remote computing device, such as, for example, computing device 202 or server 203, is established through communication links 210 or 220. In one aspect, the communication link between the device 201 and the remote computing device is established using a wireless connection. In another aspect, the communication between the device 201 and the remote computing device is established using a wired connection such as, for example, by connecting the device 201 to the remote computing device using a USB cable.

[0090] In certain embodiments, when the device 201 is connected to a computing device 202, the computing device 202 is configured to execute an upgrade module to assist in transferring data from the sever 203 to the device 201. In one aspect, the device 201 is configured to receive the upgrades directly from the server 203.

[0091] Once communication between the device 201 and the remote computing device is established, the remote computing device identifies the connected device 201 (702). In certain embodiments, the connected device 201 is identified

using a serial number of the device 201, a partial serial number of the device 201, or other such identifier.

[0092] When the device 201 has been identified by the remote computing device, the compatibility table associated with the device 201 is checked to determine a version of the software currently being executed on the device 201 as well as the versions of software for each of the microprocessors of the device 201 (703). Once the software version of the device 201 is identified, available upgrades for the device 201 are determined (704). In certain embodiments, the remote computing device stores all available upgrades for the various devices. When determining available upgrades for an identified device 201, a processor of the remote computing device compares a current version of the software and/or firmware of the device 201 from the compatibility table to available software and firmware upgrades.

[0093] If an upgrade is available, the compatibility table associated with the device 201 is checked by the processor of the remote computing device to determine which components of the device 201 need to be upgraded. Only the components of the device 201 that need to be upgraded to support the new version of the software are upgraded (705). For example, if the identified device 201 is executing Release 10 of the software 610 (FIG. 6) and the available upgrade is software Release 14, when the software 610 for the device 201 is upgraded, software for the first microprocessor 620 is upgraded from Release 10 to Release 12, and software for the third microprocessor 630 is upgraded from Release 6 to Release 7. As shown in the compatibility table 600, Release 14 of the software 610 does not require that the second microprocessor 630 be upgraded. As such, only the required data for the upgrade is downloaded an installed on the device 201. In certain embodiments, the device 201 and the microprocessors of the device 201 are upgraded using the method 300 described above with respect to FIG. 3. Additionally, the user-configurable settings of the device 201 may be mapped from Release 10 of the software 610 of the device 201 to Release 14 of the software 610 of the device 201 according to the method 500 described above with respect to FIG. 5.

[0094] In certain embodiments, prior to upgrading the software of the device 201, a processor of the remote computing device determines a hardware version of each

of the microprocessors of the device 201 and further determines whether the hardware version of each of the microprocessors can execute the software release required to run the new version of the software for the device 201. If the hardware version of the microprocessors cannot execute the required software release version, the software upgrade for the device 201 will not be installed on the device 201.

[0095] For example, as shown in the compatibility table 600, Release 15 of the software 610 requires that the first microprocessor 620 execute Release 12 version of the software, the second microprocessor 630 execute Release 8 version of the software, and the third microprocessor 640 execute Release 7 version of the software. If however, the hardware version of the first microprocessor 620 cannot execute Release 12 version of the software, the Release 15 version of the software 610 will not be installed on the device 201.

[0096] In certain embodiments, the current version of the bootloader of the device 201 may also be stored in a compatibility table associated with the device 201. As available software upgrades for the device 201 and each of the microprocessors of the device are determined, available upgrades for the bootloader of the device 201 may also be determined. If upgrades to the bootloader are available, the bootloader is upgraded along with the software version of the device 201 and/or the microprocessors of the device 201.

[0097] FIG. 8 is a flow chart illustrating a method 800 for reverting to a previous version of software for a device according to embodiments of the present disclosure. In certain embodiments, the method 800 described with reference to FIG. 8 may be used to restore functionality to a device, such as, for example device 201 (FIG. 2) when the device 201 has lost manufacturing settings (e.g., the device 201 is a dead device) or when a user upgraded the software on the device 201 and wishes to revert to a software version that was previously installed on the device 201 (e.g., the version of the software that was installed on the device 201 prior to the upgrade being installed on the device 201).

[0098] The routine for reverting to a previous version of software for the device 201 begins when a communication link is established between the device 201 and a remote computing device (801). In certain embodiments, the communication link between the device 201 and the remote computing device, such as, for example,

computing device 202 or server 203, is established through communication links 210 or 220. In one aspect, the communication link between the device 201 and the remote computing device is established using a wireless connection. In another aspect, the communication link between the device 201 and the remote computing device is established using a wired connection such as, for example, by connecting the device 201 to the remote computing device using a USB cable.

[0099] In certain embodiments, when the device 201 is connected to a computing device 202, the computing device 202 is configured to execute an upgrade module configured to transfer reversion data (e.g., data corresponding to the previously installed software version) from the sever 203 to the device 201. In one aspect, the device 201 is configured to receive the reversion data directly from the server 203.

[0100] Once communication between the device 201 and the remote computing device is established, the remote computing device identifies the connected device 201 (802). In certain embodiments, the connected device 201 is identified using a serial number of the device 201, a partial serial number of the device 201, or other such identifier. In situations where the device 201 is being recovered from being dead (e.g., manufacturing data of the device 201 is lost) the user may need to manually identify the device 201 such as, for example, by manually inputting a serial number or partial serial number of the device 201 into a user interface provided on the remote computing device. In certain embodiments, a user may contact customer service of the manufacturer of the device and provide the serial number of the device 201 to a customer service representative.

[0101] Once the device 201 has been identified, a desired software version for the identified device 201 is determined (803). In certain embodiments, the determination of the desired software version of the identified device 201 is made by a user manually selecting a previous version of software for the device 201 from a compatibility table, such as, for example compatibility table 600 (FIG. 6). In another embodiment, the customer service representative may use the serial number of the device 201 to access the compatibility table corresponding to the device 201 and transmit the desired software version of the device 201 to the user. In another embodiments, a processor of the remote computing device identifies the most recent software version that was stored on the device and

transmits the latest version of the software and associated data to the device 201. For example, when the device 201 is being recovered from being dead, the desired software version may correspond to the latest software version stored in the compatibility table 600 (e.g., Release 15 of the software 610). Thus, Release 15 of the software 610, and the corresponding user-configurable settings and/or manufacturing settings, are transmitted to the device 201. Although the latest version of the software is specifically mentioned, it is contemplated that any previous version of software stored in the compatibility table 600 may be identified and transmitted to the device 201 when recovering a dead device or when reverting to a previous version of software for the device 201.

[0102] When the desired software version of the identified device 201 is determined, the desired version of the software of the device 201, including the associated manufacturing settings and user-configurable settings of the device 201, are downloaded and stored on the identified device 201 (804). In certain embodiments, the desired version of software for the device 201 is downloaded to the identified device 201 using the method 300 described above with reference to FIG. 3. If the desired version of the software for the identified device 201 requires that user-configurable settings be mapped from the current version of the software being executed on the device 201 to the desired version of the software for the device, the user-configurable data is mapped according to the method 500 described above with reference to FIG. 5. Once the desired version of the software of the device 201 has been downloaded to the identified device 201, the desired version of the software of the device 201 is executed by a microprocessor of the indentified device 201 (805).

[0103] If the device 201 is recovering from being a dead device, a desired version of the software of the identified device 201, including the manufacturing settings and user-configurable settings of the device 201, are loaded on a bootloader of the device 201 (e.g., either directly from a server or through a connection to a computing device). When the device 201 boots, the bootloader of the device 201 loads and executes the desired version of the software for the identified device 201 (805) including the corresponding software for each of the microprocessors of the device 201. Once the device 201 has recovered from being dead using the bootloader, the desired version of the software, along with the manufacturing

settings and user-configurable settings of the device 201 associated with the desired version of the software, are stored in a memory of the device 201.

[0104] One aspect of the present disclosure includes establishing a connection between a medical device and a remote computing device; receiving an upgrade command at the medical device; storing a current version of persistent data and a current version of executable code in a first storage area of the medical device; transmitting at least the current version of the persistent data to the remote computing device, wherein the remote computing device is configured to convert the current version of the persistent data from a first format to a second format; receiving the second format of the current version of the persistent data and an upgraded version of executable code at the medical device; storing the second format of the current version of the persistent data and the upgraded version of the executable code in a second storage area of the medical device; and executing the upgraded version of the executable code with the second format of the current version of the persistent data.

[0105] One embodiment further includes verifying the integrity of the upgraded version of the executable code and the second format of the current version of the persistent data prior to executing the upgraded version of the executable code.

[0106] Moreover, in one embodiment, the integrity of the upgraded version of the executable code and the second format of the current version of the persistent data is verified using a cyclic redundancy check.

[0107] In another embodiment, converting the current version of the persistent data from the first format to the second format includes modifying the layout of the data associated with the current version of the persistent data.

[0108] Another embodiment further includes copying the upgraded executable code and the second format of the current version of the persistent data from the second storage area to the first storage area.

[0109] In another embodiment, the current version of the persistent data is one or more of user-configurable data or manufacturing data.

[0110] Yet another embodiment includes executing the current version of executable code with the current version of the persistent data when an error associated with the upgraded version of the executable code or the second format of the current version of the persistent data is detected.

[0111] In another aspect, an apparatus includes one or more processors; and a memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to establish a connection to a remote computing device, receive an upgrade command, store a current version of persistent data and a current version of executable code in a first storage area of the memory, transmit at least the current version of the persistent data to the remote computing device, wherein the remote computing device is configured to convert the current version of the persistent data from a first format to a second format, receive the second format of the current version of the persistent data and an upgraded version of executable code, store the second format of the current version of the persistent data and the upgraded version of the executable code in a second storage area of the memory, and execute the upgraded version of the executable code with the second format of the current version of the persistent data.

[0112] Another aspect of the present disclosure includes establishing a connection between a first medical device and a remote computing device; storing user-configurable data associated with the first medical device on the remote computing device; establishing a connection between a second medical device and the remote computing device; converting the user-configurable data associated with the first medical device from a first format to a second format, wherein the second format of the user-configurable data corresponds to the second medical device; and transmitting the second format of the user-configurable data to the second medical device, wherein the second format of the user-configurable data is configured to alter at least one setting of the second medical device.

[0113] In one embodiment, converting the user-configurable data associated with the first medical device from a first format to a second format includes changing the layout of the user-configurable data.

[0114] In another embodiment, changing the layout of the user-configurable data includes altering a number of bits of each data element associated with the user-configurable data.

[0115] Another embodiment includes verifying the integrity of the second format of the user-configurable data prior to altering at least one setting of the second medical device based on the second format of the user-configurable data.

[0116] Moreover, in one embodiment, the integrity of the second format of the user-configurable data is verified using a cyclic redundancy check.

[0117] In one aspect, a system includes a remote computing device; a first medical device in signal communication with the remote computing device; and a second medical device in signal communication with the remote computing device; wherein the remote computing device is configured to store user-configurable data associated with the first medical device; convert the user-configurable data associated with the first medical device from a first format to a second format, wherein the second format of the user-configurable data corresponds to the second medical device; and transmit the second format of the user-configurable data to the second medical device, wherein the second format of the user-configurable data is configured to alter at least one setting of the second medical device.

[0118] Another aspect of the present disclosure includes establishing a connection between a medical device and a remote computing device; identifying the medical device; comparing a current version of software of the medical device with one or more available versions of software for the medical device using a compatibility table, wherein the compatibility table is associated with the identified medical device; and transmitting an available version of the software for the medical device to the medical device.

[0119] One embodiment includes selectively transmitting a plurality of the available versions of software to the medical device based on the compatibility table.

[0120] In another embodiment, one or more of the available one or more versions of software for the medical device includes firmware.

[0121] In yet another embodiment, the available one or more versions of software for the medical device includes software for one or more processors of the medical device.

[0122] In another embodiment, the available one or more versions of software for the medical device includes firmware for one or more processors of the medical device.

[0123] In yet still another embodiment, the available one or more versions of software for the medical device are based, at least in part, on a hardware version of at least one component of the medical device.

[0124] Moreover, in one embodiment, the hardware version of the at least one component of the medical device is stored in the compatibility table.

[0125] In another embodiment, the medical device is identified by a serial number of the medical device.

[0126] In another aspect of the present disclosure, an apparatus includes one or more processors; and a memory for storing instructions which when executed by the one or more processors, causes the one or more processors to establish a connection to a medical device, identify the medical device, compare a current version of software of the medical device with one or more available versions of software for the medical device using a compatibility table, wherein the compatibility table is associated with the identified medical device, and transmit an available version of the software for the medical device to the medical device.

[0127] Another aspect includes establishing a connection between a medical device and a remote computing device; identifying the medical device; receiving a request for data corresponding to at least one of a version of persistent data for the medical device or a version of executable code for the medical device; identifying the requested data based at least in part on a compatibility table; and transmitting the identified data corresponding to the at least one of the version of persistent data for the medical device or the version of executable code for the medical device.

[0128] In one embodiment, the medical device is identified by a serial number of the medical device.

[0129] In another embodiment, the compatibility table is identified based on the serial number of the medical device.

[0130] In yet another embodiment, the version of the persistent data corresponds to at least one of user-selectable data or manufacturing data.

[0131] In still another embodiment, the version of the persistent data is configured to replace persistent data stored on the medical device.

[0132] In another embodiment, the version of the executable code for the medical device is configured to replace executable code stored on the medical device.

[0133] In another aspect of the present disclosure, an apparatus includes one or more processors; and a memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to establish a connection between a medical device and a remote computing device, identify the medical device, receive a request for data corresponding to at least one of a version of persistent data for the medical device or a version of executable code for the medical device, identify the requested data based at least in part on a compatibility table, and transmit the identified data corresponding to the at least one of the version of persistent data for the medical device or the version of executable code for the medical device.

[0134] Various other modifications and alterations in the structure and method of operation of this disclosure will be apparent to those skilled in the art without departing from the scope and spirit of the embodiments of the present disclosure. Although the present disclosure has been described in connection with particular embodiments, it should be understood that the present disclosure as claimed should not be unduly limited to such particular 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:

establishing a connection between a medical device and a remote computing device;

receiving an upgrade command at the medical device;

storing a current version of persistent data and a current version of executable code in a first storage area of the medical device;

transmitting at least the current version of the persistent data to the remote computing device, wherein the remote computing device is configured to convert the current version of the persistent data from a first format to a second format;

receiving the second format of the current version of the persistent data and an upgraded version of executable code at the medical device;

storing the second format of the current version of the persistent data and the upgraded version of the executable code in a second storage area of the medical device; and

executing the upgraded version of the executable code with the second format of the current version of the persistent data.

2. The method of claim 1, further comprising, verifying the integrity of the upgraded version of the executable code and the second format of the current version of the persistent data prior to executing the upgraded version of the executable code.

3. The method of claim 2, wherein the integrity of the upgraded version of the executable code and the second format of the current version of the persistent data is verified using a cyclic redundancy check.

4. The method of claim 1, wherein converting the current version of the persistent data from the first format to the second format includes modifying the layout of the data associated with the current version of the persistent data.

5. The method of claim 1, further comprising copying the upgraded executable code and the second format of the current version of the persistent data from the second storage area to the first storage area.

6. The method of claim 1, wherein the current version of the persistent data is one or more of user-configurable data or manufacturing data.

7. The method of claim 1, further comprising executing the current version of executable code with the current version of the persistent data when an error associated with the upgraded version of the executable code or the second format of the current version of the persistent data is detected.

8. An apparatus, comprising:

one or more processors; and

a memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to establish a connection to a remote computing device, receive an upgrade command, store a current version of persistent data and a current version of executable code in a first storage area of the memory, transmit at least the current version of the persistent data to the remote computing device, wherein the remote computing device is configured to convert the current version of the persistent data from a first format to a second format, receive the second format of the current version of the persistent data and an upgraded version of executable code, store the second format of the current version of the persistent data and the upgraded version of the executable code in a second storage area of the memory, and execute the upgraded version of the executable code with the second format of the current version of the persistent data.

9. The apparatus of claim 8, wherein the memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to verify the integrity of the upgraded version of the executable code and the second format of the current version of the persistent data prior to executing the upgraded version of the executable code.

10. The apparatus of claim 9, wherein the integrity of the upgraded version of the executable code and the second format of the current version of the persistent data is verified using a cyclic redundancy check.

11. The apparatus of claim 8, wherein converting the current version of the persistent data from the first format to the second format includes modifying the layout of the data associated with the current version of the persistent data.

12. The apparatus of claim 8, wherein the memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to copy the upgraded executable code and the second format of the current version of the persistent data from the second storage area to the first storage area.

13. The apparatus of claim 8, wherein the current version of the persistent data is one or more of user-configurable data or manufacturing data.

14. The apparatus of claim 8, wherein the memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to execute the current version of executable code with the current version of the persistent data when an error associated with the upgraded version of the executable code or the second format of the current version of the persistent data is detected.

15. A method comprising:

establishing a connection between a first medical device and a remote computing device;

storing user-configurable data associated with the first medical device on the remote computing device;

establishing a connection between a second medical device and the remote computing device;

converting the user-configurable data associated with the first medical device from a first format to a second format, wherein the second format of the user-configurable data corresponds to the second medical device; and

transmitting the second format of the user-configurable data to the second medical device, wherein the second format of the user-configurable data is configured to alter at least one setting of the second medical device.

16. The method of claim 15, wherein converting the user-configurable data associated with the first medical device from a first format to a second format includes changing the layout of the user-configurable data.

17. The method of claim 16, wherein changing the layout of the user-configurable data includes altering a number of bits of each data element associated with the user-configurable data.

18. The method of claim 15, further comprising, verifying the integrity of the second format of the user-configurable data prior to altering at least one setting of the second medical device based on the second format of the user-configurable data.

19. The method of claim 18, wherein the integrity of the second format of the user-configurable data is verified using a cyclic redundancy check.

20. A system, comprising:

a remote computing device;

a first medical device in signal communication with the remote computing device; and

a second medical device in signal communication with the remote computing device;

wherein the remote computing device is configured to:

store user-configurable data associated with the first medical device;

convert the user-configurable data associated with the first medical device from a first format to a second format, wherein the second format of the user-configurable data corresponds to the second medical device; and

transmit the second format of the user-configurable data to the second medical device, wherein the second format of the user-configurable data is configured to alter at least one setting of the second medical device.

21. The system of claim 20, wherein converting the user-configurable data associated with the first medical device from a first format to a second format includes changing the layout of the user-configurable data.

22. The system of claim 21, wherein changing the layout of the user-configurable data includes altering a number of bits of each data element associated with the user-configurable data.

23. The system of claim 20, wherein the second medical device is configured to verify the integrity of the second format of the user-configurable data prior to altering at least one setting based on the second format of the user-configurable data.

24. The system of claim 21, wherein the integrity of the second format of the user-configurable data is verified using a cyclic redundancy check.

25. A method comprising:

establishing a connection between a medical device and a remote computing device;

identifying the medical device;

comparing a current version of software of the medical device with one or more available versions of software for the medical device using a compatibility table, wherein the compatibility table is associated with the identified medical device; and

transmitting an available version of the software for the medical device to the medical device.

26. The method of claim 25, further comprising selectively transmitting a plurality of the available versions of software to the medical device based on the compatibility table.

27. The method of claim 25, wherein one or more of the available one or more versions of software for the medical device includes firmware.

28. The method of claim 25, wherein the available one or more versions of software for the medical device includes software for one or more processors of the medical device.

29. The method of claim 25, wherein the available one or more versions of software for the medical device includes firmware for one or more processors of the medical device.

30. The method of claim 25, wherein the available one or more versions of software for the medical device are based, at least in part, on a hardware version of at least one component of the medical device.

31. The method of claim 30, wherein the hardware version of the at least one component of the medical device is stored in the compatibility table.

32. The method of claim 25, wherein the medical device is identified by a serial number of the medical device.

33. An apparatus, comprising:

one or more processors; and

a memory for storing instructions which when executed by the one or more processors, causes the one or more processors to establish a connection to a medical device, identify the medical device, compare a current version of software of the medical device with one or more available versions of software for the medical device using a compatibility table, wherein the compatibility table is associated with the identified medical device, and transmit an available version of the software for the medical device to the medical device.

34. The apparatus of claim 33, wherein the memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to selectively transmit a plurality of available versions of software to the medical device based on the compatibility table.

35. The apparatus of claim 33, wherein one or more of the available one or more versions of software for the medical device includes firmware.

36. The apparatus of claim 33, wherein the one or more available versions of software for the medical device includes software for one or more processors of the medical device.

37. The apparatus of claim 33, wherein the one or more available versions of software for the medical device includes firmware for one or more processors of the medical device.

38. The apparatus of claim 33, wherein the available one or more versions of software for the medical device are based, at least in part, on a hardware version of at least one component of the medical device.

39. The apparatus of claim 38, wherein the hardware version of the at least one component of the medical device is stored in the compatibility table.

40. The apparatus of claim 33, wherein the medical device is identified by a serial number of the medical device.

41. A method comprising:

establishing a connection between a medical device and a remote computing device;

identifying the medical device;

receiving a request for data corresponding to at least one of a version of persistent data for the medical device or a version of executable code for the medical device;

identifying the requested data based at least in part on a compatibility table; and

transmitting the identified data corresponding to the at least one of the version of persistent data for the medical device or the version of executable code for the medical device.

42. The method of claim 41, wherein the medical device is identified by a serial number of the medical device.

43. The method of claim 41, wherein the compatibility table is identified based on the serial number of the medical device.

44. The method of claim 41, wherein the version of the persistent data corresponds to at least one of user-selectable data or manufacturing data.

45. The method of claim 41, wherein the version of the persistent data is configured to replace persistent data stored on the medical device.

46. The method of claim 41, wherein the version of the executable code for the medical device is configured to replace executable code stored on the medical device.

47. An apparatus, comprising:

one or more processors; and

a memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to establish a connection between a medical device and a remote computing device, identify the medical device, receive a request for data corresponding to at least one of a version of persistent data for the medical device or a version of executable code for the medical device, identify the requested data based at least in part on a compatibility table, and transmit the identified data corresponding to the at least one of the version of persistent data for the medical device or the version of executable code for the medical device.

48. The apparatus of claim 47, wherein the medical device is identified by a serial number of the medical device.

49. The apparatus of claim 47, wherein the compatibility table is identified based on the serial number of the medical device.

50. The apparatus of claim 47, wherein the version of the persistent data corresponds to at least one of user-selectable data or manufacturing data.

51. The apparatus of claim 47, wherein the version of the persistent data is configured to replace persistent data stored on the medical device.

52. The apparatus of claim 47, wherein the version of the executable code for the medical device is configured to replace executable code stored on the medical device.

101
102
103
104
105
Sensor Unit
Transmitter Unit
Primary Receiver Unit
Data Processing Terminal/ Infusion Section
Secondary Receiver Unit
106
100

FIG. 1

FIG. 2

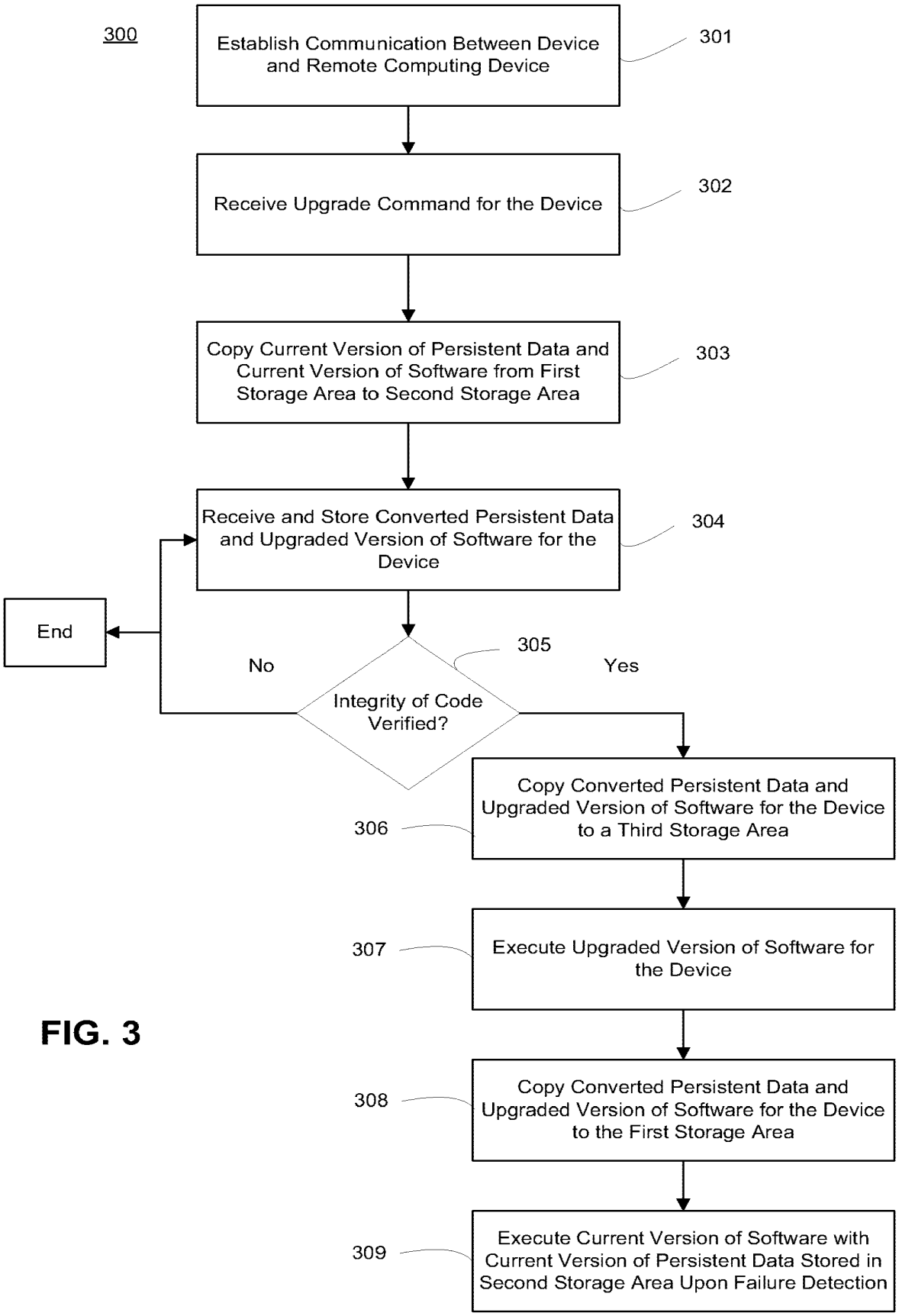

300
Establish Communication Between Device and Remote Computing Device
301
Receive Upgrade Command for the Device
302
Copy Current Version of Persistent Data and Current Version of Software from First Storage Area to Second Storage Area
303
Receive and Store Converted Persistent Data and Upgraded Version of Software for the Device
304
End
No
305
Yes
Integrity of Code Verified?
Copy Converted Persistent Data and Upgraded Version of Software for the Device to a Third Storage Area
306
Execute Upgraded Version of Software for the Device
307
Copy Converted Persistent Data and Upgraded Version of Software for the Device to the First Storage Area
308
Execute Current Version of Software with Current Version of Persistent Data Stored in Second Storage Area Upon Failure Detection
309

FIG. 3

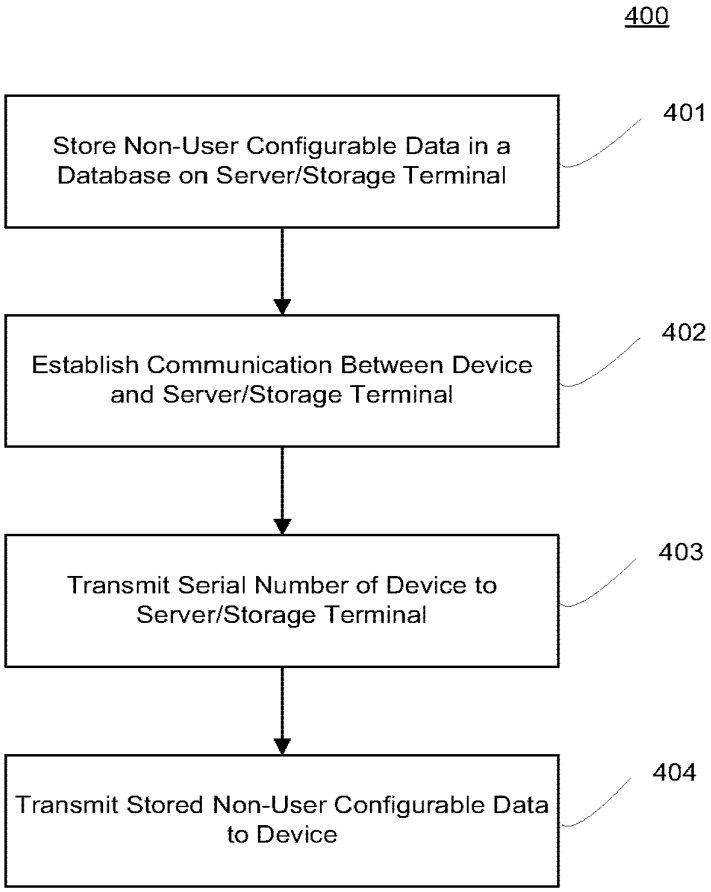

400
Store Non-User Configurable Data in a Database on Server/Storage Terminal
401
Establish Communication Between Device and Server/Storage Terminal
402
Transmit Serial Number of Device to Server/Storage Terminal
403
Transmit Stored Non-User Configurable Data to Device
404

FIG. 4

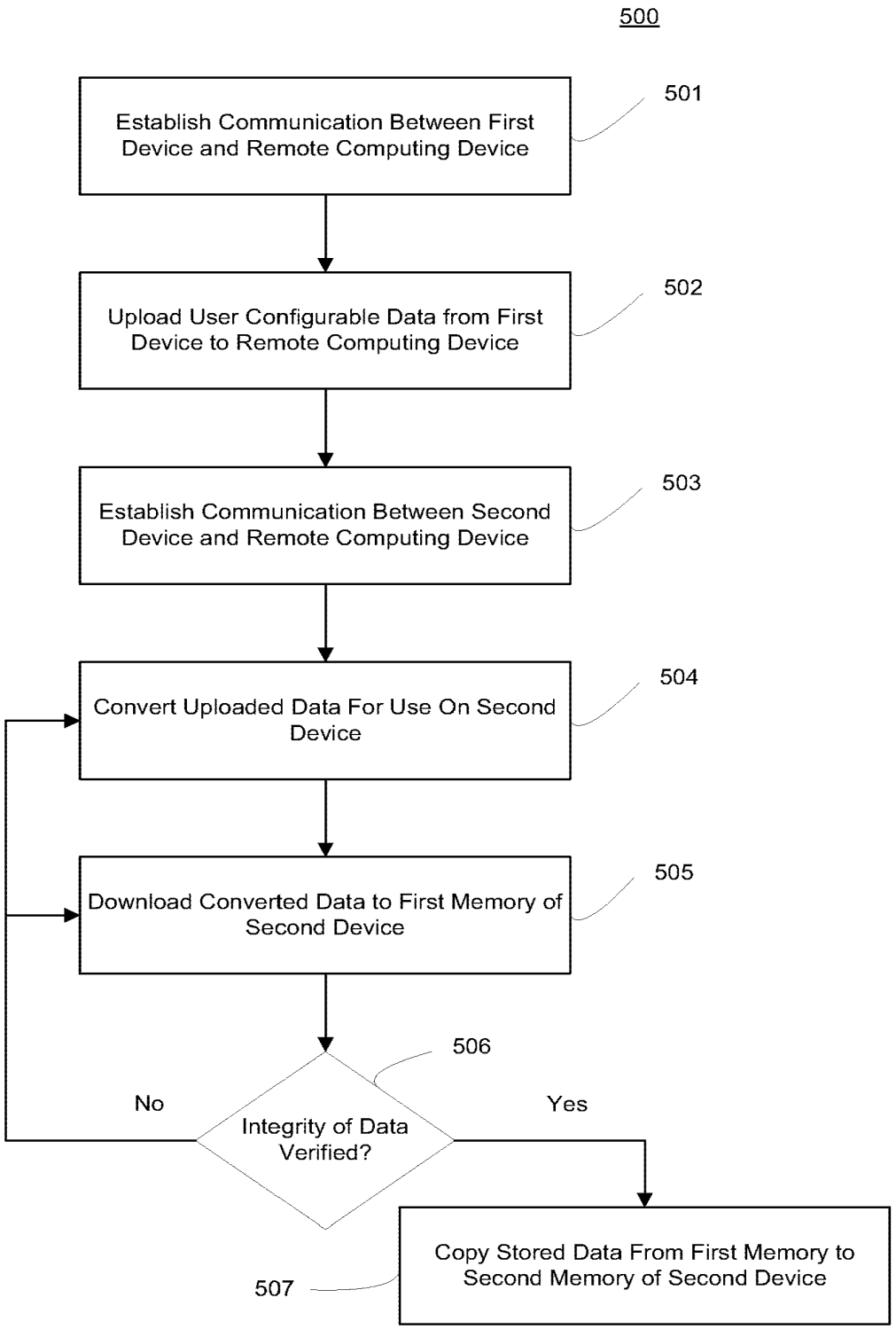

500
Establish Communication Between First Device and Remote Computing Device
501
Upload User Configurable Data from First Device to Remote Computing Device
502
Establish Communication Between Second Device and Remote Computing Device
503
Convert Uploaded Data For Use On Second Device
504
Download Converted Data to First Memory of Second Device
505
Integrity of Data Verified?
506
No
Yes
Copy Stored Data From First Memory to Second Memory of Second Device
507

FIG. 5

610 620 630 640

Device Software	First Microprocessor	Second Microprocessor	Third Microprocessor
Release 10	Release 10	Release 8	Release 6
Release 14	Release 12	Release 8	Release 7
Release 15	Release 12	Release 8	Release 7

FIG. 6 600

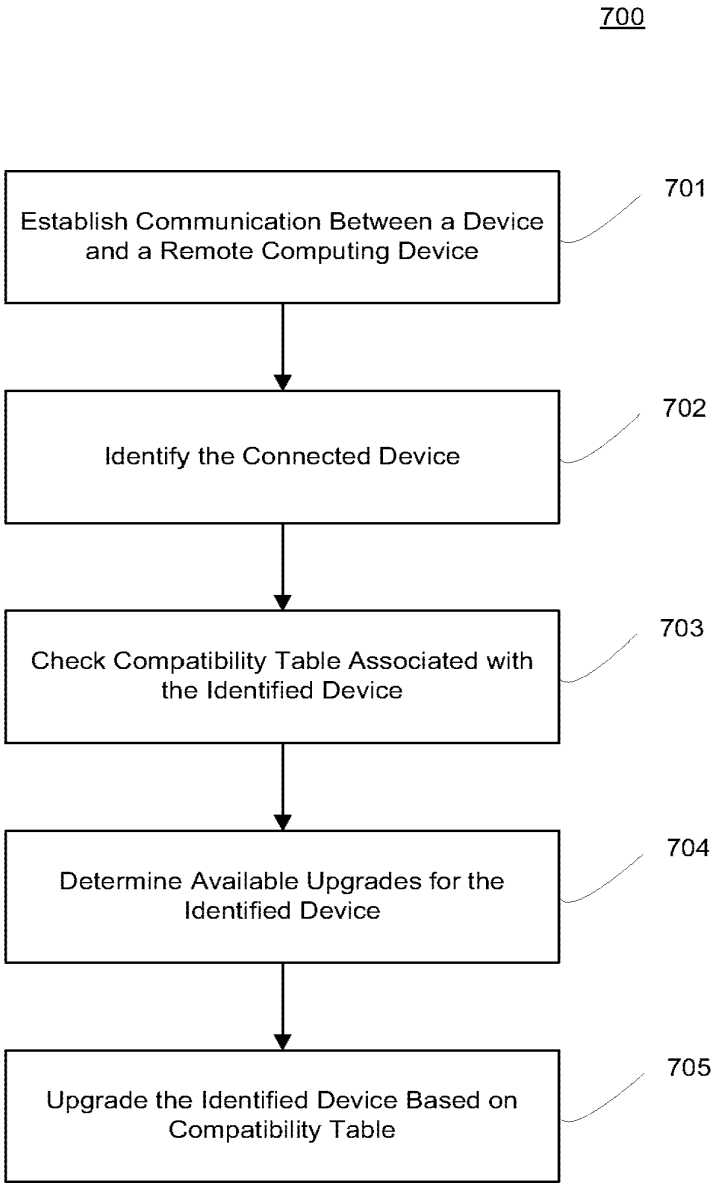

700
Establish Communication Between a Device and a Remote Computing Device
701
Identify the Connected Device
702
Check Compatibility Table Associated with the Identified Device
703
Determine Available Upgrades for the Identified Device
704
Upgrade the Identified Device Based on Compatibility Table
705

FIG. 7

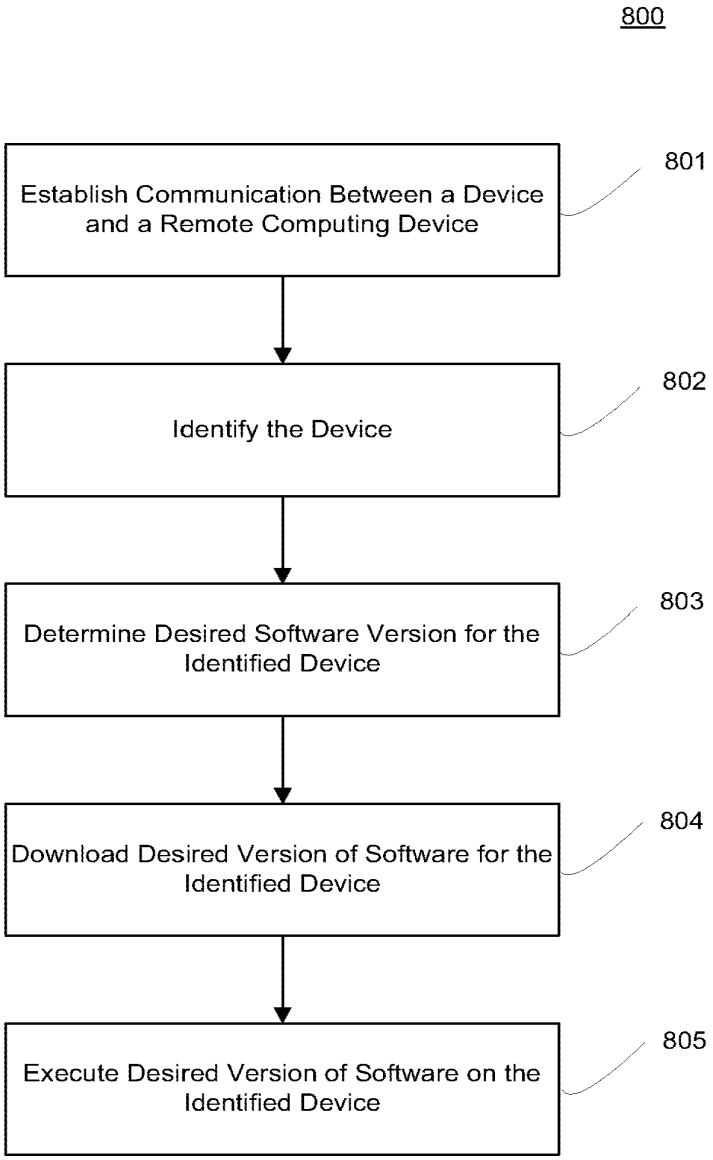

800
Establish Communication Between a Device and a Remote Computing Device
801
Identify the Device
802
Determine Desired Software Version for the Identified Device
803
Download Desired Version of Software for the Identified Device
804
Execute Desired Version of Software on the Identified Device
805

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/037547

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - G06F 15/16 (2010.01)
USPC - 709/ 219
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) - G06F 7/00; G06F 15/16; G06F 15/02; G06F 15/173 (2010.01)
USPC - 5/600; 700/302, 306; 707/104.1; 709/219, 202, 226, 227; 705/3

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)
MicroPatent, GooglePatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2006/0173644 Al (DAI et al) 03 August 2006 (03.08.2006) entire document	1-16, 18-21, 23 & 24 --- 17, 22, 25-52
Y	US 6,445,462 B2 (ARITOMI) 03 September 2002 (03.09.2002) entire document	17, 22
Y	US 7,178,141 B2 (PIAZZA) 13 February 2007 (13.02.2007) entire document	25-31, 33-39, 41, 44-47, 50-52
Y	US 2003/0208465 Al (YURKO et al) 06 November 2003 (06.11.2003) entire document	32, 40, 42, 43, 48, 49
A	US 2007/0192140 Al (GROPPER) 16 August 2007 (16.08.2007) entire document	1-52
A	US 7,321,811 BI (RAWLS-MEEHAN) 22 January 2008 (22.01.2008) entire document	1-52
A	US 2007/0027506 Al (STENDER et al) 01 February 2007 (01.02.2007) entire document	1-52

☐ 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	Date of mailing of the international search report
16 July 2010	27 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)

Electronic Patent Application Fee Transmittal

Application Number:	17019110
Filing Date:	11-Sep-2020
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0107.01C8

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4200	4200
Pages:				
Claims:				
Miscellaneous-Filing:				
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $0 paid	1253	1	1480	1480
Miscellaneous:				
RCE- 1ST REQUEST	1801	1	1360	1360
		Total in USD ($)		**7180**

Electronic Acknowledgement Receipt

EFS ID:	44326485
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	19-NOV-2021
Filing Date:	11-SEP-2020
Time Stamp:	15:42:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$7180
RAM confirmation Number	E2021AIF42404681
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	10297USC21_A0130_0107_01C9_Track_One_Request.pdf	152775 9d366ea142972f3ad26f8afd0683684277e6af94	no	2
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	10297USC16_A0130_0107_01C8_RCE_Transmital.pdf	1349979 59e1e8f8651b02d5854cea9b5cbe09f00357400e	no	3
Warnings:					
Information:					
3		10297USC16_A0130_0107_01C8_Response_to_FOA_dated_6_9_21.pdf	569278 6404ac9c6542ad2352265900c121c3971b0a48e9	yes	15

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	15

Warnings:					
Information:					
4	Affidavit-Rule 131-pre-AIA (FTI) ONLY	10297USC16_A0130_0107_01C8_Joint_Declaration.pdf	2056905 081b4e0d14e0c3bb5cb4ccc9217de666f9e09041	no	15
Warnings:					
Information:					
5	Affidavit-Rule 131-pre-AIA (FTI) ONLY	Exhibit2.pdf	2428051 5fda68c691058be0dd0e026608c42a2864312920	no	24

Warnings:					
Information:					
6	Affidavit-Rule 131-pre-AIA (FTI) ONLY	Exhibit3.pdf	357385 3c96d5e1e084e24795f289b3b51518af647dadca	no	6
Warnings:					
Information:					
7	Affidavit-Rule 131-pre-AIA (FTI) ONLY	Exhibit4.pdf	391673 d9ae2a85e6a6bb98268df6287972abdaceb732c4	no	7
Warnings:					
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8	Affidavit-Rule 131-pre-AIA (FTI) ONLY	Exhibit5.pdf	428151 7545f838a51c9859c1274cc57cfbef24d47bf33a	no	7
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Information:					
9	Affidavit-Rule 131-pre-AIA (FTI) ONLY	Exhibit6.pdf	444961 6322027eb2a7e9d63f8d27b85bd389fac73c62cf	no	7
Warnings:					
Information:					
10	Affidavit-Rule 131-pre-AIA (FTI) ONLY	Exhibit7.pdf	492625 07fc112524d5b25b338e654b99ca1528535f6fed	no	8
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11	Affidavit-Rule 131-pre-AIA (FTI) ONLY	Exhibit8.pdf	13459089 c71c2089982ff2afaa96a49bfcaedc0f3e030225	no	223
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12	Affidavit-Rule 131-pre-AIA (FTI) ONLY	Exhibit1.pdf	17059091 01726f6ae49482ab51e50726618d408aa3fdba37	no	187
Warnings:					
Information:					

13	Affidavit-Rule 131-pre-AIA (FTI) ONLY	AppendixA.pdf	2072419 6b9e08746e0aef84ad6ba6fd597c433faa35606e	no	41
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14	Affidavit-Rule 131-pre-AIA (FTI) ONLY	AppendixB.pdf	1892491 7223f3ede4b5719d951796ad68fc715aeadaf37d	no	37
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15	Transmittal Letter	10297USC16_A0130_0107_01C8_IDS_Transmittal.pdf	115543 2b91123534f4d0923822b4bacf4fdf92393ee023	no	4
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16	Information Disclosure Statement (IDS) Form (SB08)	10297USC16_A0130_0107_01C8_IDS_1449.pdf	146891 4ca0e286986ccb1a885c79b366b0fd3de53d4c8a	no	5
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Information:					
This is not an USPTO supplied IDS fillable form					
17	Foreign Reference	GB2067764B.pdf	326961 8d36408d83e0bd58db46a2f6e2517be1090735b0	no	9
Warnings:					
Information:					
18	Foreign Reference	JP2004214014A.pdf	335254 de56cc218df4da1571cf76c23fdbd70d6bbf9987	no	12
Warnings:					
Information:					
19	Foreign Reference	WO0158348A2.pdf	2043712 3eb00dc411b24866c6ee7401c039e3ab73521af0	no	52
Warnings:					
Information:					

20	Foreign Reference	WO0164105A1.pdf	1895645 d578d15a82220c96fea24eae53ddfa4e86952413	no	39
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21	Foreign Reference	WO0215778A1.pdf	2852669 521f556eb71db889f2cf3e982ae4bacda99db8a3	no	50
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22	Foreign Reference	WO03056319A2.pdf	2604576 5031d7b737c14b1beec7aeda30fddf9bfc282221	no	55
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23	Foreign Reference	WO2004049237A2.pdf	873615 68511667cbd070e2fdff2ea7f72c59991356029e	no	24
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24	Foreign Reference	WO2005018450A2.pdf	509761 bbd22bd2dbc9b7468a9617e9a9c57b48938cc2a1	no	12
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25	Foreign Reference	WO2006026741A1.pdf	2954558 26493c9ee36dd7f6e5cbe36e90fb1491f940055a	no	66
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26	Foreign Reference	WO2006040083A1.pdf	2382884 dbdae97b23b1726ae757d751d13ebd88334d895f	no	49
Warnings:					
Information:					

27	Foreign Reference	WO2006086423A2.pdf	1345085 c8f00d193368661fa554d86f1d235c69cc213265	no	26
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29	Foreign Reference	WO2006114297A1.pdf	1068726 b4d698b93f70c10ed05cfe271abf761f12cfa879	no	28
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30	Foreign Reference	WO2007097754A1.pdf	12588507 fa454776c80ac21bade98f37123f9a93bb04e5f4	no	250
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33	Foreign Reference	WO2008138006A2.pdf	2623182 f8d1d7e0acab593f04675ce786fd6e4fabf1fc33	no	68
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34	Foreign Reference	WO2008157821A1.pdf	2096986 7952108d6bc048910e948a2b2a6b0b01b700b253	no	45
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Information:					
35	Foreign Reference	WO2010141922A1.pdf	2509631 cd95469d130f104297d995cd2f04aa0a6954e717	no	55
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Information:					
36	Non Patent Literature	NPL_Ambade.pdf	798872 67687f82f8aa8b89264d4a24c383086c36463261	no	3
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Information:					
37	Non Patent Literature	NPL_ASTM.pdf	2801736 5c7887518733e5e2a409f4b727254310401ccaf7	no	13
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38	Non Patent Literature	NPL_Biosensors1.pdf	11880167 f23c7663eda0c36b28f292a02bb371c79e6cf81a	no	196
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39	Non Patent Literature	NPL_Biosensors2.pdf	12261806 df0c2c77118f2e1a7bdda6dae550b7cebfc7cf01	no	197
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Information:					
40	Non Patent Literature	NPL_Biosensors3.pdf	11769673 684b57e1cfeb2384c58ed6cf169fcef8278d0c5a	no	196
Warnings:					
Information:					

41	Non Patent Literature	NPL_Biosensors4.pdf	12102084 6577274c7938d88b7acf37a999f61f764a67f733	no	197
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42	Non Patent Literature	NPL_Bluetooth_Core_Specification.pdf	8879239 df9fb604659c6794ac55ba38b4f6c31d1e2924aa	no	89
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43	Non Patent Literature	NPL_Clarke.pdf	229451 735887f28762d245004f7838904787c4a4729c22	no	10
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44	Non Patent Literature	NPL_Cunningham.pdf	8859015 13484be226518ce17b98add5a0c5ed77a90c5f7a	no	466
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45	Non Patent Literature	NPL_Decuir.pdf	7144999 58508130821e7a7343e6124f913127c2c44854ea	no	68
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47	Non Patent Literature	NPL_STS_User_Guide.pdf	1809373 be887fb79bd92a787b18a43443c67cd0382537d3	no	57
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Information:					

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49	Non Patent Literature	NPL_ECMA.pdf	1085337 75ced61c7190955faa7cfff24989c8e128d38a7f	no	65
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50	Non Patent Literature	NPL_Facchinetti.pdf	163378 78ce89ae82fa78218aa603d72f0b13bd6713a426	no	9
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51	Non Patent Literature	NPL_Fujipoly.pdf	54174 93ff94b1b43ebc6ac20905b62f06015756de6c52	no	7
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52	Non Patent Literature	NPL_Gilligan.pdf	2041367 2756de85c3b9d855a596226a70427b611c134ff1	no	6
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54	Non Patent Literature	NPL_Heise.pdf	118380 93b90326e70028c2197a649f85420cf06aec6096	no	9
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55	Non Patent Literature	NPL_Heller.pdf	338272 9d0d5233b598812ba9cee8cce4dc1bd3c1014a81	no	25
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56	Non Patent Literature	NPL_FR.pdf	17494844 42a791af124e4f74d09e119bc8045d3b141c216b	no	13
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57	Non Patent Literature	NPL_Klonoff.pdf	1440581 74465fea4bd6ab7fda3c3bfe2c01468d909ee889	no	6
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58	Non Patent Literature	NPL_Leon.pdf	2395242 2b76d21ea767a75d0fc09ad808026fb0c27d997a	no	7
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59	Fee Worksheet (SB06)	fee-info.pdf	49531 cbfc20a07285f5de5005c0e354e8b04a309df649	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	204336759	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/AIA/424 (03-14)

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

First Named Inventor:	Manuel Luis Donnay	Nonprovisional Application Number (if known):	
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES		

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

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

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

3. The applicable box is checked below:

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

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

---OR---

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

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

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

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

Signature /Glen Liu/	Date 11/19/2021
Name (Print/Typed) Glen Liu	Practitioner Registration Number 75,058

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

☑ *Total of 1 forms are submitted.

Privacy Act Statement

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

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

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

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/019,110	Filing Date 09/11/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	11/19/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 27	Minus	** 35	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LASHAWN R MORGAN/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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) or (c), 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 **183890**.

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 183890 to sign statements under 37 CFR 3.73(b) or (c) 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) or (c) to the address associated with Customer Number 183890.

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: 1420 Harbor Bay Parkway, Alameda, CA 94502	
Signature of Declarant or Assignee:	Date: 11/11/22
Full Name of Declarant: Paul D. Yasger If Other Than Assignee:	
Title of Declarant: Assistant Secretary	
Address of Declarant: 1420 Harbor Bay Parkway, Alameda, CA 94502	

Electronic Acknowledgement Receipt

EFS ID:	44356756
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	23-NOV-2021
Filing Date:	11-SEP-2020
Time Stamp:	16:36:36
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	Assignee showing of ownership per 37 CFR 3.73	A0130_0107_01C8_373Form.pdf	104653 e6c668dd2efe306f3f6d6fb790d3fa6e34d31825	no	3

Warnings:

Information:					
2	Power of Attorney	ADC_US_POA_183890.pdf	283502 6cd8a3e4f388b02a6fc1f4299921e8dd2621202f	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	388155	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. 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 displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Manuel Luis Donnay, et al.

Application No./Patent No.: 17/019,110 Filed/Issue Date: 09/11/2020

Titled: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

ABBOTT DIABETES CARE INC., a CORPORATION

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

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

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 053858, Frame 0315, or for which a copy thereof is attached.

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.

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**.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. 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 displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

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.

4. 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.

5. 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.

6. 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(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Glen Liu/	11/23/2021
Signature	Date
Glen Liu	75,058
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

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

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

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

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
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8

CONFIRMATION NO. 1087

183890
One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

POA ACCEPTANCE LETTER

OC000000130076098

Date Mailed: 11/30/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/23/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/rmohamed/

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
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8

CONFIRMATION NO. 1087

POWER OF ATTORNEY NOTICE

95508
One LLP
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

OC000000130076078

Date Mailed: 11/30/2021

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/23/2021.

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

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/rmohamed/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

183890 7590 12/07/2021

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

EXAMINER
NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
12/07/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPdocketing@onellp.com
adc_alameda_ip_dept@abbott.com
gliu@onellp.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/019,110	**Applicant(s)** Donnay et al.	
	Examiner JoAnne L Burke	**Art Unit** OPET	**AIA (FITF) Status** No

1. THE REQUEST FILED 19 November 2021 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☐ for an original nonprovisional application (Track I).
B. ☑ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to JoAnne Burke at (571)272-4584. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/JOANNE L BURKE/
Lead Paralegal Specialist, OPET

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

183890 7590 01/21/2022

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

EXAMINER
NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 01/21/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

TITLE OF INVENTION: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	04/21/2022

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

183890 7590 01/21/2022

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

TITLE OF INVENTION: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	04/21/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
NGUYEN, HUONG Q	3791	600-583000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

183890 7590 01/21/2022

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 01/21/2022

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

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 17/019,110	Applicant(s) Donnay et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status No

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 11/19/2021.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 26-39,43 and 45-56 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

43. (Currently amended) The glucose monitoring assembly of claim 26,

wherein the inserter further comprises an inserter housing and a sheath and wherein the inserter housing is configured to move in a downward direction towards ~~the~~ a skin surface relative to the sheath in response to an application of force on the inserter housing, and

wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing.

Response to Amendment

The declaration filed on 11/19/2021 under 37 CFR 1.131(a) is sufficient to overcome the Thomas et al (20100198034) reference.

The subject matter of provisional application 61/361374 (Exhibit 1) dated 7/02/2010 as well as the PowerPoint in Exhibit 2 adequately show conception of the invention prior to the 8/05/2010 date of Thomas et al, particularly, the limitation in Claim 26 regarding the plurality of

recesses including a first and second recess on a periphery of the on body electronics unit housing and detachably engaged with the inserter.

Exhibits 3-7 show adequate diligence to constructive reduction to practice with monthly progress reports between before 8/05/2010 to 11/8/2010, the date of provisional application 61/411262 (Exhibit 8), which provides support for the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit:

https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	**Art Unit**
	Huong Q NGUYEN	3791

CPC						
Symbol					**Type**	**Version**
A61B	/	5	/	150022	F	2013-01-01
A61B	/	5	/	15113	I	2013-01-01
A61B	/	5	/	15117	I	2013-01-01
A61B	/	5	/	1513	I	2013-01-01
A61B	/	5	/	1519	I	2013-01-01
A61B	/	5	/	15194	I	2013-01-01
A61B	/	5	/	14532	I	2013-01-01
A61B	/	5	/	6865	I	2013-01-01
A61M	/	5	/	158	I	2013-01-01
A61B	/	5	/	150282	I	2013-01-01
A61B	/	5	/	150396	I	2013-01-01
A61B	/	5	/	150419	I	2013-01-01
A61B	/	5	/	150427	I	2013-01-01
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A61B	/	5	/	14503	I	2013-01-01
A61B	/	5	/	1411	I	2013-01-01
A61B	/	5	/	15107	I	2013-01-01
A61B	/	5	/	15186	I	2013-01-01
A61B	/	5	/	14542	I	2013-01-01
A61B	/	5	/	14546	I	2013-01-01
A61B	/	17	/	34	I	2013-01-01
A61B	/	5	/	0002	A	2013-01-01
A61B	/	5	/	01	A	2013-01-01
A61M	/	2005	/	1585	A	2013-01-01
A61B	/	5	/	150732	A	2013-01-01
A61B	/	5	/	15016	A	2013-01-01

H.Q. Nguyen	30 December 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	27	
/DEVIN B HENSON/ Primary Examiner, Art Unit 3791	07 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	130

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	**Art Unit**
	Huong Q NGUYEN	3791

CPC							
Symbol						**Type**	**Version**
A61B	/	2560	/	063		A	2013-01-01
A61B	/	2017	/	00384		A	2013-01-01
A61B	/	5	/	00		A	2013-01-01

CPC Combination Sets								
Symbol						**Type**	**Set**	**Ranking**	**Version**
	/		/						

H.Q. Nguyen	30 December 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	27	
/DEVIN B HENSON/ Primary Examiner, Art Unit 3791	07 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	130

U.S. Patent and Trademark Office — Part of Paper No.: 20211230

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	**Art Unit**
	Huong Q NGUYEN	3791

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61B5/15	/	5	/	15
A61B5/151	/	5	/	151
A61B5/145	/	5	/	145
A61B5/00	/	5	/	00
A61B5/157	/	5	/	157
A61B17/34	/	17	/	34

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

H.Q. Nguyen	30 December 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	27	
/DEVIN B HENSON/ Primary Examiner, Art Unit 3791	07 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	130

U.S. Patent and Trademark Office — Part of Paper No.: 20211230

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	**Art Unit**
	Huong Q NGUYEN	3791

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	26	10	35		44	25	53								
2	27	11	36	16	45	26	54								
3	28	12	37	17	46	18	55								
4	29	13	38	19	47	27	56								
7	30	14	39	21	48										
5	31		40	22	49										
6	32		41	23	50										
8	33		42	24	51										
9	34	15	43	20	52										

H.Q. Nguyen	30 December 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	27	
/DEVIN B HENSON/ Primary Examiner, Art Unit 3791	07 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	130

U.S. Patent and Trademark Office Part of Paper No.: 20211230

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	Art Unit
	Huong Q NGUYEN	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B5/14503,1473,14865,6849,14532	03/13/2021	HQN
A61B2560/063	03/13/2021	HQN
A61B17/3468	03/13/2021	HQN
A61M2005/1585	03/13/2021	HQN
A61B5/15144,15113,15186,15188,1519,15192,15194	03/13/2021	HQN
A61B2017/347	03/13/2021	HQN
A61B5/1411,15029,150282,15107,15117	06/04/2021	HQN
Updated	06/04/2021	HQN
Updated	12/30/2021	HQN

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
600	583-584	06/04/2021	HQN

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/H.Q.N/ Examiner, Art Unit 3791	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	Art Unit
	Huong Q NGUYEN	3791

Search Notes		
Search Notes	**Date**	**Examiner**
EAST search history	03/13/2021	HQN
Inventor search	03/13/2021	HQN
Updated	06/04/2021	HQN
Updated	12/30/2021	HQN

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61B5/ 14503,1473,14 865,6849,1453 2		12/30/2021	HQN
A61B2560/063		12/30/2021	HQN
A61B17/3468		12/30/2021	HQN
A61M2005/ 1585		12/30/2021	HQN
A61B5/ 15144,15113,1 5186,15188,15 19,15192,1519 4		12/30/2021	HQN
A61B2017/347		12/30/2021	HQN
A61B5/ 1411,15029,15 0282,15107,15 117		12/30/2021	HQN

/H.Q.N/ Examiner, Art Unit 3791	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S9	510	abbott.as. and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:23
S10	400	(sensor with electronics) same glucose same ((implant$5 insert$5) with skin)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:24
S11	8	600/584.ccls. and ((hole aperture opening) same electronic same sensor)	US-PGPUB; USPAT;	OR	OFF	2021/03/13 13:45

			USOCR; FPRS; EPO; JPO; IBM_TDB			
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S13	149	yodfat-ofer$.in. and infusion and skin and securable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 14:37
S14	46	Donnay-Manuel$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:37
S15	29	Nguyen-Tuan$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:37
S16	96	Pace-Louis$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38

S17	55	Robinson-Peter$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38
S18	107	S14 S15 S16 S17	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38
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			IBM_TDB			
S22	138	(US-4970145-$ | US-4974929-$ | US-4986271-$ | US-4994167-$ | US-5001054-$ | US-5035860-$ | US-5036860-$ | US-5050612-$ | US-5058592-$ | US-5070535-$ | US-5082550-$ | US-5082786-$ | US-5089112-$ | US-5095904-$ | US-5101814-$ | US-5108564-$ | US-5109850-$ | US-5120420-$ | US-5126034-$ | US-5133856-$ | US-5135003-$ | US-5141868-$ | US-5161532-$ | US-5165407-$ | US-5174291-$ | US-5190041-$ | US-5192416-$ | US-5198367-$ | US-5202261-$ | US-5205920-$ | US-5208154-$ | US-5209229-$ | US-5217595-$ | US-5229282-$ | US-5250439-$ | US-5262035-$ | US-5262305-$ | US-5264103-$ | US-5264104-$ | US-5264106-$ | US-5271815-$ | US-5279294-$ | US-5284156-$ | US-5286362-$ | US-5286364-$ | US-5288636-$ | US-5293546-$ | US-5320098-$ | US-5320725-$ | US-5322063-$ | US-5337747-$ | US-5352348-$ | US-5356786-$ | US-5368028-$ | US-5372133-$ | US-5376251-$ | US-5378628-$ | US-5387327-$ | US-5390671-$ | US-5391250-$ | US-5395504-$ | US-5400782-$ | US-5411647-$ | US-5431160-$ | US-5437999-$ | US-5469846-$ | US-5491474-$ | US-5494562-$ | US-5496453-$ | US-5497772-$ | US-5531878-$ | US-5545191-$ | US-5560357-$ | US-5562713-$ | US-5565085-$ | US-5567302-$ | US-5568806-$ | US-5569186-$ | US-5582184-$ | US-5582697-$ | US-5582698-$ | US-5586553-$ | US-5589326-$ | US-5593852-$ | US-5596150-$ | US-5617851-$ | US-5628890-$ | US-5651869-$ | US-5660163-$ | US-5665222-$ | US-5670031-$ | US-5680858-$ | US-5682233-$ | US-5695623-$ | US-5708247-$ | US-5711297-$ | US-5711861-$ | US-5711862-$ | US-5741211-$ | US-5771001-$ | US-5791344-$ | US-5800420-$ | US-5807375-$ | US-5820551-$ | US-5820622-$ | US-5822715-$ | US-5827184-$ | US-5840020-$ | US-5842983-$ | US-5885211-$ | US-5899855-$ | US-5954643-$ | US-5954685-$ | US-5957854-$ | US-5964993-$ | US-5971922-$ | US-5972199-$ | US-6001067-$ | US-6024699-$ | US-6093172-$ | US-6103033-$ | US-6120676-$ | US-6122351-$ | US-6134461-$ | US-6143164-$ | US-6175752-$ | US-6338790-$ | US-6368141-$ | US-6368274-$ | US-6409740-$ | US-6695860-$ | US-6699188-$ | US-6746582-$ | US-6770030-$ | US-6936006-$ | US-6990366-$ | US-7381184-$ | US-RE32947-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:44
S23	53	(US-20030002682-$ | US-20080004512-$ | US-20070027381-$ | US-20080027474-$ | US-20080033318-$ | US-20060036139-$ | US-	US-PGPUB; USPAT;	OR	OFF	2021/03/13 16:44

		20070038044-$ | US-20040064133-$ | US-20080064941-$ | US-20080065646-$ | US-20090069658-$ | US-20030078560-$ | US-20080086044-$ | US-20050090850-$ | US-20090102678-$ | US-20080112848-$ | US-20020130042-$ | US-20040133164-$ | US-20080133702-$ | US-20060155317-$ | US-20030155656-$ | US-0158207-$ | US-0173741-$ | US-0188731-$ | US-0189939-$ | US-0212766-$ | US-0244368-$ | US-0249922-$ | US-20060264888-$ | US-20080269673-$ | US-20080275313-$ | US-20080283396-$ | US-20020130042-$ | US-20030002682-$ | US-20030078560-$ | US-20030155656-$ | US-20040064133-$ | US-20040133164-$ | US-20040158207-$ | US-20050090850-$ | US-20060036139-$ | US-20060155317-$ | US-20060189939-$ | US-20060264888-$ | US-20070027381-$ | US-20070038044-$ | US-20070173741-$ | US-20070244368-$ | US-20070249922-$ | US-20080004512-$ | US-20080027474-$ | US-20080033318-$ | US-20080064941-$ | US-20080065646-$ | US-20080086044-$ | US-20080112848-$ | US-20080133702-$ | US-20080188731-$ | US-20080269673-$ | US-20080275313-$ | US-20080283396-$ | US-20090069658-$ | US-20090102678-$ | US-20090212766-$ | US-3260656-$ | US-3653841-$ | US-3719564-$ | US-3776832-$).did.	USOCR; FPRS; EPO; JPO; IBM_TDB			
S24	119	(US-3837339-$ | US-3926760-$ | US-3972320-$ | US-3979274-$ | US-4008717-$ | US-4016866-$ | US-4055175-$ | US-4059406-$ | US-4076596-$ | US-4098574-$ | US-4100048-$ | US-4129128-$ | US-4151845-$ | US-4168205-$ | US-4172770-$ | US-4178916-$ | US-4206755-$ | US-4224125-$ | US-4240438-$ | US-4247297-$ | US-4340458-$ | US-4352960-$ | US-4356074-$ | US-4365637-$ | US-4366033-$ | US-4375399-$ | US-4384586-$ | US-4390621-$ | US-4401122-$ | US-4404066-$ | US-4418148-$ | US-4427770-$ | US-4431004-$ | US-4436094-$ | US-4440175-$ | US-4450842-$ | US-4458686-$ | US-4461691-$ | US-4469110-$ | US-4477314-$ | US-4484987-$ | US-4522690-$ | US-4524114-$ | US-4526661-$ | US-4534356-$ | US-4538616-$ | US-4543955-$ | US-4545382-$ | US-4552840-$ | US-4560534-$ | US-4571292-$ | US-4573994-$ | US-4581336-$ | US-4595011-$ | US-4619754-$ | US-4627445-$ | US-4627908-$ | US-4633878-$ | US-4637403-$ | US-4650547-$ | US-4654197-$ | US-4655880-$ | US-4655885-$ | US-4671288-$ | US-4679562-$ | US-4680268-$ | US-4682602-$ | US-4684537-$ | US-4685463-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:44

		US-4703756-$ | US-4711245-$ | US-4717673-$ | US-4721601-$ | US-4721677-$ | US-4726378-$ | US-4726716-$ | US-4731726-$ | US-4757022-$ | US-4758323-$ | US-4759371-$ | US-4759828-$ | US-4764416-$ | US-4776944-$ | US-4781798-$ | US-4784736-$ | US-4795707-$ | US-4796634-$ | US-4805624-$ | US-4813424-$ | US-4815469-$ | US-4820399-$ | US-4822337-$ | US-4830959-$ | US-4832797-$ | US-4840893-$ | US-4848351-$ | US-4871351-$ | US-4871440-$ | US-4874500-$ | US-4890620-$ | US-4894137-$ | US-4897162-$ | US-4897173-$ | US-4909908-$ | US-4911794-$ | US-4917800-$ | US-4919141-$ | US-4919767-$ | US-4923586-$ | US-4927516-$ | US-4934369-$ | US-4935105-$ | US-4935345-$ | US-4938860-$ | US-4944299-$ | US-4950378-$ | US-4953552-$ | US-4954129-$ | US-4969468-$).DID.				
S25	9	("20080269774" | "5873879" | "4950288" | "20080058830" | "20020026241").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:58
S26	16	"649323".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:00
S27	1	"20120238857".did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:12
S28	45	(US-3123790-$ | US-3581062-$ | US-3670727-$ | US-3949388-$ | US-4036749-$ | US-4120292-$ | US-4245634-$ | US-4294258-$ | US-4327725-$ | US-4344438-$ | US-4349728-$ | US-4373527-$ | US-4425920-$ | US-4478976-$ | US-4494950-$ | US-4509531-$ | US-4527240-$ | US-4619793-$ | US-4627842-$ | US-4685466-$ | US-4698057-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2021/03/13 17:25

		US-4711247-$ | US-4729672-$ | US-4749985-$ | US-4755173-$ | US-4777953-$ | US-4779618-$ | US-4781683-$ | US-4854322-$ | US-4895147-$ | US-4921199-$ | US-4925268-$ | US-4988341-$ | US-4995402-$ | US-4401400-$ | US-5000180-$ | US-5013161-$ | US-5019974-$ | US-5035860-$ | US-5047044-$ | US-5055171-$ | US-5106365-$ | US-5108889-$ | US-5122925-$).DID.	IBM_TDB			
S29	91	(US-5140985-$ | US-5234835-$ | US-5238729-$ | US-5246867-$ | US-5264105-$ | US-5285792-$ | US-5293877-$ | US-5299571-$ | US-5340722-$ | US-5342789-$ | US-5360404-$ | US-5372427-$ | US-5379238-$ | US-5408999-$ | US-5425361-$ | US-5431921-$ | US-5462645-$ | US-5472317-$ | US-5489414-$ | US-5507288-$ | US-5509410-$ | US-5514718-$ | US-5551427-$ | US-5575563-$ | US-5584813-$ | US-5601435-$ | US-5609575-$ | US-5613978-$ | US-5628310-$ | US-5632557-$ | US-5640954-$ | US-5653239-$ | US-5665071-$ | US-5711001-$ | US-5733044-$ | US-5735285-$ | US-5749656-$ | US-5766131-$ | US-5772586-$ | US-5779665-$ | US-5851197-$ | US-5865804-$ | US-5924979-$ | US-5925021-$ | US-5931814-$ | US-5948006-$ | US-5951521-$ | US-5961451-$ | US-5965380-$ | US-5987353-$ | US-5995860-$ | US-6017335-$ | US-6022368-$ | US-6026321-$ | US-6027459-$ | US-6049727-$ | US-6068399-$ | US-6083710-$ | US-6088608-$ | US-6091975-$ | US-6091976-$ | US-6117290-$ | US-6119028-$ | US-6121009-$ | US-6121611-$ | US-6159147-$ | US-6162611-$ | US-6200265-$ | US-6212416-$ | US-6219574-$ | US-6248067-$ | US-6254536-$ | US-6254586-$ | US-6275717-$ | US-6283761-$ | US-6283982-$ | US-6284478-$ | US-6293925-$ | US-6295506-$ | US-6306104-$ | US-6309884-$ | US-6329161-$ | US-6348640-$ | US-6359444-$ | US-6360888-$ | US-6366794-$ | US-6377828-$ | US-6379301-$ | US-6413393-$ | US-6418332-$ | US-6424847-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:25
S30	105	(US-6427088-$ | US-6437679-$ | US-6440068-$ | US-6478736-$ | US-6484045-$ | US-6484046-$ | US-6514718-$ | US-6520326-$ | US-6522927-$ | US-6551494-$ | US-6554798-$ | US-6558320-$ | US-6558321-$ | US-6560471-$ | US-6561978-$ | US-6562001-$ | US-6564105-$ | US-6565509-$ | US-6571128-$ | US-6572566-$ | US-6576101-$ | US-6577899-$ | US-6579690-$ | US-6585644-$ | US-6589229-$ | US-6591125-$ | US-6595919-$ | US-6605200-$ | US-6605201-$ | US-6607509-$ | US-6610012-$ | US-6633772-$ | US-6635014-$ | US-6648821-$ | US-6654625-$ | US-6659948-$ | US-6666849-$ | US-6668196-$ | US-6676290-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:25

		US-6687546-$ | US-6689056-$ | US-6694191-$ | US-6702857-$ | US-6733446-$ | US-6740075-$ | US-6741877-$ | US-6758810-$ | US-6790178-$ | US-6809653-$ | US-6810290-$ | US-6811533-$ | US-6811534-$ | US-6813519-$ | US-6837858-$ | US-6837885-$ | US-6849052-$ | US-6854882-$ | US-6862465-$ | US-6873268-$ | US-6881551-$ | US-6892085-$ | US-6895265-$ | US-6931327-$ | US-6932894-$ | US-6942518-$ | US-6950708-$ | US-6958705-$ | US-6959211-$ | US-6968294-$ | US-6971274-$ | US-6974437-$ | US-6990366-$ | US-6997907-$ | US-6998247-$ | US-7003336-$ | US-7003340-$ | US-7003341-$ | US-7024245-$ | US-7025743-$ | US-7041068-$ | US-7041468-$ | US-7052483-$ | US-7056302-$ | US-7074307-$ | US-7081195-$ | US-7097637-$ | US-7098803-$ | US-7108778-$ | US-7110803-$ | US-7113821-$ | US-7134999-$ | US-7136689-$ | US-7171274-$ | US-7190988-$ | US-7192450-$ | US-7198606-$ | US-7207974-$ | US-7226978-$ | US-7276029-$ | US-7278983-$ | US-7297151-$ | US-7299082-$ | US-7310544-$ | US-7318816-$ | US-7324012-$).DID.				
S31	81	(US-7329239-$ | US-7335294-$ | US-7340287-$ | US-7340309-$ | US-7354420-$ | US-7364592-$ | US-7366556-$ | US-7379765-$ | US-7402153-$ | US-7416541-$ | US-7424318-$ | US-7455663-$ | US-7460898-$ | US-7467003-$ | US-7471972-$ | US-7494465-$ | US-7497827-$ | US-7519408-$ | US-7583990-$ | US-7591801-$ | US-7599726-$ | US-7613491-$ | US-7615007-$ | US-7632228-$ | US-7637868-$ | US-7640048-$ | US-7651596-$ | US-7654956-$ | US-7657297-$ | US-7666149-$ | US-7682338-$ | US-7697967-$ | US-7711402-$ | US-7713574-$ | US-7715893-$ | US-7727147-$ | US-7731657-$ | US-7736344-$ | US-7763042-$ | US-7822454-$ | US-20060009727-$ | US-20020013538-$ | US-20020019022-$ | US-20020022855-$ | US-20020023852-$ | US-20020042090-$ | US-20020057993-$ | US-20020066764-$ | US-20020076966-$ | US-20020082487-$ | US-20020103499-$ | US-20020106709-$ | US-20020119711-$ | US-20020128594-$ | US-20020154050-$ | US-20020161288-$ | US-20020165462-$ | US-20020198444-$ | US-20030023317-$ | US-20030023461-$ | US-20030032867-$ | US-20030032874-$ | US-20030042137-$ | US-20030060753-$ | US-20030065308-$ | US-20030069510-$ | US-20030078481-$ | US-20030083686-$ | US-20030097092-$ | US-20030100040-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:26

		20030134347-$ | US-20030135333-$ | US-20030144581-$ | US-20030144608-$ | US-20030168338-$ | US-20030176933-$ | US-20030187338-$ | US-20030199790-$ | US-20030199910-$ | US-20030212379-$).did.				
S32	82	(US-20030217966-$ | US-20030225361-$ | US-20040010207-$ | US-20040011671-$ | US-20040040840-$ | US-20040045879-$ | US-20040054263-$ | US-20040064068-$ | US-20040096959-$ | US-20040106858-$ | US-20040106859-$ | US-20040116865-$ | US-20040116866-$ | US-20040122353-$ | US-20040122489-$ | US-20040133164-$ | US-20040135684-$ | US-20040138588-$ | US-20040147996-$ | US-20040152622-$ | US-20040167801-$ | US-20040171921-$ | US-20040176672-$ | US-20040186362-$ | US-20040186365-$ | US-20040193090-$ | US-20040199059-$ | US-20040204687-$ | US-20040210122-$ | US-20040225338-$ | US-20040236200-$ | US-20040236251-$ | US-20040254433-$ | US-20040254434-$ | US-20040267300-$ | US-20050003470-$ | US-20050004494-$ | US-20050010269-$ | US-20050027177-$ | US-20050027180-$ | US-20050031689-$ | US-20050043598-$ | US-20050070819-$ | US-20050085872-$ | US-20050090607-$ | US-20050106713-$ | US-20050112169-$ | US-20050114068-$ | US-20050121322-$ | US-20050131346-$ | US-20050143635-$ | US-20050154410-$ | US-20050165404-$ | US-20050176136-$ | US-20050182306-$ | US-20050187720-$ | US-20050192557-$ | US-20050195930-$ | US-20050197554-$ | US-20050199494-$ | US-20050203360-$ | US-20050222518-$ | US-20050239154-$ | US-20050239156-$ | US-20050241957-$ | US-20050245795-$ | US-20050245799-$ | US-20050245844-$ | US-20050277164-$ | US-20050287620-$ | US-20060001538-$ | US-20060004303-$ | US-20060010098-$ | US-20060015020-$ | US-20060015024-$ | US-20060016700-$ | US-20060019327-$ | US-20060020186-$ | US-20060020187-$ | US-20060020188-$ | US-20060020189-$ | US-20060020190-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:26
S33	85	(US-20060020191-$ | US-20060020192-$ | US-20060036140-$ | US-20060036141-$ | US-20060036142-$ | US-20060036143-$ | US-20060036144-$ | US-20060036145-$ | US-20060047220-$ | US-20060129173-$ | US-20060155210-$ | US-20060166629-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/13 17:26

		20060173444-$ | US-20060189863-$ | US-20060195029-$ | US-20060200181-$ | US-20060200970-$ | US-20060222566-$ | US-20060226985-$ | US-20060247508-$ | US-20060253086-$ | US-20060258929-$ | US-20060276724-$ | US-20060287591-$ | US-20070016381-$ | US-20070060814-$ | US-20070073129-$ | US-20070078320-$ | US-20070078321-$ | US-20070078322-$ | US-20070088377-$ | US-20070106135-$ | US-20070110124-$ | US-20070123819-$ | US-20070149875-$ | US-20070163880-$ | US-20070173706-$ | US-20070191701-$ | US-20070203407-$ | US-20070203966-$ | US-20070235331-$ | US-20070244398-$ | US-20080004573-$ | US-20080009692-$ | US-20080009805-$ | US-20080017522-$ | US-20080021666-$ | US-20080029391-$ | US-20080033254-$ | US-20080033268-$ | US-20080039702-$ | US-20080045824-$ | US-20080064937-$ | US-20080064944-$ | US-20080071156-$ | US-20080083617-$ | US-20080086042-$ | US-20080086273-$ | US-20080097246-$ | US-20080108942-$ | US-20080114280-$ | US-20080119707-$ | US-20080161664-$ | US-20080167578-$ | US-20080183061-$ | US-20080183399-$ | US-20080189051-$ | US-20080194935-$ | US-20080194936-$ | US-20080194937-$ | US-20080194938-$ | US-20080195232-$ | US-20080195967-$ | US-20080197024-$ | US-20080200788-$ | US-20080200789-$ | US-20080200791-$ | US-20080200897-$ | US-20080208025-$ | US-20080214481-$ | US-20080214915-$ | US-20080214918-$ | US-20080228051-$ | US-20080228054-$ | US-20080242961-$).did.	JPO; IBM_TDB			
S34	69	(US-20080262469-$ | US-20080283396-$ | US-20080287764-$ | US-20080287765-$ | US-20080287766-$ | US-20080294096-$ | US-20080296155-$ | US-20080300476-$ | US-20080306368-$ | US-20080306434-$ | US-20080306435-$ | US-20080306444-$ | US-20090012379-$ | US-20090018424-$ | US-20090030294-$ | US-20090036758-$ | US-20090036763-$ | US-20090036915-$ | US-20090043181-$ | US-20090043182-$ | US-20090043525-$ | US-20090043541-$ | US-20090043542-$ | US-20090045055-$ | US-20090054866-$ | US-20090062633-$ | US-20090062635-$ | US-20090076356-$ | US-20090076359-$ | US-20090076360-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:27

		20090076361-$ | US-20090082693-$ | US-20090099436-$ | US-20090105569-$ | US-20090124877-$ | US-20090124878-$ | US-20090124879-$ | US-20090124964-$ | US-20090124979-$ | US-20090131768-$ | US-20090131769-$ | US-20090131776-$ | US-20090131777-$ | US-20090137886-$ | US-20090137887-$ | US-20090143659-$ | US-20090143660-$ | US-20090156919-$ | US-20090156924-$ | US-20090163790-$ | US-20090163791-$ | US-20090171182-$ | US-20090178459-$ | US-20090182217-$ | US-20090192366-$ | US-20090192380-$ | US-20090192722-$ | US-20090192724-$ | US-20090192745-$ | US-20090192751-$ | US-20090198215-$ | US-20090203981-$ | US-20090204341-$ | US-20090216103-$ | US-20090240120-$ | US-20090240128-$ | US-20090240193-$ | US-20090242399-$ | US-20090242425-$).DID.				
S35	61	(US-20090247855-$ | US-20090247856-$ | US-20090259201-$ | US-20090259202-$ | US-20090270765-$ | US-20090287073-$ | US-20090287074-$ | US-20090292184-$ | US-20090292185-$ | US-20090299155-$ | US-20090299156-$ | US-20090299162-$ | US-20090299276-$ | US-20100010324-$ | US-20100010331-$ | US-20100010332-$ | US-20100016687-$ | US-20100016698-$ | US-20100022855-$ | US-20100022863-$ | US-20100030038-$ | US-20100030053-$ | US-20100030484-$ | US-20100030485-$ | US-20100036215-$ | US-20100036216-$ | US-20100036222-$ | US-20100036223-$ | US-20100036225-$ | US-20100036281-$ | US-20100041971-$ | US-20100045465-$ | US-20100049014-$ | US-20100049024-$ | US-20100063373-$ | US-20100069728-$ | US-20100076283-$ | US-20100081908-$ | US-20100081910-$ | US-20100087724-$ | US-20100096259-$ | US-20100099970-$ | US-20100099971-$ | US-20100100113-$ | US-20100106088-$ | US-20100119693-$ | US-20100121169-$ | US-20100168677-$ | US-20100324392-$ | US-20100331647-$ | US-20110021889-$ | US-20110046456-$ | US-20110082484-$ | US-20110106126-$ | US-20110257521-$ | US-20110288574-$ | US-20110319729-$ | US-20120123385-$ | US-20120184909-$ | US-20120296327-$ | US-20130047981-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:27

S36	948	S20 S21 S22 S23 S24 S28 S29 S30 S31 S32 S33 S34 S35	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:28
S37	390	S36 and (sensor with electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:30
S38	351	S37 not (S9 S10)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:30
S39	217	S38 and (insert$5 with sensor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:31
S40	14,590	A61B5/14503,1473,14865,6849.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:36
S41	1,112	A61B2560/063.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2021/03/13 17:36

			JPO; IBM_TDB			
S42	10,711	A61B17/3468.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:37
S43	25,187	S40 S41 S42	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:37
S44	45,210	A61B5/14532.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:38
S45	5,048	A61M2005/1585.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:42
S47	11,078	A61B5/15144,15113,15186,15188,1519,15192,15194.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:47
S48	3,608	A61B2017/347.cpc.	US-PGPUB;	OR	ON	2021/03/13 17:47

			USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB			
S52	29,666	S43 S45	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:57
S57	9,851	S52 and S44	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:04
S58	1,762	S57 and (sensor and electronics) and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:04
S59	1	S58 and S48	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:05
S60	43	S58 and S47	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2021/03/13 18:08

			IBM_TDB			
S61	11	S48 and (sensor and electronics) and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:09
S62	23	S48 and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:10
S63	7	(US-20050158207-$ | US-20070173741-$ | US-20080188731-$ | US-20060189939-$ | US-20090212766-$ | US-20070244368-$ | US-20070249922-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 18:43
S68	5	(("20080114280") or ("20040204687") or ("20100324392") or ("20040133164")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/22 22:44
S89	7	"9402544".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/25 19:39
S90	3,906	A61B5/1411.cpc.	US-PGPUB; USPAT;	OR	ON	2021/03/25 22:17

			USOCR; FPRS; EPO; JPO; IBM_TDB			
S91	2,049	A61B5/15029,150282.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/25 22:23
S92	8,552	A61B5/15107,15117.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/25 22:23
S93	11,837	S90 S91 S92	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/25 23:21
S94	386	S93 and ((snap detent) with spring)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/25 23:21
S96	4	"9215992".did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/08 19:42

S97	1,274	600/583.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/08 20:51
S98	121	600/583.ccls. and bulge	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/10 15:29
S103	2	"5100626".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/12 12:35
S108	69	600/583.ccls. and (cap with distal)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/13 12:40
S109	12	600/583.ccls. and (cap with thread)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/13 12:43
S110	281	600/547.ccls. and ((heart cardiac cardiovascular dialysis) same (oedema edema lymphoedema))	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/05/27 00:12

			JPO; IBM_TDB			
S111	94	600/547.ccls. and ((heart cardiac cardiovascular dialysis) same (oedema edema lymphoedema) same electrode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/27 00:57
S112	281	600/547.ccls. and ((heart cardiac cardiovascular dialysis) same (oedema edema lymphoedema))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/06/01 21:26
S113	94	600/547.ccls. and ((heart cardiac cardiovascular dialysis) same (oedema edema lymphoedema) same electrode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/06/01 21:26
S114	187	S112 not S113	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/06/01 21:26
S115	1	"7630763".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/06/05 01:17
S116	862	"therasense" and "electronic" and sensor	US-PGPUB;	OR	OFF	2021/09/14 18:10

			USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB			
S117	70	(US-20060001538-$ | US-20050003470-$ | US-20060004303-$ | US-20050004494-$ | US-20080004573-$ | US-20080009692-$ | US-20060009727-$ | US-20080009805-$ | US-20060010098-$ | US-20040010207-$ | US-20050010269-$ | US-20100010324-$ | US-20100010331-$ | US-20100010332-$ | US-20040011671-$ | US-20090012379-$ | US-20020013538-$ | US-20060015020-$ | US-20060015024-$ | US-20070016381-$ | US-20100016687-$ | US-20100016698-$ | US-20060016700-$ | US-20080017522-$ | US-20090018424-$ | US-20020019022-$ | US-20060019327-$ | US-20060020186-$ | US-20060020187-$ | US-20060020188-$ | US-20060020189-$ | US-20060020190-$ | US-20060020191-$ | US-20060020192-$ | US-20080021666-$ | US-20110021889-$ | US-20020022855-$ | US-20100022863-$ | US-20030023317-$ | US-20030023461-$ | US-20020023852-$ | US-20050027177-$ | US-20050027180-$ | US-20080029391-$ | US-20100030038-$ | US-20100030053-$ | US-20090030294-$ | US-20100030484-$ | US-20100030485-$ | US-20050031689-$ | US-20030032867-$ | US-20030032874-$ | US-20080033254-$ | US-20080033268-$ | US-20060036140-$ | US-20060036141-$ | US-20060036142-$ | US-20060036143-$ | US-20060036144-$ | US-20060036145-$ | US-20100036215-$ | US-20100036216-$ | US-20100036222-$ | US-20100036223-$ | US-20100036225-$ | US-20100036281-$ | US-20090036758-$ | US-20090036763-$ | US-20090036915-$ | US-20080039702-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/09/14 18:15
S118	65	(US-20040040840-$ | US-20100041971-$ | US-20020042090-$ | US-20030042137-$ | US-20090043181-$ | US-20090043182-$ | US-20090043525-$ | US-20090043541-$ | US-20090043542-$ | US-20050043598-$ | US-20090045055-$ | US-20100045465-$ | US-20080045824-$ | US-20040045879-$ | US-20110046456-$ | US-20060047220-$ | US-20130047981-$ | US-20100049014-$ | US-20100049024-$ | US-20040054263-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/09/14 18:15

		20090054866-$ | US-20020057993-$ | US-20030060753-$ | US-20070060814-$ | US-20090062633-$ | US-20090062635-$ | US-20100063373-$ | US-20040064068-$ | US-20080064937-$ | US-20080064944-$ | US-20030065308-$ | US-20020066764-$ | US-20030069510-$ | US-20100069728-$ | US-20050070819-$ | US-20080071156-$ | US-20070073129-$ | US-20100076283-$ | US-20090076356-$ | US-20090076359-$ | US-20090076360-$ | US-20090076361-$ | US-20020076966-$ | US-20070078320-$ | US-20070078321-$ | US-20070078322-$ | US-20030078481-$ | US-20100081908-$ | US-20100081910-$ | US-20110082484-$ | US-20020082487-$ | US-20090082693-$ | US-20080083617-$ | US-20030083686-$ | US-20050085872-$ | US-20080086042-$ | US-20080086273-$ | US-20100087724-$ | US-20070088377-$ | US-20050090607-$ | US-20100096259-$ | US-20040096959-$ | US-20030097092-$ | US-20080097246-$ | US-20090099436-$).did.				
S119	61	(US-20100099970-$ | US-20100099971-$ | US-20030100040-$ | US-20100100113-$ | US-20020103499-$ | US-20090105569-$ | US-20100106088-$ | US-20110106126-$ | US-20070106135-$ | US-20020106709-$ | US-20050106713-$ | US-20040106858-$ | US-20040106859-$ | US-20080108942-$ | US-20030109775-$ | US-20070110124-$ | US-20050112169-$ | US-20050114068-$ | US-20080114280-$ | US-20040116865-$ | US-20040116866-$ | US-20100119693-$ | US-20080119707-$ | US-20020119711-$ | US-20100121169-$ | US-20050121322-$ | US-20040122353-$ | US-20040122489-$ | US-20120123385-$ | US-20070123819-$ | US-20090124877-$ | US-20090124878-$ | US-20090124879-$ | US-20090124964-$ | US-20090124979-$ | US-20020128594-$ | US-20060129173-$ | US-20050131346-$ | US-20090131768-$ | US-20090131769-$ | US-20090131776-$ | US-20090131777-$ | US-20040133164-$ | US-20030134347-$ | US-20030135333-$ | US-20040135684-$ | US-20090137886-$ | US-20090137887-$ | US-20040138588-$ | US-20050143635-$ | US-20090143659-$ | US-20090143660-$ | US-20030144581-$ | US-20030144608-$ | US-20040147996-$ | US-20070149875-$ | US-20040152622-$ | US-20020154050-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/09/14 18:16

		20050154410-$ | US-20060155210-$ | US-20090156919-$).did.				
S120	39	(US-20090156924-$ | US-20020161288-$ | US-20080161664-$ | US-20090163790-$ | US-20090163791-$ | US-20070163880-$ | US-20050165404-$ | US-20020165462-$ | US-20060166629-$ | US-20080167578-$ | US-20040167801-$ | US-20030168338-$ | US-20100168677-$ | US-20090171182-$ | US-20040171921-$ | US-20060173444-$ | US-20070173706-$ | US-20050176136-$ | US-20040176672-$ | US-20030176933-$ | US-20090178459-$ | US-20090182217-$ | US-20050182306-$ | US-20080183061-$ | US-20080183399-$ | US-20120184909-$ | US-20040186362-$ | US-20010186365-$ | US-20030187338-$ | US-20050187720-$ | US-20080189051-$ | US-20060189863-$ | US-20070191701-$ | US-20090192366-$ | US-20090192380-$ | US-20050192557-$ | US-20090192722-$ | US-20090192724-$ | US-20090192745-$ | US-20090192751-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/09/14 18:16
S121	50	(US-20040193090-$ | US-20080194935-$ | US-20080194936-$ | US-20080194937-$ | US-20080194938-$ | US-20060195029-$ | US-20080195232-$ | US-20050195930-$ | US-20080195967-$ | US-20080197024-$ | US-20050197554-$ | US-20090198215-$ | US-20020198444-$ | US-20040199059-$ | US-20050199494-$ | US-20030199790-$ | US-20030199910-$ | US-20060200181-$ | US-20080200788-$ | US-20080200789-$ | US-20080200791-$ | US-20080200897-$ | US-20060200970-$ | US-20050203360-$ | US-20070203407-$ | US-20070203966-$ | US-20090203981-$ | US-20090204341-$ | US-20040204687-$ | US-20080208025-$ | US-20040210122-$ | US-20030212379-$ | US-20080214481-$ | US-20080214915-$ | US-20080214918-$ | US-20090216103-$ | US-20030217966-$ | US-20050222518-$ | US-20060222566-$ | US-20040225338-$ | US-20030225361-$ | US-20060226985-$ | US-20080228051-$ | US-20080228054-$ | US-20070235331-$ | US-20040236200-$ | US-20040236251-$ | US-20050239154-$ | US-20050239156-$ | US-20090240120-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/09/14 18:17
S122	53	(US-20090240128-$ | US-20090240193-$ | US-20050241957-$ | US-20090242399-$ | US-20090242425-$ | US-20080242961-$ | US-20070244398-$ | US-20050245795-$ | US-	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/09/14 18:18

		20050245799-$ | US-20050245844-$ | US-20060247508-$ | US-20090247855-$ | US-20090247856-$ | US-20060253086-$ | US-20040254433-$ | US-20040254434-$ | US-20110257521-$ | US-20060258929-$ | US-20090259201-$ | US-20090259202-$ | US-20080262469-$ | US-20040267300-$ | US-20090270765-$ | US-20060276724-$ | US-20050277164-$ | US-20080283396-$ | US-0286118-$ | US-20090287073-$ | US-20090287074-$ | US-20060287591-$ | US-20050287620-$ | US-20080287764-$ | US-20080287765-$ | US-20080287766-$ | US-20110288574-$ | US-20090292184-$ | US-20090292185-$ | US-20080294096-$ | US-20080296155-$ | US-20120296327-$ | US-20090299155-$ | US-20090299156-$ | US-20090299162-$ | US-20090299276-$ | US-20080300476-$ | US-20080306368-$ | US-20080306434-$ | US-20080306435-$ | US-20080306444-$ | US-20110319729-$ | US-20100324392-$ | US-20100331647-$).did.	FPRS; EPO; JPO; IBM_TDB			
S123	338	S117 S118 S119 S120 S121 S122	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/09/14 18:18
S124	110	S123 and (sensor and electronics) and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/09/14 18:19
S125	3,966	A61B5/1411.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/09/14 18:20
S126	2,080	A61B5/15029,150282.cpc.	US-PGPUB;	OR	ON	2021/09/14 18:20

			USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB			
S127	8,640	A61B5/15107,15117.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/09/14 18:20
S128	11,984	S125 S126 S127	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/09/14 18:20
S129	729	S128 and (electronic same sensor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/09/14 18:20
S130	314	S128 and (sensor and electronics) and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/09/14 18:21
S131	261	S116 and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2021/09/14 18:35

			IBM_TDB			
S132	202	S131 not (S124 S130)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/09/14 18:37
S133	2	"20080009692".did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/09/17 12:57
S134	2	"8333714".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/09/17 13:10
S135	60	(US-20020010390-$ | US-20020016568-$ | US-20020151770-$ | US-20030028184-$ | US-20030077642-$ | US-20030153900-$ | US-20040061232-$ | US-20040106860-$ | US-20050004439-$ | US-20050027462-$ | US-20050038332-$ | US-20050151976-$ | US-20050215871-$ | US-20050261563-$ | US-20050267325-$ | US-20050283208-$ | US-20050283209-$ | US-20060001551-$ | US-20060025663-$ | US-20060276771-$ | US-20070032706-$ | US-20070208246-$ | US-20070255116-$ | US-20080058830-$ | US-20080119710-$ | US-20080278333-$ | US-20090005666-$ | US-20090006034-$ | US-20090054737-$ | US-20090150454-$ | US-20090299152-$ | US-20100137695-$ | US-20100174168-$ | US-20100191472-$ | US-20100198314-$ | US-20100230285-$ | US-20100274515-$ | US-4639062-$ | US-4675346-$ | US-4703756-$ | US-4852025-$ | US-5006110-$ | US-5162407-$ | US-5228449-$ | US-5482473-$ | US-5516832-$ | US-5770028-$ | US-5823802-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/12/03 11:26

		US-6304766-$ | US-6336269-$ | US-6442413-$ | US-6510344-$ | US-6603995-$ | US-6604050-$ | US-6706159-$ | US-6730072-$ | US-7220387-$ | US-7568619-$ | US-7643798-$ | US-7885697-$).DID.				
S136	60	(US-20020010390-$ | US-20020016568-$ | US-20020151770-$ | US-20030028184-$ | US-20030077642-$ | US-20030153900-$ | US-20040061232-$ | US-20040106860-$ | US-20050004439-$ | US-20050027462-$ | US-20050038332-$ | US-20050151976-$ | US-20050215871-$ | US-20050261563-$ | US-20050267325-$ | US-20050283208-$ | US-20050283209-$ | US-20060001551-$ | US-20060025663-$ | US-20060276771-$ | US-20070032706-$ | US-20070208246-$ | US-20070255116-$ | US-20080058830-$ | US-20080119710-$ | US-20080278333-$ | US-20090005666-$ | US-20090006034-$ | US-20090054737-$ | US-20090150454-$ | US-20090299152-$ | US-20100137695-$ | US-20100174168-$ | US-20100191472-$ | US-20100198314-$ | US-20100230285-$ | US-20100274515-$ | US-4639062-$ | US-4675346-$ | US-4703756-$ | US-4852025-$ | US-5006110-$ | US-5162407-$ | US-5228449-$ | US-5482473-$ | US-5516832-$ | US-5770028-$ | US-5823802-$ | US-6304766-$ | US-6336269-$ | US-6442413-$ | US-6510344-$ | US-6603995-$ | US-6604050-$ | US-6706159-$ | US-6730072-$ | US-7220387-$ | US-7568619-$ | US-7643798-$ | US-7885697-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/12/03 23:16
S137	27	S136 and (electronic same sensor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/12/03 23:16
S138	59	(US-20020010390-$ | US-20020016568-$ | US-20020151770-$ | US-20030028184-$ | US-20030077642-$ | US-20030153900-$ | US-20040061232-$ | US-20040106860-$ | US-20050004439-$ | US-20050027462-$ | US-20050038332-$ | US-20050151976-$ | US-20050215871-$ | US-20050261563-$ | US-20050267325-$ | US-20050283208-$ | US-20050283209-$ | US-20060001551-$ | US-20060025663-$ | US-20060276771-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/12/30 22:59

		20070032706-$ | US-20070208246-$ | US-20070255116-$ | US-20080119710-$ | US-20080278333-$ | US-20090005666-$ | US-20090006034-$ | US-20090054737-$ | US-20090112123-$ | US-20090150454-$ | US-20090299152-$ | US-20100174168-$ | US-20100191472-$ | US-20100198314-$ | US-20100230285-$ | US-20100274515-$ | US-4639062-$ | US-4675346-$ | US-4703756-$ | US-4852025-$ | US-5006110-$ | US-5162407-$ | US-5228449-$ | US-5482473-$ | US-5516832-$ | US-5770028-$ | US-5823802-$ | US-6304766-$ | US-6336269-$ | US-6442413-$ | US-6510344-$ | US-6603995-$ | US-6604050-$ | US-6706159-$ | US-6730072-$ | US-7220387-$ | US-7568619-$ | US-7643798-$ | US-7885697-$).DID.				

12/30/2021 11:13:37 PM
C:\Users\hnguyen50\Documents\EAST\Workspaces\cases FY 2021\Second Quarter\17019110 inserting device for implantable sensor abbott.wsp

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Peter G. Robinson, Alamo, CA;

**** CONTINUING DATA ***************************

This application is a CON of 16/002,847 06/07/2018
which is a CON of 13/436,768 03/30/2012 PAT 10010280
which is a CON of 13/071,461 03/24/2011 PAT 9215992
which claims benefit of 61/411,262 11/08/2010
and claims benefit of 61/361,374 07/02/2010
and claims benefit of 61/345,562 05/17/2010
and claims benefit of 61/317,243 03/24/2010

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

09/22/2020

Foreign Priority claimed ❑ Yes ☑ No 35 USC 119(a-d) conditions met ❑ Yes ☑ No Verified and Acknowledged /Hnguyen / Examiner's Signature	❑ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	99	26	1

ADDRESS

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660
UNITED STATES

TITLE

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

FILING FEE RECEIVED		
3620	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

BIB (Rev. 05/07).

4PTO/SB/08a (08-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	4

Complete if Known

Application Number	17/019,110
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	3791
Examiner Name	Huong Q. Nguyen
Attorney Docket Number	A0130.0107.01C8

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	1	4,639,062	01-27-1987	Taniguchi et al.
	2	4,675,346	06-23-1987	Lin et al.
	3	4,703,756	11-03-1987	Gough et al.
	4	4,852,025	07-25-1989	Herpichböhm
	5	5,006,110	04-09-1991	Garrison et al.
	6	5,162,407	11-10-1992	Turner
	7	5,228,449	07-20-1993	Christ et al.
	8	5,482,473	01-09-1996	Lord et al.
	9	5,516,832	05-14-1996	Kennan et al.
	10	5,770,028	06-23-1998	Maley et al.
	11	5,823,802	10-20-1998	Bartley
	12	6,304,766 B1	10-16-2001	Colvin, Jr.
	13	6,336,269 B1	01-08-2002	Eldridge et al.
	14	6,442,413 B1	08-27-2002	Silver
	15	6,510,344 B1	01-21-2003	Halpern
	16	6,603,995 B1	08-05-2003	Carter
	17	6,604,050 B2	08-05-2003	Trippel et al.
	18	6,706,159 B2	03-16-2004	Moerman et al.
	19	6,730,072 B2	05-04-2004	Shawgo et al.
	20	7,220,387 B2	05-22-2007	Flaherty et al.
	21	7,568,619 B2	08-04-2009	Todd et al.
	22	7,643,798 B2	01-05-2010	Ljung
	23	7,885,697 B2	02-08-2011	Brister et al.
	24	2002/0010390 A1	01-24-2002	Guice et al.
	25	2002/0016568 A1	02-07-2002	Lebel et al.
	26	2002/0151770 A1	10-17-2002	Noll et al.
	27	2003/0028184 A1	02-06-2003	Lebel et al.
	28	2003/0077642 A1	04-24-2003	Fritsch et al.
	29	2003/0153900 A1	08-14-2003	Aceti et al.
	30	2004/0061232 A1	04-01-2004	Shah et al.
	31	2004/0106860 A1	06-03-2004	Say et al.
	32	2005/0004439 A1	01-06-2005	Shin et al.

Examiner Signature	/H Q NGUYEN/	Date Considered	12/30/2021

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known	
Application Number	17/019,110
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	3791
Examiner Name	Huong Q. Nguyen
Attorney Docket Number	A0130.0107.01C8

	33	2005/0027462 A1	02-03-2005	Goode, Jr. et al.
	34	2005/0038332 A1	02-17-2005	Saidara et al.
	35	2005/0151976 A1	07-14-2005	Toma
	36	2005/0215871 A1	09-29-2005	Feldman et al.
	37	2005/0261563 A1	11-24-2005	Zhou et al.
	38	2005/0267325 A1	12-01-2005	Bouchier et al.
	39	2005/0283208 A1	12-22-2005	Von Arx et al.
	40	2005/0283209 A1	12-22-2005	Katoozi et al.
	41	2006/0001551 A1	01-05-2006	Kraft et al.
	42	2006/0025663 A1	02-02-2006	Talbot et al.
	43	2006/0276771 A1	12-07-2006	Galley et al.
	44	2007/0032706 A1	02-08-2007	Kamath et al.
	45	2007/0208246 A1	09-06-2007	Brauker et al.
	46	2007/0255116 A1	11-01-2007	Mehta et al.
	47	2008/0119710 A1	05-22-2008	Reggiardo et al.
	48	2008/0278333 A1	11-13-2008	Fennell et al.
	49	2009/0005666 A1	01-01-2009	Shin et al.
	50	2009/0006034 A1	01-01-2009	Hayter et al.
	51	2009/0054737 A1	02-26-2009	Magar et al.
	52	2009/0112123 A1	04-30-2009	Freeman et al.
	53	2009/0150454 A1	06-11-2009	Gejdos et al.
	54	2009/0299152 A1	12-03-2009	Taub et al.
	55	2010/0174168 A1	07-08-2010	Goode, Jr. et al.
	56	2010/0191472 A1	07-29-2010	Doniger et al.
	57	2010/0198314 A1	08-05-2010	Wei
	58	2010/0230285 A1	09-16-2010	Hoss et al.
	59	2010/0274515 A1	10-28-2010	Hoss et al.
	60			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
	61	GB 2 067 764 B	01-25-1984	National Development Corporation	
	62	JP 2004-214014 A	07-29-2004	Shinetsu Polymer Co.	Y
	63	WO 01/58348 A2	08-16-2001	Minimed Inc.	

Examiner Signature	/H Q NGUYEN/	Date Considered	12/30/2021

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Substitute for form 1449A/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/019,110
				Filing Date	September 11, 2020
				First Named Inventor	Manuel Luis Donnay
				Art Unit	3791
(use as many sheets as necessary)				Examiner Name	Huong Q. Nguyen
Sheet	3	of	4	Attorney Docket Number	A0130.0107.01C8

	64	WO 01/64105 A1	09-07-2001	Inverness Medical Technology, Inc.	
	65	WO 02/15778 A1	02-28-2002	Cygnus, Inc.	
	66	WO 03/056319 A2	07-10-2003	Oxford Biosensors Limited	
	67	WO 2004/049237 A2	06-10-2004	S.C. Johnson & Son, Inc.	
	68	WO 2005/018450 A2	03-03-2005	iSense Corporation	
	69	WO 2006/026741 A1	03-09-2006	Lifescan Scotland Limited	
	70	WO 2006/040083 A1	04-20-2006	Roche Diagnostics GmbH	Y
	71	WO 2006/086423 A2	08-17-2006	Therasense, Inc.	
	72	WO 2006/094513 A2	09-14-2006	Coloplast A/S et al.	
	73	WO 2006/114297 A1	11-02-2006	Disetronic Licensing AG	Y
	74	WO 2007/097754 A1	08-30-2007	Dexcom, Inc.	
	75	WO 2008/021913 A2	02-21-2008	Abbott Diabetes Care Inc.	
	76	WO 2008/115409 A1	09-25-2008	Bayer Healthcare LLC	
	77	WO 2008/138006 A2	11-13-2008	Abbott Diabetes Care Inc.	
	78	WO 2008/157821 A1	12-24-2008	Abbott Diabetes Care, Inc.	
	79	WO 2010/141922 A1	12-09-2010	Abbott Diabetes Care Inc.	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials'	Cite No.[1]	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]
	80	AMBADE, V. N., et al., "Methods for Estimation of Blood Glucose: A Comparative Evaluation", Medical Journal Armed Forces India, 1998, Vol. 54, No. 2, pgs. 131-133.	
	81	ASTM International, Designation D2240-05, 2010, pgs. 1-13.	
	82	Biosensors: Fundamentals and Applications, Turner et al., Eds., 1987, pgs. 1-786.	
	83	Bluetooth Core Specification 4.0, June 30, 2010, Master Table of Contents & Compliance Requirements, pgs. 1-89.	
	84	CLARKE, W., et al., "Statistical Tools to Analyze Continuous Glucose Monitor Data", Diabetes Technology & Therapeutics, 2009, Vol. 11, Suppl. 1, pgs. S-45 – S-54.	
	85	*In Vivo* Glucose Sensing, Cunningham et al., Eds., 2010, Chemical Analysis, Vol. 174, pgs. 1-466.	
	86	DECUIR, J., "Bluetooth 4.0: Low Energy", IEEE SCV Consultants' Network of Silicon Valley, 2012, pgs. 1-68.	
	87	DEMENTYEV, A., et al., "Power Consumption Analysis of Bluetooth Low Energy, ZigBee and ANT Sensor Nodes in a Cyclic Sleep Scenario", IEEE International Wireless Symposium	

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				Filing Date	September 11, 2020
				First Named Inventor	Manuel Luis Donnay
				Art Unit	3791
(use as many sheets as necessary)				Examiner Name	Huong Q. Nguyen
Sheet	4	of	4	Attorney Docket Number	A0130.0107.01C8

		(IWS), 2013, Beijing, China, pgs. 1-4.	
	88	DexCom™ STS™ Continuous Glucose Monitoring System User's Guide, 2006, pgs. 1-57.	
	89	Dexcom STS®-7 Continuous Glucose Monitoring System User's Guide, 2007, pgs. 1-74.	
	90	ECMA International Standard ECMA-340, Near Field Communication Interface and Protocol (NFCIP-1), 2nd Edition, 2004, pgs. 1-65.	
	91	FACCHINETTI, A., et al., "A New Index to Optimally Design and Compare Continuous Glucose Monitoring Glucose Prediction Algorithms", Diabetes Technology & Therapeutics, 2011, Vol. 13, No. 2, pgs. 111–119.	
	92	Fujipoly Silver ZEBRA® Connector Data Sheet FSDS 01-34, Version 5, 2006, pgs. 1-7.	
	93	GILLIGAN, B. J., et al., "Evaluation of a Subcutaneous Glucose Sensor out to 3 Months in a Dog Model", Diabetes Care, 1994, Vol. 17, No. 8, pgs. 882-887.	
	94	GUERRA, S., et al., "A Dynamic Risk Measure from Continuous Glucose Monitoring Data", Diabetes Technology & Therapeutics, 2011, Vol. 13, No. 8, pgs. 843–852.	
	95	HEISE, T., et al., "Hypoglycemia Warning Signal and Glucose Sensors: Requirements and Concepts", Diabetes Technology & Therapeutics, 2003, Vol. 5, No. 4, pgs. 563-571.	
	96	HELLER, A., "Implanted Electrochemical Glucose Sensors for the Management of Diabetes", Annnu. Rev. Biomed. Eng., 1999, Vol. 1, pgs. 153-175.	
	97	"In Vitro Diagnostic Products for Human Use", Federal Register, 1974, Vol. 39, No. 126, pgs. 24136-24147.	
	98	KLONOFF, D. C., "A Review of Continuous Glucose Monitoring Technology", Diabetes Technology & Therapeutics, 2005, Vol. 7, No. 5, pgs. 770-775.	
	99	LEÓN, L. P., et al., "Continuous-Flow Analysis for Glucose in Serum, with Use of Hexokinase and Glucose-6-Phosphate Dehydrogenase Co-Immobilized in Tubular Form", Clinical Chemistry, 1980, Vol. 26, No. 1, pgs. 123-129.	
	100	MORAK, J., et al., "Design and Evaluation of a Telemonitoring Concept Based on NFC-Enabled Mobile Phones and Sensor Devices", IEEE Transactions on Information Technology in Biomedicine, 2012, Vol. 16, No. 1, pgs. 17-23.	
	101	MOVASSAGHI, S., et al., "Wireless Technologies for Body Area Networks: Characteristics and Challenges", 2012 International Symposium on Communications and Information Technologies (ISCIT), 2012, Gold Coast, QLD, Australia, pgs. 42-47.	
	102	PASSEY, R. B., et al., "Evaluation and Comparison of 10 Glucose Methods and the Reference Method Recommendation in the Proposed Product Class Standard (1974)", Clinical Chemistry, 1977, Vol. 23, No. 1, pgs. 131-139.	
	103	SANDHAM, W., et al., "Blood Glucose Prediction for Diabetes Therapy Using a Recurrent Artificial Neural Network", 9th European Signal Processing Conference, 1998, Rhodes,	

Examiner Signature	/H Q NGUYEN/	Date Considered	12/30/2021

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(use as many sheets as necessary)				Examiner Name	Huong Q. Nguyen
Sheet	5	of	4	Attorney Docket Number	A0130.0107.01C8

		Greece, pgs. 1-4.	
	104	SPARACINO, G., et al., "Glucose Concentration Can Be Predicted Ahead in Time from Continuous Glucose Monitoring Sensor Time-Series", IEEE Transactions on Biomedical Engineering, 2007, Vol. 54, No. 5, pgs. 931-937.	
	105	TOWNSEND, K., et al., "Getting Started with Bluetooth Low Energy – Chapter 1", 2014, pgs. 1-26.	
	106	U.S. Provisional Application No. 60/587,787 filed July 13, 2004, pgs. 1-69.	
	107	U.S. Provisional Application No. 60/606,334 filed August 31, 2004, pgs. 1-38.	
	108	WANG, X.H., et al., "Bluetooth: Opening a blue sky for healthcare", Mobile Information Systems, 2006, Vol. 2, pgs. 151-167.	
	109	Z-Carbon Connector, retrieved from http://www.zaxisconnector.com/SS_zc.shtml, 2004, 2 pages.	
	110	Z-Silver Connector, retrieved from http://www.zaxisconnector.com/SS_zs.shtml, 2004, 2 pages.	
	111		
	112		
	113		
	114		
	115		

Examiner Signature	/H Q NGUYEN/	Date Considered	12/30/2021

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(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

TITLE OF INVENTION: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	04/21/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
NGUYEN, HUONG Q	3791	600-583000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

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(A) NAME OF ASSIGNEE: ABBOTT DIABETES CARE INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Alameda, CA

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Glen Liu/ Date January 21, 2022

Typed or printed name Glen Liu Registration No. 75,058

Electronic Patent Application Fee Transmittal

Application Number:	17019110
Filing Date:	11-Sep-2020
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0107.01C8

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1200**

Electronic Acknowledgement Receipt

EFS ID:	44807852
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	183890
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	21-JAN-2022
Filing Date:	11-SEP-2020
Time Stamp:	18:14:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1200
RAM confirmation Number	E20221KI14193421
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	10297USC16_A0130_0107_01C8_Issue_Fee_Transmittal.pdf	331426 61d05a3ff8e7ba2225c52a3e19a09a1f66349ae0	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37737 f3084cb26140712a5a9e9fa1295396965ed0fd46	no	2
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		Total Files Size (in bytes):	369163		

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New Applications Under 35 U.S.C. 111

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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

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Courtesy Reminder for
Application Serial No: 17/019,110

Attorney Docket No: A0130.0107.01C8
Customer Number: 183890
Date of Electronic Notification: 01/21/2022

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

	Complete if Known
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned

Sheet	7	of	20	Attorney Docket No: A0130.0107.01C8

Change(s) applied to document, /D.M./ 1/26/2022

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-7,335,294	02-26-2007/2008	Heller, et al.	
		US-7,340,287	03-04-2008	Mason, et al.	
		US-7,340,309	03-04-2008	Miazga, et al.	
		US-7,354,420	04-08-2008	Steil, et al.	
		US-7,364,592	04-29-2008	Carr-Brendel, et al.	
		US-7,366,556	04-29-2008	Brister, et al.	
		US-7,379,765	05-27-2008	Petisce, et al.	
		US-7,402,153	07-22-2008	Steil, et al.	
		US-7,416,541	08-26-2008	Yuzhakov, et al.	
		US-7,424,318	09-09-2008	Brister, et al.	
		US-7,455,663	11-25-2008	Bikovsky	
		US-7,460,898	12-02-2008	Brister, et al.	
		US-7,467,003	12-16-2008	Brister, et al.	
		US-7,471,972	12-30-2008	Rhodes, et al.	
		US-7,494,465	02-24-2009	Brister, et al.	
		US-7,497,827	03-03-2009	Brister, et al.	
		US-7,519,408	04-14-2009	Rasdal, et al.	
		US-7,583,990	09-01-2009	Goode Jr., et al.	
		US-7,591,801	09-22-2009	Brauker, et al.	
		US-7,599,726	10-06-2009	Goode Jr., et al.	
		US-7,613,491	11-03-2009	Boock, et al.	
		US-7,615,007	11-10-2009	Shults, et al.	
		US-7,632,228	12-15-2009	Brauker, et al.	
		US-7,637,868	12-29-2009	Saint, et al.	
		US-7,640,048	12-29-2009	Dobbles, et al.	
		US-7,651,596	01-26-2010	Petisce, et al.	
		US-7,654,956	02-02-2010	Brister, et al.	
		US-7,657,297	02-02-2010	Simpson, et al.	
		US-7,666,149	02-23-2010	Simons, et al.	
		US-7,682,338	03-23-2010	Griffin	
		US-7,697,967	04-13-2010	Stafford	
		US-7,711,402	05-04-2010	Shults, et al.	
		US-7,713,574	05-11-2010	Brister, et al.	
		US-7,715,893	05-11-2010	Kamath, et al.	
		US-7,727,147	06-01-2010	Osorio, et al.	
		US-7,731,657	06-08-2010	Stafford.	
		US-7,736,344	06-15-2010	Moberg, et al.	
		US-7,763,042	07-27-2010	Iio, et al.	
		US-7,822,454	10-26-2010	Alden, et al.	
		US-2002/0013538	01-31-2002	Teller	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

	Complete if Known
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned

Sheet	1	of	20	Attorney Docket No: A0130.0107.01C8

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-3,123,790	03-03-1964	Tyler	
		US-3,581,062	05-21-1971	Aston	
		US-3,670,727	06-20-1972	Reiterman	
		US-3,949,388	04-06-1976	Fuller	
		US-4,036,749	07-19-1977	Anderson	
		US-4,120,292	10-17-1978	LeBlanc Jr., et al.	
		US-4,245,634	01-20-1981	Albisser, et al.	
		US-4,294,258	10-13-1981	Bernard	
		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-4,425,920	01-17-1984	Bourland, et al.	
Change(s) applied to document, /D.M./ 1/26/2022		US-4,478,976	10-23-~~1994~~ 1984	Goertz, et al.	
		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-4,619,793	10-28-1986	Lee	
		US-4,627,842	12-09-1986	Katz	
		US-4,685,466	08-11-1987	Rau	
		US-4,698,057	10-06-1987	Joishy	
		US-4,711,247	12-08-1987	Fishman	
		US-4,781,683	11-01-1988	Wozniak, et al.	
		US-4,729,672	03-08-1988	Takagi	
		US-4,749,985	06-07-1988	Corsberg	
		US-4,755,173	07-05-1988	Konopka	
		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-4,895,147	01-23-1990	Bodicky, et al.	
		US-4,921,199	05-01-1990	Villaveces	
		US-4,925,268	05-15-1990	Iyer, et al.	
		US-4,988,341	01-21-1991	Columbus, et al.	
		US-4,995,402	02-26-1991	Smith, et al.	
		US-5,000,180	03-19-1991	Kuypers, et al.	
		US-5,013,161	05-07-1991	Zaragoza, et al.	
		US-5,019,974	05-28-1991	Beckers	
		US-5,035,860	07-30-1991	Kleingeld, et al.	
		US-5,047,044	09-10-1991	Smith, et al.	
		US-5,055,171	10-08-1991	Peck	

EXAMINER /H Q NGUYEN/ **DATE CONSIDERED** 03/13/2021

Substitute Disclosure Statement Form (PTO-1449)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	9	of	13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

	271	2006/0155317 A1	07-13-2006	List
	272	2006/0189939 A1	08-24-2006	Gonnelli et al.
	273	2006/0264888 A1	11-23-2006	Moberg et al.
	274	2007/0027381 A1	02-01-2007	Stafford
	275	2007/0038044 A1	02-15-2007	Dobbles et al.
	276	2007/0173741 A1	07-26-2007	Deshmukh et al.
	277	2007/0244368 A1	10-18-2007	Bayloff et al.
	278	2007/0249922 A1	10-25-2007	Peyser et al.
	279	2008/0004512 A1	01-03-2008	Funderbunk et al.
	280	2008/0027474 A1	01-31-~~2007~~ 2008	Curry et al.
	281	2008/0033318 A1	02/07/2008	Mace et al.
	282	2008/0065646 A1	03-13-2008	Zhang et al.
	283	2008/0064941 A1	03-13-2008	Funderbunk et al.
	284	2008/0086044 A1	04-10-2008	Brister et al.
	285	2008/0112848 A1	05-15-2008	Huffstodt et al.
	286	2008/0133702 A1	06-25-2008	Sharma et al.
	287	2008/0188731 A1	08-07-2008	Brister et al.
	288	2008/0269673 A1	10-31-2008	Butoi et al.
	289	2008/0275313 A1	11-06-2008	Brister et al.
	290	2008/0283396 A1	11-20-2008	Wang et al.
	291	2009/0069658 A1	03-12-2009	Say et al.
	292	2009/0102678 A1	04-23-2009	Mazza et al.
	293	2009/0212766 A1	08-27-2009	Olson et al.
	294			
	295			

Change(s) applied to document, /D.M./ 1/26/2022

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
	296	WO 2008/065646	06-05-2008	Medingo Ltd	
	297	WO 2008/133702	11-06-2008	Medtronic Minimed Inc	
	298	WO 2010/112521	10-07-2010	Unomedical AS	
	299				
	300				

Examiner Signature	/H Q NGUYEN/	Date Considered	03/13/2021

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 8 of 13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

	237	5,954,685	09-21-1999	Tierny
	238	5,957,854	09-28-1999	Besson, et al.
	239	5,964,993	10-12-1999	Blubaugh Jr. et al.
	240	5,971,922	10-26-1999	Arita et al.
	241	5,972,199	10-26-1999	Heller et al.
	242	5,120,420	06/1992 ~~11-09-1999~~	Nankai et al.
Change(s) applied	243	6,001,067	12-14-1999	Shults et al.
to document,	244	6,024,699	02-15-2000	Surwit et al.
/D.M./	245	6,093,172	07-25-2000	Funderburk et al.
1/26/2022	246	6,103,033	08-15-2000	Say et al.
	247	6,120,676	09-19-2000	Heller et al.
	248	6,122,351	09-19-2000	Schlueter Jr. et al.
	249	6,134,461	10-17-2000	Say et al.
	250	6,143,164	11-07-2000	Heller et al.
	251	6,175,752 B1	01-16-2001	Say et al.
	252	6,338,790 B1	01-15-2002	Feldman et al.
	253	6,368,141 B1	04-09-2002	Van Antwerp et al.
	254	6,368,274 B1	04-09-2002	Van Antwerp et al.
	255	6,409,740 B1	06-25-2002	Kuhr et al.
	256	6,695,860 B1	02-24-2004	Ward et al.
	257	6,699,188 B2	03-02-2004	Wessel
	258	6,746,582 B2	06-08-2004	Heller et al.
	259	6,770,030 B1	08-03-2004	Schaupp et al.
	260	6,936,006 B2	08-30-2005	Sabra
	261	7,381,184 B2	06-03-2008	Funderburk et al.
	262	2002/0130042 A1	09-19-2002	Moerman et al.
	263	2003/0078560 A1	04-24-2003	Miller et al.
	264	2003/0155656 A1	08-21-2003	Chiu et al.
	265	2003/0002682 A1	01/2003 ~~01-01-2004~~	~~Kovelman et al.~~ Smith, et al.
	266	2004/0064133 A1	04-01-2004	Miller et al.
	267	2004/0133164 A1	07-08-2004	Funderburk et al.
	268	2004/0158207 A1	08-12-2004	Hunn et al.
	269	2005/0090850 A1	04-28-2005	Thoes et al.
	270	2006/0036139 A1	02-16-2006	Brister et al.

Examiner Signature	/H Q NGUYEN/	Date Considered	03/13/2021

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

	203	5,582,184	12-10-1996	Erickson et al.
	204	5,582,697	12-10-1996	Ikeda et al.
	205	5,582,698	12-10-1996	Flaherty et al.
	206	5,586,553	12-24-1996	Halli et al.
	207	5,589,326	12-31-1996	Deng et al.
	208	5,593,852	01-14-1997	Heller et al.
	209	5,596,150	01-21-1997	Arndt et al.
	210	5,617,851	04-18-1997	Lipkovker
	211	5,628,890	05-13-1997	Carter et al.
	212	5,651,869	07-29-1997	Yoshioka et al.
	213	5,660,163	08-26-2007 1997	Schulman et al.
	214	5,665,222	09-09-1997	Heller et al.
	215	5,670,031	09-23-1997	Hintsche et al.
	216	5,680,858	10-28-1997	Hansen et al.
	217	5,682,233	10-28-1997	Brinda
	218	5,695,623	12-09-1997	Michel et al.
	219	5,708,247	01-13-1998	McAleer et al.
	220	5,711,297	01-27-1998	Iliff et al.
	221	5,711,861	01-27-1998	Ward et al.
	222	5,711,862	01-27-1998	Sakoda et al.
	223	5,741,211	04-21-1998	Renirie et al.
	224	5,771,001	06-23-1998	Cobb
	225	5,791,344	08-11-1998	Schulman et al.
	226	5,800,420	09-01-1998	Gross et al.
	227	5,807,375	09-15-1998	Gross et al.
	228	5,820,551	10-13-1998	Hill et al.
	229	5,820,622	10-13-1998	Gross et al.
	230	5,822,715	10-13-1998	Worthington et al.
	231	5,827,184	10-27-1998	Netherly et al.
	232	5,840,020	11-24-1998	Heinonen et al.
	233	5,842,983	12-01-1998	Abel et al.
	234	5,885,211	03-23-1999	Eppstein et al.
	235	5,899,855	05-04-1999	Brown
	236	5,954,643	09-21-1999	Van Antwerp

Change(s) applied to document, /D.M./ 1/26/2022

Examiner Signature	/H Q NGUYEN/	Date Considered	03/13/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicants unique citation designation number (optional). [2]See Kinds of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

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