

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
9 November 2006 (09.11.2006)

PCT

(10) International Publication Number  
**WO 2006/118947 A2**

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

(21) International Application Number:  
PCT/US2006/016027

(22) International Filing Date: 26 April 2006 (26.04.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
11/118,794 29 April 2005 (29.04.2005) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

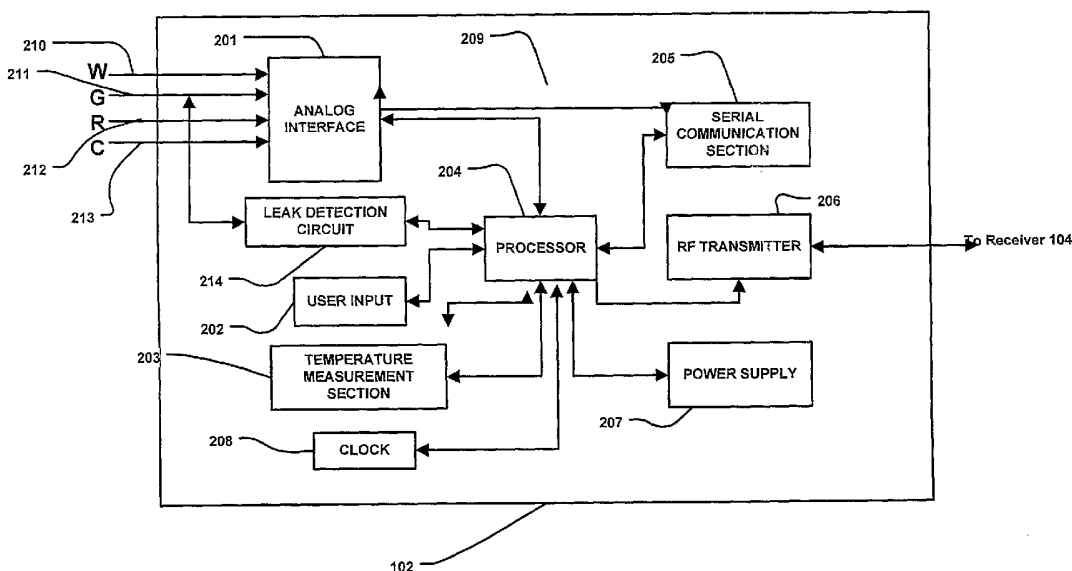
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

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

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR PROVIDING LEAK DETECTION IN DATA MONITORING AND MANAGEMENT SYSTEMS



(57) Abstract: Method and apparatus for providing a leak detection circuit for data monitoring and management system using the guard trace of a glucose sensor by applying a leak detection test signal to determine whether a leakage current is present is provided. The leak detection circuit may includes an interface circuit such as a capacitor coupled to the guard trace to detect the leakage current when the leak detection test signal is applied to the guard trace, such that the user or patient using the data monitoring and management system such as glucose monitoring systems may be promptly and accurately notified of a failed sensor, and to alert the user to replace the sensor.

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METHOD AND APPARATUS FOR PROVIDING LEAK DETECTION  
IN DATA MONITORING AND MANAGEMENT SYSTEMS

PRIORITY

5 This PCT application claims priority to United States Patent Application No. 11/118,794,  
filed April 29, 2005 and is hereby incorporated by reference.

BACKGROUND

10 The present invention relates to data monitoring and management systems. More  
specifically, the present invention relates to method and apparatus for providing leak detection in  
sensors used in data monitoring systems such as glucose monitoring systems.

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  
15 electrometer, and RF signals to transmit the collected data. One aspect of such glucose monitoring  
systems include a sensor configuration which is, for example, mounted on the skin of a subject  
whose glucose level is to be monitored. The sensor cell may use a three-electrode (work, reference  
and counter electrodes) configuration driven by a controlled potential (potentiostat) analog circuit  
connected through a contact system.

20 The current level detected by the work electrode of the sensor is relatively small such that  
even a small amount of leakage current from the reference or counter electrodes typically will affect  
the signal quality, and thus may have adverse effect upon the accuracy of the measured glucose  
level. This is especially true when foreign matter is present that causes a false high glucose reading,  
and which may lead to improper patient treatment. Furthermore, when the glucose monitoring  
25 system is calibrated, the offset and gain of the sensor-transmitter pair is established. If the leakage  
current level changes (i.e., either increases or decreases), then the offset established will likely  
change and a resulting gain error may result for future calibration points.

In view of the foregoing, it would be desirable to have an approach to detect leakage current  
in sensor configuration of data monitoring systems such as in glucose monitoring systems such that  
30 detective sensors resulting from leakage current may be identified that are not detecting signals  
accurately.

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### 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 apparatus for performing leak detection in the sensor of a glucose monitoring system such as continuous or discrete glucose monitoring system. The sensor  
5 may include subcutaneous or transcutaneous sensor and configured to detect glucose levels of a patient, in particular, diabetic patients.

In one embodiment, there is provided a capacitance to a guard electrode of the sensor, and a test signal is applied to the guard electrode to determine whether a current flow can be detected over  
10 the capacitance. If the test signal results in the current flow, it is determined that the current flow is as a result of the existence of leakage current in the sensor, and the user or patient is alerted that the sensor is not functioning properly. In other words, a detection of the leakage current prompts the patient that the sensor is no longer measuring accurate glucose levels, and that replacement of the sensor is recommended.

### 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 of the data monitoring and management system  
20 shown in FIG. 1 in accordance with one embodiment of the present invention;

FIG. 3 illustrates the front end section of the analog interface of the transmitter in accordance with one embodiment of the present invention;

FIGS. 4A-4B respectively show detailed illustrations of the current to voltage circuit and the counter-reference servo circuit of the analog interface shown in FIG. 3 in accordance with one  
25 embodiment of the present invention;

FIG. 5 illustrates the leak detection circuit in accordance with one embodiment of the present invention;

FIGS. 6A-6B illustrate the output response of the current to voltage circuit in the transmitter of the data monitoring and management system of FIG. 1 for 100 MOhm leakage resistance between

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the work and guard electrodes of the sensor with leak detection test signal held for 500 and 250 mseconds, respectively, in accordance with one embodiment of the present invention;

FIGS. 7A-7B illustrate the output response of the current to voltage circuit in the transmitter of the data monitoring and management system of FIG. 1 for 1,000MOhm and 10,000 MOhm leakage resistance, respectively, between work and guard electrodes of the sensor, with leak detection test signal held low for 500 mseconds in accordance with one embodiment; and

FIG. 8 is a flowchart for performing the leak detection test in the sensor of the data monitoring and management system in accordance with one embodiment of the present invention.

### DETAILED DESCRIPTION

FIG. 1 illustrates a data monitoring and management system such as, for example, a glucose monitoring system 100 in accordance with one embodiment of the present invention. In such embodiment, the glucose monitoring system 100 includes a sensor 101, a transmitter 102 coupled to the sensor 101, and a receiver 104 which is configured to communicate with the transmitter 102 via a communication link 103. The receiver 104 may be further configured to transmit data to a data processing terminal 105 for evaluating the data received by the receiver 104. Only one sensor 101, transmitter 102, communication link 103, receiver 104, and data processing terminal 105 are shown in the embodiment of the glucose monitoring system 100 illustrated in FIG. 1. However, it will be appreciated by one of ordinary skill in the art that the glucose monitoring system 100 may include one or more sensor 101, transmitter 102, communication link 103, receiver 104, and data processing terminal 105, where each receiver 104 is uniquely synchronized with a respective transmitter 102. Moreover, within the scope of the present invention, the glucose monitoring system 100 may be a continuous monitoring system, or a semi-continuous or discrete monitoring system.

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

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which corresponds to a sampled glucose level of the user, for transmission to the receiver 104 via the communication link 103.

In one embodiment, the glucose monitoring system 100 is configured as a one-way RF communication path from the transmitter 102 to the receiver 104. In such embodiment, the transmitter 102 transmits the sampled data signals received from the sensor 101 without acknowledgement from the receiver 104 that the transmitted sampled data signals have been received. For example, the transmitter 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 104 may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals. Alternatively, the glucose monitoring system 10 may be configured with a bi-directional RF communication between the transmitter 102 and the receiver 104.

Additionally, in one aspect, the receiver 104 may include two sections. The first section is an analog interface section that is configured to communicate with the transmitter 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 102, which are thereafter, demodulated with a local oscillator and filtered through a band-pass filter. The second section of the receiver 104 is a data processing section which is configured to process the data signals received from the transmitter 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 104 is configured to detect the presence of the transmitter 102 within its range based on, for example, the strength of the detected data signals received from the transmitter 102 or a predetermined transmitter identification information. Upon successful synchronization with the corresponding transmitter 102, the receiver 104 is configured to begin receiving from the transmitter 102 data signals corresponding to the user's detected glucose level. More specifically, the receiver 104 in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized transmitter 102 via the communication link 103 to obtain the user's detected glucose 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

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(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 glucose level of the user.

5           Within the scope of the present invention, the data processing terminal 105 may include an infusion device such as an insulin infusion pump, which may be configured to administer insulin to patients, and which is configured to communicate with the receiver unit 104 for receiving, among others, the measured glucose 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  
10   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 glucose levels received from the transmitter 102.

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  
15   Figure, the transmitter 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 (W) 210, guard contact (G) 211, reference electrode (R) 212, and  
20   counter electrode (C) 213, each operatively coupled to the analog interface 201 of the transmitter 102 for connection to the sensor unit 201 (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, for example, such as carbon which may be printed, or metal foil (e.g., gold) which may be etched.

25           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 102 to provide the necessary power for the transmitter 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.

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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 102, while a unidirectional output is established from the output of the RF transmitter 206 of the transmitter 102 for transmission to the receiver 104. In this manner, a data path is shown in FIG. 2 between the  
5 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 102 is configured to transmit to the receiver 104 (FIG. 1), via the communication link 103 (FIG. 1), processed and encoded data signals received from the sensor 101 (FIG. 1). Additionally, the  
10 unidirectional communication data path between the analog interface 201 and the RF transmitter 206 discussed above allows for the configuration of the transmitter 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 102 during the operation of the transmitter 102. In one  
15 embodiment, the transmitter processor 204 also includes a memory (not shown) for storing data such as the identification information for the transmitter 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 104 under the control of the transmitter processor 204. Furthermore, the power supply 207 may include a commercially available battery.

The transmitter 102 is also configured such that the power supply section 207 is capable of  
20 providing power to the transmitter for a minimum of three months of continuous operation after having been stored for 18 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  $\mu$ A of current. Indeed, in one  
25 embodiment, the final step during the manufacturing process of the transmitter 102 may place the transmitter 102 in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter 102 may be significantly improved.

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

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transmitter 206 of the transmitter 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 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 102 of the data monitoring and management system 100. As discussed in further detail below in conjunction with FIGS. 7-11, the leak detection circuit 214 in accordance with the various embodiments the leak detection circuit 214 is configured to detect leakage current in the sensor 101 to determine whether the measured sensor data are corrupt or whether the measured data from the sensor 101 is accurate.

Additional detailed description of the continuous glucose 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, and the disclosures of each of which are incorporated herein by reference for all purposes.

FIG. 3 illustrates the front end section of the analog interface of the transmitter in accordance with one embodiment of the present invention. Referring to the Figure, the front end section of the analog interface 201 includes a current to voltage circuit 301 which is configured to operatively couple to the work electrode 210 and the guard electrode 211, and a counter-reference servo circuit 302 which is configured to operatively couple to the reference electrode 212 and the counter electrode 213. It can be further seen from the Figure that the guard electrode 211 is also coupled to the leak detection circuit 214 of the transmitter 102. As discussed in further detail below, under the operation and control of the processor 204 of the transmitter, the leak detection circuit 214 in one embodiment may be configured to detect leakage current in the sensor 101 of the data monitoring and management system 100.

FIGS. 4A-4B illustrate detailed illustrations of the current to voltage circuit and the counter-reference servo circuit, respectively, of the analog interface shown in FIG. 3 in accordance with one embodiment of the present invention. Referring to FIG. 4A, the current to voltage circuit 301 (FIG.

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3) in one embodiment includes an operational amplifier 402 having a non-inverting input terminal 405, and an inverting input terminal 404. Also shown in the Figure is a resistor 401 operatively coupled to the inverting input terminal 404 of the operational amplifier 402, and an output terminal 406.

5 Referring again to FIG. 4A, the work electrode 210 is operatively coupled to the inverting input terminal 404 of the operational amplifier 402, while the guard electrode 211 is operatively coupled to the non-inverting input terminal 405 of the operational amplifier 402. It can be further seen that the work voltage source  $V_w$  is provided to the non-inverting terminal 405 of the operational amplifier 402. In this manner, in accordance with one embodiment of the present  
10 invention, a separate contact, the guard electrode 211 is operatively coupled to the analog interface 201 (FIG. 2) of the transmitter 102 (FIG. 2). The guard electrode 211 as discussed in further detail below is provided at a substantially equipotential to the work electrode 210 such that any current leakage path to the work electrode 210 (from either the reference electrode 212 or the counter electrode 213, for example) is protected by the guard electrode 211 by maintaining the guard  
15 electrode 211 at substantially the same potential as the work electrode 210.

Referring now to FIG. 4B, the counter-reference servo unit 302 in accordance with one embodiment includes an operational amplifier 407 having an inverting input terminal 408 and a non-inverting input terminal 409, as well as an output terminal 410. In one embodiment, the reference electrode 212 is operatively coupled to the inverting input terminal 408, while the counter electrode  
20 213 is operatively coupled to the output terminal 410 of the operational amplifier 407 in the counter-reference servo unit 302. It can also be seen from FIG. 4B that a reference voltage source  $V_r$  is provided to the non-inverting input terminal 409 of the operational amplifier 407 in the counter-reference servo unit 302.

Referring back to FIGS. 3 and 4A-4B, in accordance with one embodiment of the present  
25 invention, the current to voltage circuit 301 and the counter-reference servo unit 302 are operatively coupled to the remaining sections of the analog interface 201 of the transmitter 102, and configured to convert the detected glucose level at the sensor unit 101 (FIG. 1) into an analog signal for further processing in the transmitter unit 102. It should also be noted that, in the manner described, the Poise voltage (for example, at a value of 40 mV) may be determined based on the difference  
30 between the voltage signal level of the work voltage source  $V_w$  at the non-inverting input terminal

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405 of the operational amplifier 402 in the current to voltage circuit 301, and the voltage signal level of the reference voltage source  $V_r$  at the non-inverting input terminal 409 of the operational amplifier 407 in the counter-reference servo unit 302.

FIG. 5 illustrates the leak detection circuit in accordance with one embodiment of the present invention. Referring to the Figure, leak detection circuit 214 includes, in one embodiment, a resistor 501 coupled to the guard electrode 211. As can be seen, the resistor 501 is further operatively coupled to a capacitor 503. The capacitor 503 is also operatively coupled to the processor 204 of the transmitter 102 in the data monitoring and management system. Referring to FIG. 5, in normal operation, the guard electrode 211 is biased by the guard electrode bias voltage source is coupled at node or junction 504.

In one embodiment, the guard electrode bias voltage source may be the work voltage source ( $V_w$ ) shown in FIG. 4A. As can be further seen from FIG. 5, there is also provided a resistor 502 operatively coupled to the node or junction 504. In this manner, the guard electrode 211 in the sensor 101 may be configured to function during normal operations to protect the work electrode 210 from leakage current from the other electrodes in the sensor 101, and also, in addition, to receive a leak detection test signal from the processor 204 at predetermined time intervals.

The processor 204 in one embodiment may be configured to transmit a leak detection test signal to the leak detection circuit 214. More specifically, when the processor 204 transmits a leak detection test signal discussed in further detail below, if leakage resistance is present in the sensor 101 (for example, due to contamination or water presence), a leakage current will flow from the work electrode 210 to the guard electrode 211 over the resistor 501 and capacitor 503 in the leak detection circuit 214. In turn, due to the current flow from the work electrode 210 to the guard electrode 211, the current to voltage circuit 301 (FIG. 3) in the transmitter 102 is configured to detect the current flow path, and correspondingly signal the processor 204 that leakage current exists in the sensor 101. The output response of the current to voltage circuit 301 (FIG. 3) based on the detection of leakage current described above is shown in FIGS 6A-6B and 7A-7B as described in further detail below.

On the other hand, if the leakage resistance level is below a nominal threshold level (and thus not substantially impeding sensor 101 function) , then substantially no leakage current exists

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from the work electrode 210 to the guard electrode 211 that can be detected by the current to voltage circuit 301 in the analog front end of the transmitter 102.

For example, referring back to FIG. 4A, in one embodiment, the guard electrode 211 is normally held at the signal level of the work voltage source  $V_w$  which may be within 12 millivolts of the voltage signal level at the work electrode 210. During normal operation, this helps reduce leakage current affecting the work electrode 210. When it is desired to test for the leakage current in the sensor 101, a leak detection test signal may be applied to the guard electrode 211 from the processor 204 of the transmitter 102 to detect leakage current in the sensor 101 as discussed in further detail in conjunction with FIG. 8 below.

In operation, during the leak detection test, the leak detection test signal (normally held at 3 Volts) from the processor 204 is switched from the three (3) Volts to zero (0) Volts. If moisture or other conductive contamination is present in the sensor 101, leakage current will flow into the capacitor 702 from the guard electrode 211 at a rate that is a function of the leakage resistance between the work electrode 210 and the guard electrode 211. This current produces a corresponding output signal from the transimpedance operational amplifier 402 (FIG. 4A) which is the current to voltage function that measures the sensor 101 current or signal.

Referring to the Figures, the magnitude of the output signal from the transimpedance amplifier 402 (FIG. 4A) is a function of the time that the leakage test signal is held at the zero (0) Volt, and also the leakage resistance. This can be seen from the FIGS 6A-6B and 7A-7B discussed in further detail below. Thus, it is possible to detect the presence of a leakage current in the sensor 101 of the data monitoring and management system 100, and alert the user that the measured values received from the sensor 101 may be inaccurate.

Referring back to FIG. 5, the capacitor 503 in one embodiment may include a ceramic capacitor with a very high leakage resistance, for example, a 10 GOhms of leakage resistance.

Furthermore, within the scope of the present invention, while the capacitor 503 is used in the leak detection circuit 214 to transfer alternate current (A/C) signals while blocking direct current (D/C) signals, thereby creating no offset an interface circuit may be used such as a resistor, field effect transistor (FET), an inductor, or any other circuit element which can be configured to transfer a signal from the processor 204 to the guard electrode 211. Moreover, the leak detection test signal within the present invention may include a digital signal or an analog signal such as a sine wave or a

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pulse which may also be varied in magnitude. Each of these analog and digital signals can also be varied in frequency or driven as a single pulse leak detection test signal.

FIGS. 6A-6B illustrate the output response of the current to voltage circuit 301 of the transmitter 102 for 100 MOhm leakage resistance between the work and guard electrodes with leak detection test signal held for 500 and 250 mseconds, respectively, in accordance with one embodiment of the present invention. More specifically, these Figures illustrate the response to a 100 MOhm leakage resistance that exists between the guard electrode 211 and the work electrode 210 of the sensor 101, where the response signal shown are the output of the transimpedance amplifier 402 (FIG. 4A) as detected by the processor 204 in the transmitter 102.

By comparing the responses shown in these Figures, the difference in response between a 500 millisecond test signal and a 250 millisecond leakage test signal period can be seen. In other words, the length of the leak detection testing period is directly correlated with the sensitivity of the leakage detection and thus accuracy of the leakage detection. That is, the longer the duration of the leak detection test signal, the higher the resolution of the test signal or accuracy. In other words, referring to FIGS. 6A-6B, it can be seen that in FIG. 6A, the duration of the leak detection test signal was maintained at 500 milliseconds which yielded a peak signal at greater than 300 ADC (analog to digital converter) counts corresponding to the voltage level, and which in turn, corresponding to the leakage current in the sensor 101 with the 100 Mega Ohm leakage resistance. On the other hand, as shown in FIG. 6B, with the duration of the leak detection test signal at 250 milliseconds, the peak signal was greater than 100 ADC counts based on the same 100 Mega Ohm leakage resistance.

FIGS. 7A-7B illustrate the output response of the current to voltage circuit 301 in the transmitter 102 of the system 100 (FIG. 1) for 1,000MOhm and 10,000 MOhm leakage resistance, respectively, between work and guard electrodes, with leak test signal held low for 500 mseconds in accordance with one embodiment. More specifically, FIGS 7A and 7B illustrate additional examples of a much lower leakage current with a substantially higher leakage resistance between the work electrode 210 and the guard electrode 211 of the sensor 101. In particular, it can be seen from the Figures that the leak detection test approach as disclosed in accordance with the various embodiments of the present invention is suitable to detect very high values of leakage resistance. For example, referring to FIG. 7A, with leakage resistance of 1000 MOhms and a leakage detection

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test signal duration of 500 milliseconds, the output response of greater than 15 ADC counts was detected, which can be detected and identified as the leakage current in the sensor 101. In FIG. 7B, an even higher leakage resistance of 10,000 Mega Ohms was used at a leakage detection test signal duration of 500 milliseconds which yielded an output response of approximately 3 ADC counts  
5 which can still be detected, so as to identify the presence of the leakage current in the sensor 101.

FIG. 8 is a flowchart for performing the leak detection test in the sensor of the data monitoring and management system in accordance with one embodiment of the present invention. Referring to the Figure, at step 801, an iterative variable N is set to zero (0) and the leak detection signal bit is set to Low. In one embodiment, a counter or a latch in the processor 204 may be  
10 configured to set the iterative variable to zero and to store that value (for example, in its internal memory), and at step 802, the leak detection signal from the processor 204 may be set at zero volts. Thereafter at step 803, the signal response on the guard electrode 211 is measured. For example, in one embodiment, the processor 204 is configured to detect a current on the guard electrode 211 in response to the leak detection signal set at Low (0 volts) from the processor 204.

15 Referring to FIG. 8, at step 804, the processor 204 is configured to determine whether the detected response at step 803 exceeds a normal sensor level, which, the processor 204 has pre-stored. For example, the normal sensor level in one embodiment may include the sensor signal level which was measured just prior to the leak detection test routine discussed herein. In one embodiment, an additional tolerance may be added to the sensor signal level measured prior to the  
20 leak detection routine discussed herein, where the tolerance level corresponds to an acceptable leakage level.

If the response compared at step 804 is not greater than the normal sensor level, then at step 805, it is determined that no leakage current is detected, and the procedure terminates. Referring back to the Figure, if at step 804 it is determined that the response measured at step 803 is not  
25 greater than the normal sensor level, then at step 100, the iterative variable is retrieved and compared to determine whether it exceeds a leakage confirmation value. In one embodiment, the leakage confirmation value may be three. In other words, if three consecutive response measurement detects the response to be greater than the normal threshold level (step 804), then the leakage in the sensor 101 is configured and flagged for the user to replace the sensor 101.

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Referring back to FIG. 8, if at step 806 it is determined that the iterative variable N is greater than the leakage confirmation value, then at step 807, it is confirmed that a leakage current is detected and the user may be notified that the data received from the sensor 101 may no longer be accurate. On the other hand, if at step 806 it is determined that the iterative variable N is not greater  
5 than the leakage confirmation value, then at step 808, the leak detection bit is set to High (e.g., 3 Volts), and the routine at step 809 waits for the settling time period. The settling time may be based on the selected leak detection signal duration, and in one embodiment, may be in the order of 2 or 3 seconds. Thereafter at step 810, the iterative variable N is incremented by one (1), and the routine returns to step 802.

10 In an alternate embodiment of the present invention, the routine may also include an additional step or measuring the sensor signal level at the sensor 101 (FIG. 1) after incrementing the iterative variable N 810 and prior to returning to the leak detection routine at step 802. In this case, the normal sensor level at step 804 to which the measured response (step 803) is compared will be the measured sensor signal level at the additional step described above.

15 In the manner described above, an apparatus including a leak detection circuit in one embodiment of the present invention includes a guard contact, an interface circuit coupled to the guard contact, a processor coupled to the interface circuit, the processor configured to drive a leak detection test signal via the interface circuit to the guard contact, where the processor is further configured to detect a leakage signal in response to the leak detection test signal.

20 The interface circuit may in one embodiment include a capacitor, and further, the leak detection test signal may include a digital signal or an analog signal.

Moreover, the guard contact may include in one embodiment the guard electrode of a sensor.

Furthermore, the sensor may include a plurality of electrodes, one of the plurality of electrodes including a work electrode and a guard electrode, the guard electrode including the guard  
25 trace, where the leakage signal detected by the processor includes a sensor signal from the sensor.

An apparatus including a leak detection circuit in another embodiment includes a guard electrode, a capacitor coupled to the guard electrode, and a processor coupled to the capacitor, the processor configured to drive a leak detection test signal via the capacitor to the guard electrode, where the processor is further configured to detect a leakage signal in response to the leak detection  
30 test signal.

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The capacitor in one embodiment may include a ceramic capacitor.

In a further embodiment, the apparatus may also include a sensor, the sensor having a plurality of electrodes, one of the plurality of electrodes including a work electrode and the guard electrode, and further, where the leakage signal detected by the processor may include a sensor  
5 signal from the sensor.

A method of providing a leak detection circuit in a further embodiment of the present invention includes the steps of providing a guard contact, coupling an interface circuit to the guard contact, driving a leak detection test signal via the interface circuit to the guard contact, and detecting a leakage signal in response to the leak detection test signal.

10 In one aspect, the detecting step may include the step of consecutively detecting the leakage signal a predetermined number of iterations, where in one embodiment, the predetermined number of iterations includes three.

Further, the step of driving the leak detection test signal may include the step of setting a leak detection bit to zero.

15 In the manner described above, in accordance with the various embodiments of the present invention, there is provided a method and apparatus for performing leak detection in a sensor configuration for use in data monitoring and management system such as glucose monitoring systems (continuous or discrete). In particular, in accordance with the present invention, it is possible to easily and accurately detect leakage current in the sensor configuration such that the  
20 signal integrity of the measured signals from the sensor can be maintained, and further, the user or patient of the data monitoring and management system may be alerted of the leakage detection in the sensor to replace the same in the system.

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  
25 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.

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WHAT IS CLAIMED IS:

1. An apparatus including a leak detection circuit, comprising:  
a guard contact;  
an interface circuit coupled to the guard contact; and  
5 a processor coupled to the interface circuit, the processor configured to drive a leak detection test signal via the interface circuit to the guard contact,  
wherein the processor is further configured to detect a leakage signal in response to the leak detection test signal.
- 10 2. The apparatus of claim 1 wherein the interface circuit includes a capacitor.
3. The apparatus of claim 1 wherein the leak detection test signal includes one of a digital signal and an analog signal.
- 15 4. The apparatus of claim 1, wherein the guard contact includes the guard electrode of a sensor.
5. The apparatus of claim 1 further including a sensor, the sensor including a plurality of electrodes, one of the plurality of electrodes including a work electrode and a guard electrode, the guard electrode including the guard trace.
- 20 6. The apparatus of claim 5 wherein the leakage signal detected by the processor includes a sensor signal from the sensor.
7. An apparatus including a leak detection circuit, comprising:  
25 a guard electrode;  
a capacitor coupled to the guard electrode; and  
a processor coupled to the capacitor, the processor configured to drive a leak detection test signal via the capacitor to the guard electrode,  
wherein the processor is further configured to detect a leakage signal in response to  
30 the leak detection test signal.

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8. The apparatus of claim 7 wherein the leak detection test signal includes one of a digital signal and an analog signal.

5 9. The apparatus of claim 7 wherein the capacitor includes a ceramic capacitor.

10. The apparatus of claim 7 further including a sensor, the sensor including a plurality of electrodes, one of the plurality of electrodes including a work electrode and the guard electrode.

10 11. The apparatus of claim 10 wherein the leakage signal detected by the processor includes a sensor signal from the sensor.

12. A method of providing a leak detection circuit, comprising the steps of:

providing a guard contact;

15 coupling an interface circuit to the guard contact;

driving a leak detection test signal via the interface circuit to the guard contact; and

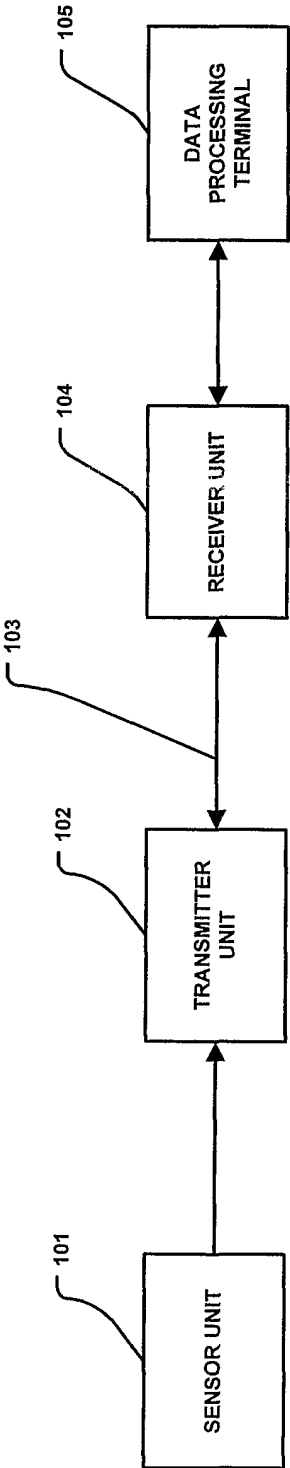
detecting a leakage signal in response to the leak detection test signal.

20 13. The method of claim 12 wherein the leak detection test signal includes one of a digital signal and an analog signal.

14. The method of claim 12 wherein the detecting step includes the step of consecutively detecting the leakage signal a predetermined number of iterations.

25 15. The method of claim 14 wherein the predetermined number of iterations includes three.

16. The method of claim 12 wherein the step of driving the leak detection test signal includes the step of setting a leak detection bit to zero.



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FIGURE 1

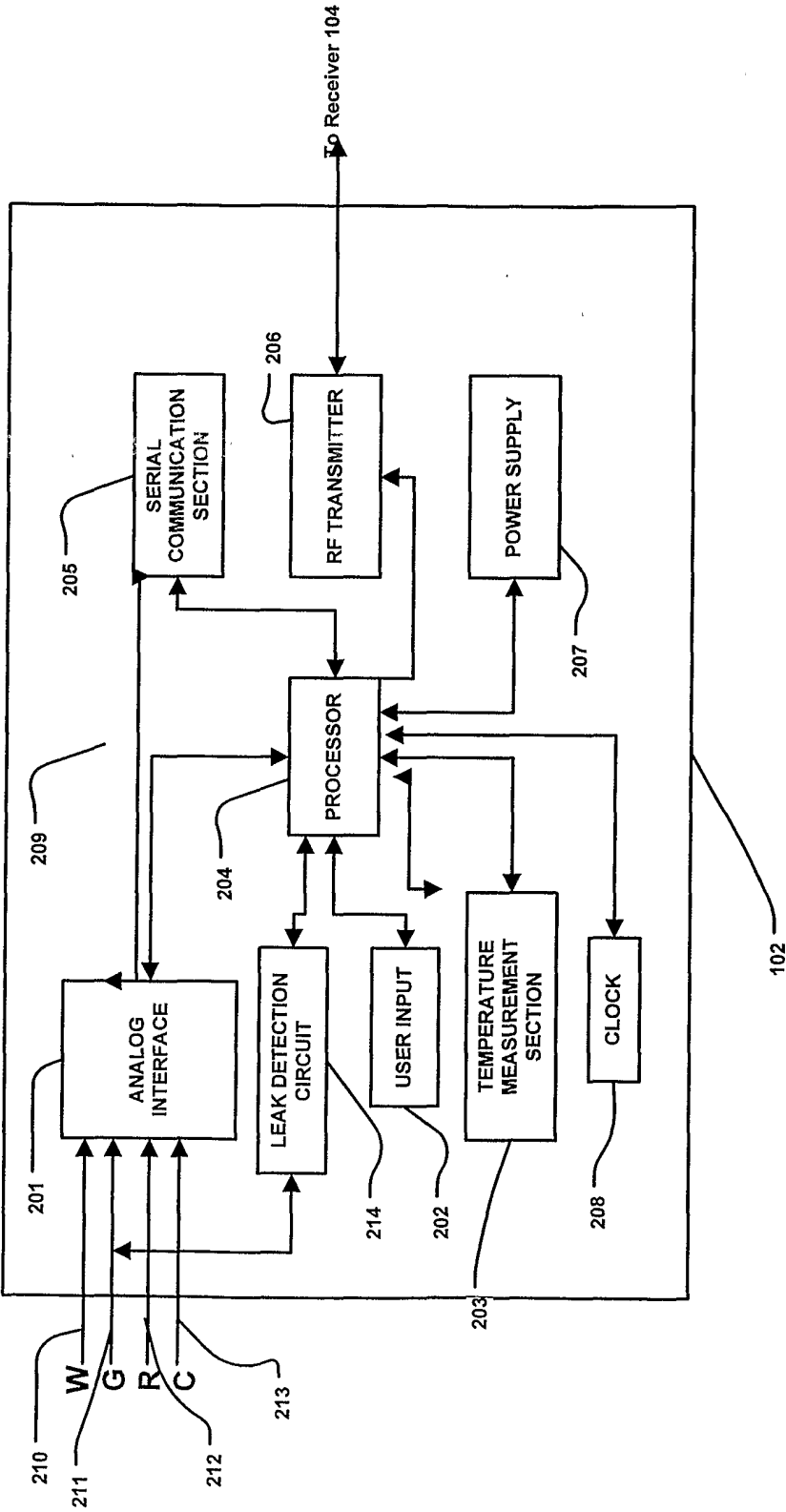


FIGURE 2

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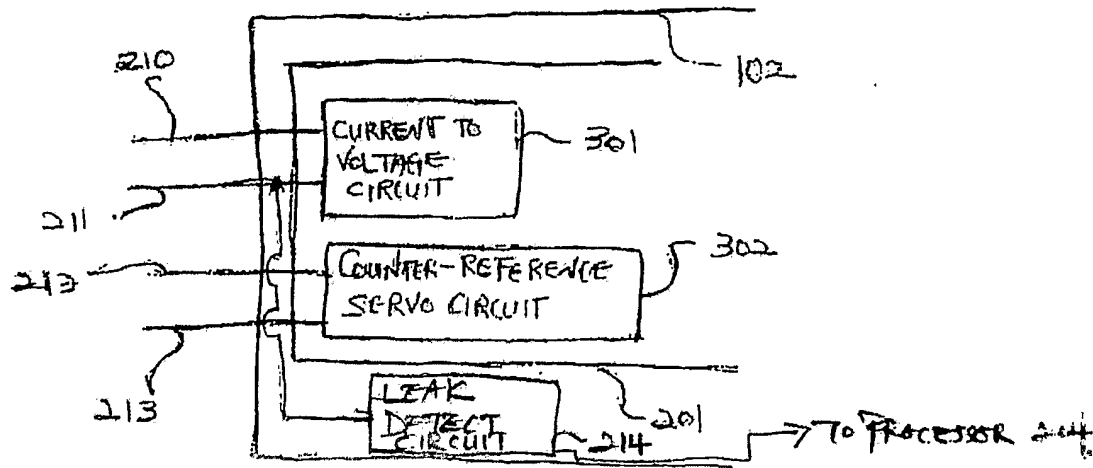


FIGURE 3

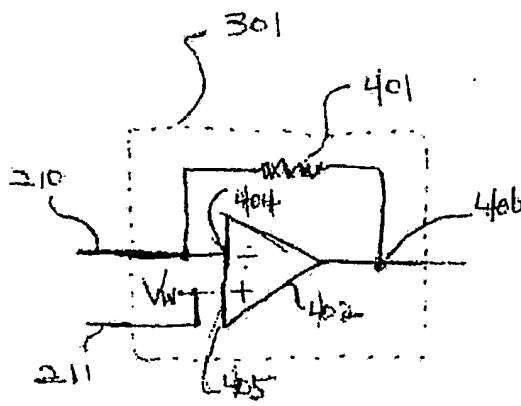


FIGURE 4A

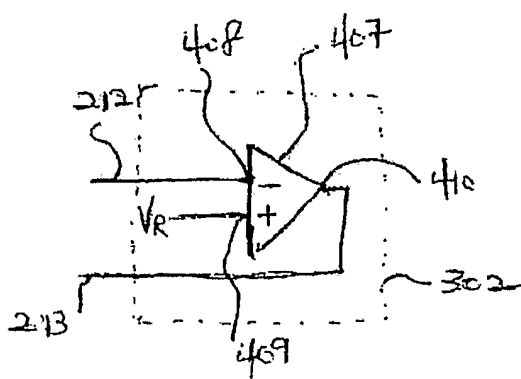


FIGURE 4B

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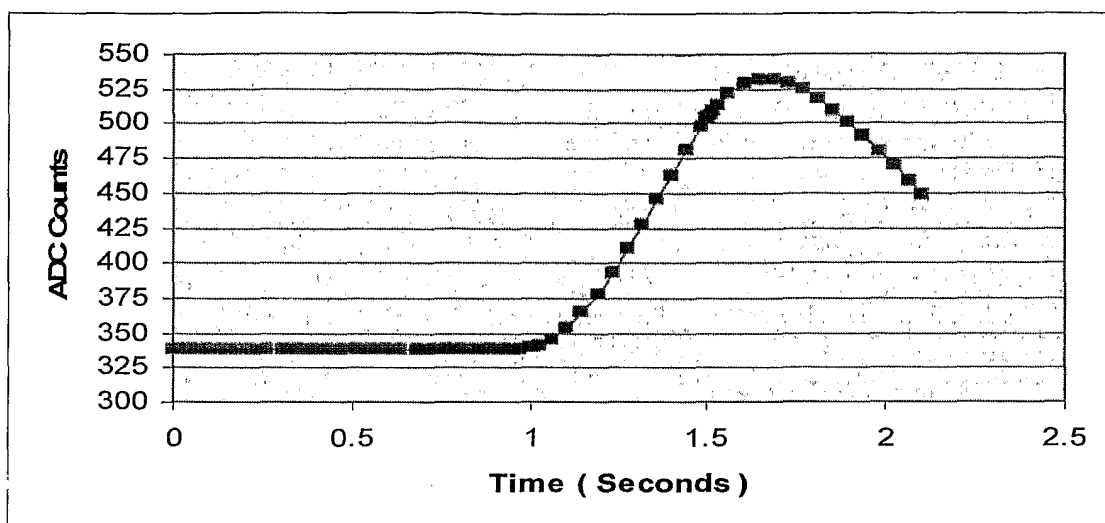


FIGURE 6A

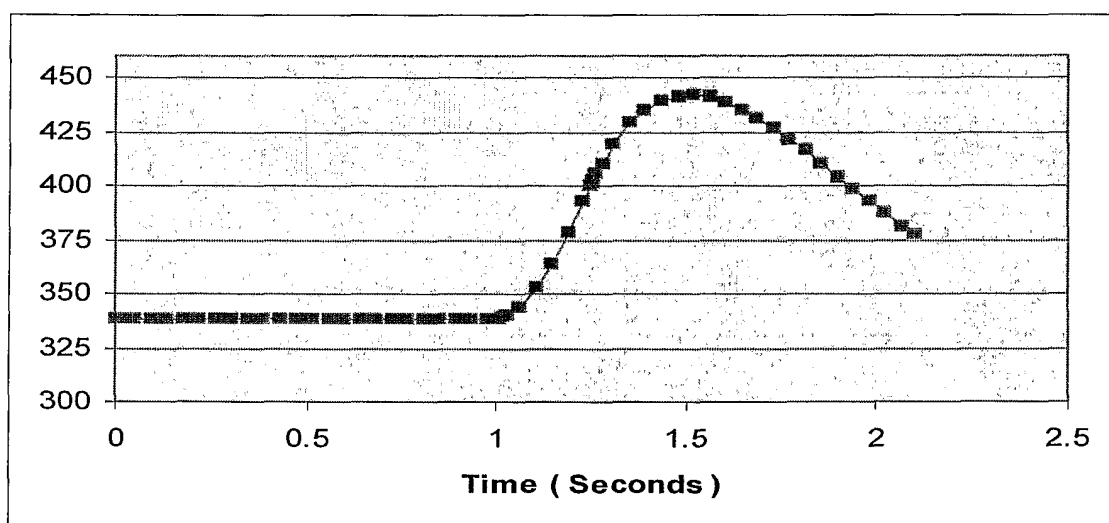


FIGURE 6B

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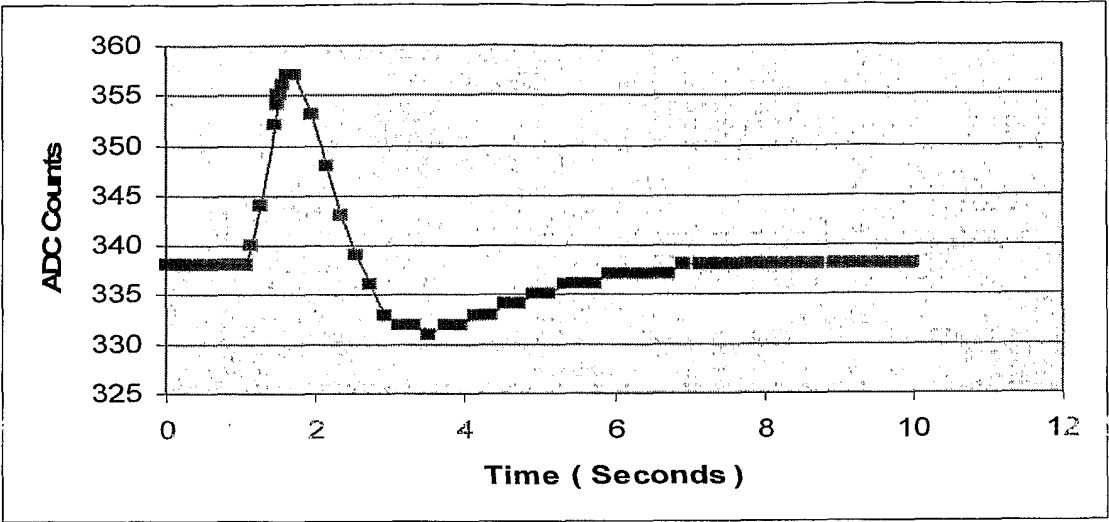


FIGURE 7A

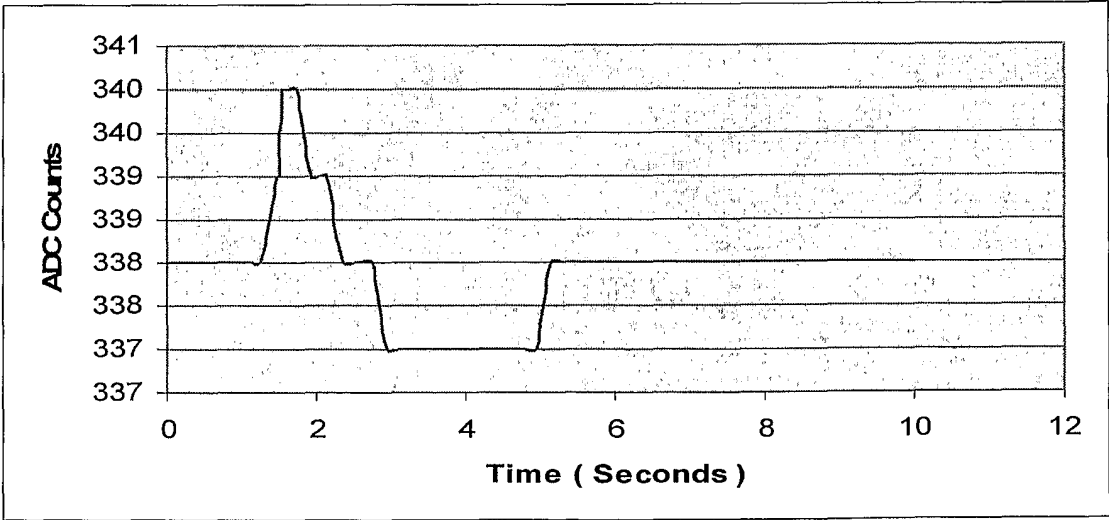


FIGURE 7B