US009743866B2

(12) **United States Patent**
Fennell

(10) **Patent No.: US 9,743,866 B2**
(45) **Date of Patent: Aug. 29, 2017**

(54) **METHOD AND APPARATUS FOR PROVIDING DYNAMIC MULTI-STAGE SIGNAL AMPLIFICATION IN A MEDICAL DEVICE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/209,741**

(22) Filed: **Jul. 13, 2016**

(65) **Prior Publication Data**

US 2016/0317071 A1 Nov. 3, 2016

Related U.S. Application Data

(63) Continuation of application No. 14/596,759, filed on Jan. 14, 2015, now Pat. No. 9,402,584, which is a continuation of application No. 14/188,659, filed on Feb. 24, 2014, now Pat. No. 8,937,540, which is a continuation of application No. 13/867,948, filed on Apr. 22, 2013, now Pat. No. 8,698,615, which is a (Continued)

(51) **Int. Cl.**

G08B 29/00	(2006.01)
A61B 5/145	(2006.01)
A61B 5/1486	(2006.01)
A61B 5/00	(2006.01)
A61M 5/172	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/14532*** (2013.01); ***A61B 5/002*** (2013.01); ***A61B 5/0004*** (2013.01); ***A61B 5/14546*** (2013.01); ***A61B 5/14865*** (2013.01); ***A61B 5/7225*** (2013.01); ***A61B 5/7246*** (2013.01); ***A61B 5/7475*** (2013.01); ***A61M 5/1723*** (2013.01); *A61B 2560/0209* (2013.01); *A61B 2560/0252* (2013.01); *A61B 2560/045* (2013.01)

(58) **Field of Classification Search**

CPC A61B 5/14532; A61B 5/14546; A61B 5/14865; A61B 5/7475; A61B 5/002; A61B 5/0004; A61B 5/7225; A61B 5/7246

USPC 340/511

See application file for complete search history.

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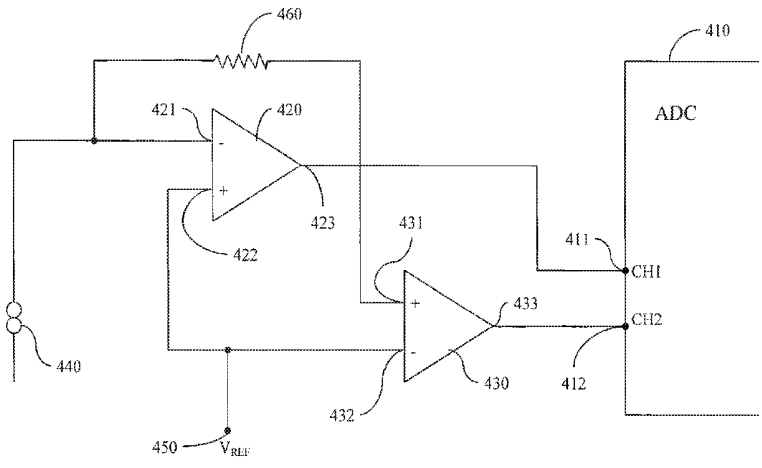
(57) **ABSTRACT**

Methods and apparatus for providing multi-stage signal amplification in a medical telemetry system are provided.

20 Claims, 4 Drawing Sheets



Related U.S. Application Data

continuation of application No. 13/437,894, filed on Apr. 2, 2012, now Pat. No. 8,427,298, which is a continuation of application No. 13/114,029, filed on May 23, 2011, now Pat. No. 8,149,103, which is a continuation of application No. 12/849,004, filed on Aug. 2, 2010, now Pat. No. 7,948,369, which is a continuation of application No. 12/102,836, filed on Apr. 14, 2008, now Pat. No. 7,768,387.

(60) Provisional application No. 60/911,866, filed on Apr. 14, 2007.

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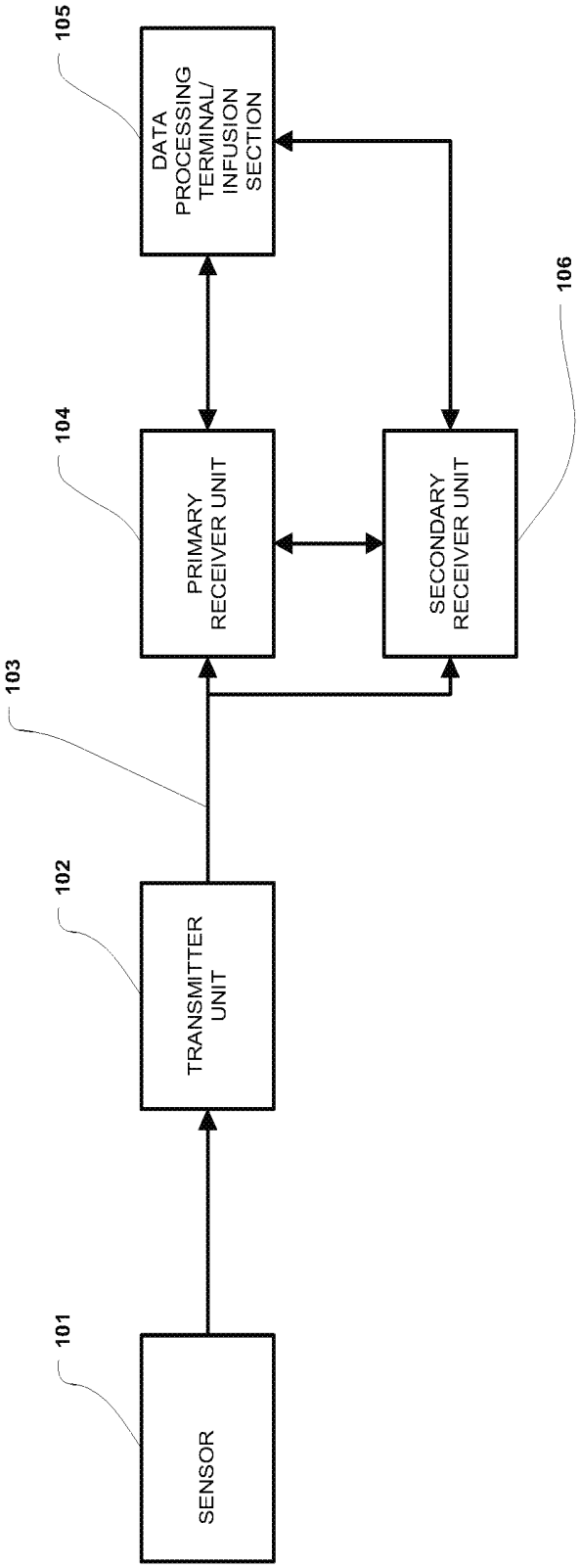
105
DATA PROCESSING TERMINAL/ INFUSION SECTION
106
104
PRIMARY RECEIVER UNIT
SECONDARY RECEIVER UNIT
103
102
TRANSMITTER UNIT
101
SENSOR

100

FIGURE 1

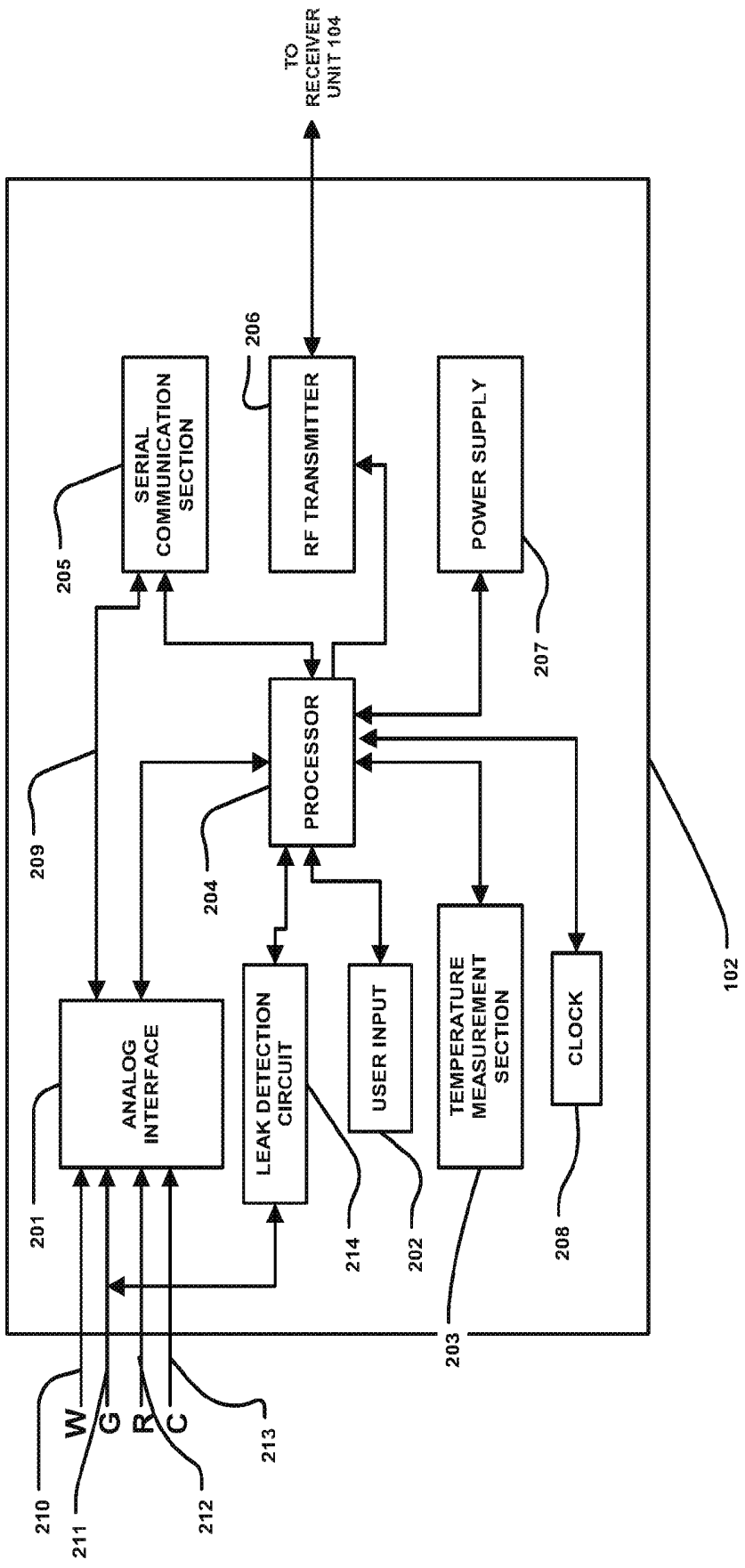
TO RECEIVER UNIT 104
206
SERIAL COMMUNICATION SECTION
RF TRANSMITTER
POWER SUPPLY
205
207
PROCESSOR
209
204
ANALOG INTERFACE
LEAK DETECTION CIRCUIT
USER INPUT
TEMPERATURE MEASUREMENT SECTION
CLOCK
102
201
214
202
208
203
W
G
R
C
213
210
211
212

FIGURE 2

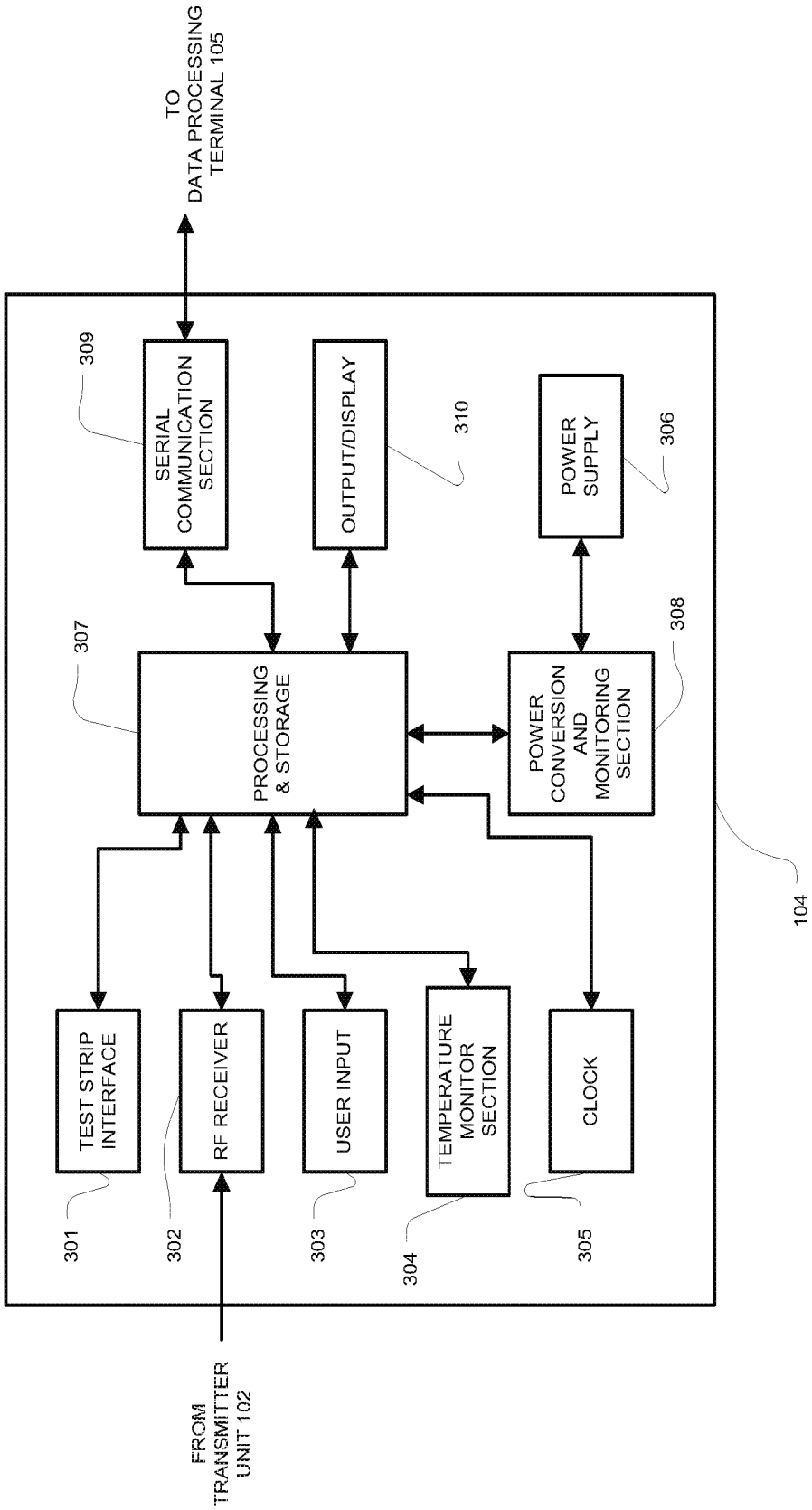
TO
DATA PROCESSING
TERMINAL 105
309
SERIAL
COMMUNICATION
SECTION
OUTPUT/DISPLAY
310
POWER
SUPPLY
306
307
PROCESSING
& STORAGE
POWER
CONVERSION
AND
MONITORING
SECTION
308
104
TEST STRIP
INTERFACE
RF RECEIVER
USER INPUT
TEMPERATURE
MONITOR
SECTION
CLOCK
301
302
303
304
305
FROM
TRANSMITTER
UNIT 102

FIGURE 3

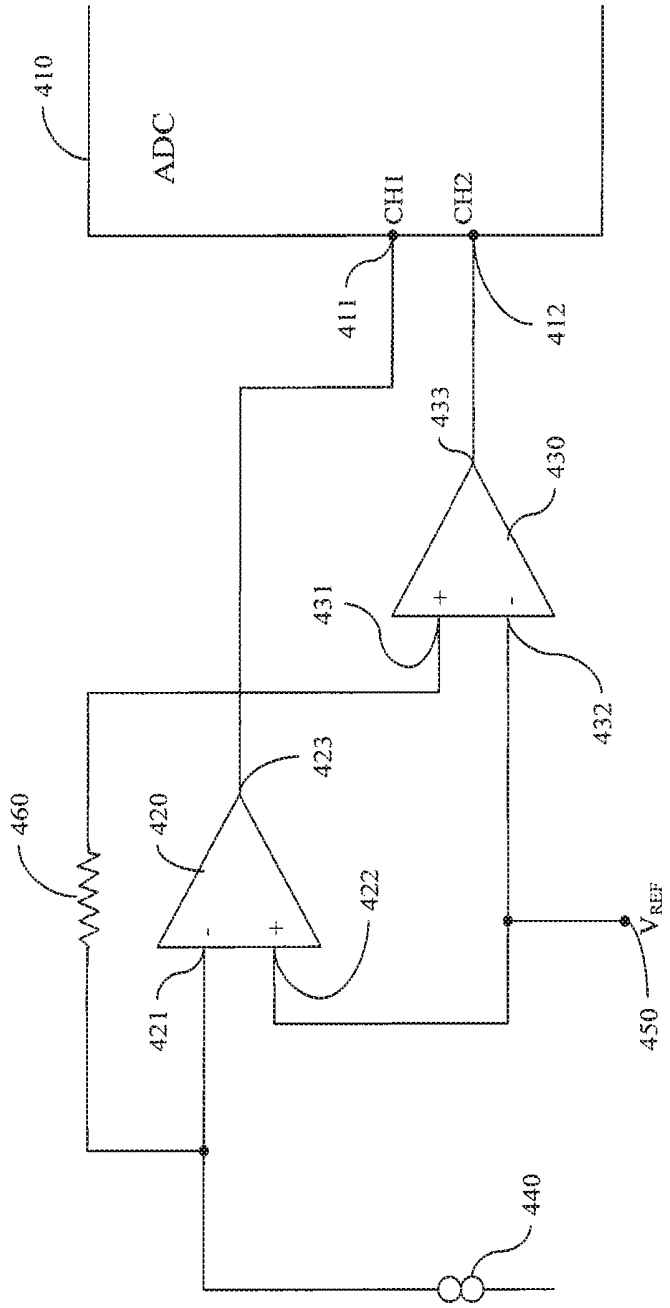
410
ADC
CH1
CH2
411
412
433
430
431
432
423
420
422
460
421
450
V_{REF}
440

FIGURE 4

METHOD AND APPARATUS FOR PROVIDING DYNAMIC MULTI-STAGE SIGNAL AMPLIFICATION IN A MEDICAL DEVICE

RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 14/596,759 filed Jan. 14, 2015, which is a continuation of U.S. patent application Ser. No. 14/188,659 filed Feb. 24, 2014, now U.S. Pat. No. 8,937,540, which is a continuation of U.S. patent application Ser. No. 13/867,948 filed Apr. 22, 2013, now U.S. Pat. No. 8,698,615, which is a continuation of U.S. patent application Ser. No. 13/437,894 filed Apr. 2, 2012, now U.S. Pat. No. 8,427,298, which is a continuation of U.S. patent application Ser. No. 13/114,029 filed May 23, 2011, now U.S. Pat. No. 8,149,103, which is a continuation of U.S. patent application Ser. No. 12/849,004 filed Aug. 2, 2010, now U.S. Pat. No. 7,948,369, which is a continuation of U.S. patent application Ser. No. 12/102,836 filed Apr. 14, 2008, now U.S. Pat. No. 7,768,387, which claims priority under §35 U.S.C. 119(e) to U.S. Provisional Application No. 60/911,866 filed Apr. 14, 2007, entitled "Method and Apparatus for Providing Dynamic Multi-Stage Signal Amplification in a Medical Device", 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, and RF signals to transmit the collected data. One aspect of certain analyte monitoring systems include a transcutaneous or subcutaneous analyte sensor configuration which is, for example, partially mounted on the skin of a subject whose analyte level is to be monitored. The sensor cell may use a two or three-electrode (work, reference and counter electrodes) configuration driven by a controlled potential (potentiostat) analog circuit connected through a contact system.

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

In view of the foregoing, it would be desirable to have a method and apparatus for providing a dynamic multi-stage amplification of signals for use in medical telemetry systems such as, for example, analyte monitoring systems.

SUMMARY OF THE INVENTION

In one embodiment, an apparatus including a first amplifier having at least one input terminal and an output terminal, the at least one input terminal coupled to a signal source, the output terminal configured to provide a first output signal, a second amplifier having at least one input terminal and an output terminal, the at least one input terminal coupled to the output terminal of the first amplifier, the output terminal of the second amplifier configured to provide a second output signal, a processor operatively coupled to receive the first output signal and the second output signal, where the first output signal is a predetermined ratio of the second output signal, and further, where the first output signal and the second output signal are associated with a monitored analyte level of a user is disclosed.

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; and

FIG. **4** is a schematic of the dynamic multi-stage signal amplification in the transmitter unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

As described in further detail below, in accordance with the various embodiments of the present invention, there is provided a method and apparatus for providing dynamic multi-stage signal amplification for use in a medical telemetry system. In particular, within the scope of the present invention, there are provided method and apparatus for a multi-stage signal amplifier configuration in the analog interface of the data transmitter unit in the data processing and management system.

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

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

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

Only one sensor **101**, transmitter unit **102**, communication link **103**, and data processing terminal **105** are shown in the embodiment of the analyte monitoring system **100** illustrated in FIG. **1**. However, it will be appreciated by one of ordinary skill in the art that the analyte monitoring system **100** may include one or more sensor **101**, transmitter unit **102**, communication link **103**, and data processing terminal **105**. Moreover, within the scope of the present 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 coupled to the sensor **101** so that both devices are positioned on the user's body, with at least a portion of the analyte sensor **101** positioned transcutaneously under the skin layer of the user. The transmitter unit **102** performs data processing such as filtering and encoding on data signals, each of which corresponds to a sampled analyte level of the user, for transmission to the primary receiver unit **104** via the communication link **103**.

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

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

In operation, upon completing the power-on procedure, the primary receiver unit **104** is configured to detect the presence of the transmitter unit **102** within its range based on, for example, the strength of the detected data signals received from the transmitter unit **102** or 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 or the like, which may be configured to administer insulin to patients, and which may be configured to communicate with the receiver unit **104** for receiving, among others, the measured analyte level. Alternatively, the receiver unit **104** may be configured to integrate an infusion device therein so that the receiver unit **104** is configured to administer insulin therapy to patients, for example, for administering and modifying basal profiles, as well as for determining appropriate boluses for administration based on, among others, the detected analyte levels received from the transmitter unit **102**.

Additionally, the transmitter unit **102**, the primary receiver unit **104** and the data processing terminal **105** may each be configured for bi-directional wireless communication such that each of the transmitter unit **102**, the primary receiver unit **104** and the data processing terminal **105** may

be configured to communicate (that is, transmit data to and receive data from) with each other via the wireless communication link. 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, where the communication link, 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 unit **104** including data processing for managing the patient's insulin therapy and analyte monitoring. In one embodiment, the communication link **103** may include one or more of an RF communication protocol, an infrared communication protocol, a Bluetooth® enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPAA 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 (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 **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, for example, such as carbon which may be printed, or metal foil (e.g., gold) which may be etched. Moreover, in a further aspect, the electrode layers may be disposed in a stacked configuration where, each of the working electrode **210**, the reference electrode **212** and the counter electrode **213** may be disposed on a substrate layer with one or more dielectric layers disposed therebetween such that at least a portion of each of the electrodes are positioned on top of one another in a stacked or layered configuration.

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

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

The transmitter unit **102** is also configured such that the power supply section **207** is capable of providing power to the transmitter for a minimum of about three months of continuous operation after having been stored for about eighteen months in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor **204** operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μA of current. Indeed, in one embodiment, the final step during the manufacturing process of the transmitter unit **102** may place the transmitter unit **102** in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter unit **102** may be significantly improved. Moreover, as shown in FIG. **2**, while the power supply unit **207** is shown as coupled to the processor **204**, and as such, the processor **204** is configured to provide control of the power supply unit **207**, it should be noted that within the scope of the present 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 primary receiver unit **104**.

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

Additional detailed description of the continuous analyte monitoring system, its various components including the functional descriptions of the transmitter are provided in U.S. Pat. No. 6,175,752 issued Jan. 16, 2001 entitled "Analyte Monitoring Device and Methods of Use", and in U.S. patent application Ser. No. 10/745,878 filed Dec. 26, 2003, now U.S. Pat. No. 7,811,231, entitled "Continuous Glucose Monitoring System and Methods of Use", each assigned to the Assignee of the present application, the disclosure of each of which are incorporated herein 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 a blood glucose test strip interface **301**, an RF receiver **302**, an input **303**, a temperature detection section **304**, and a clock **305**, each of which is operatively coupled to a receiver processor **307**. As can be further seen from the Figure, the primary receiver unit **104** also includes a power supply **306** operatively coupled to a power conversion and monitoring section **308**. Further, the power conversion and monitoring section **308** is also coupled to the receiver processor **307**. Moreover, also shown are a receiver serial communication section **309**, and an output **310**, each operatively coupled to the receiver processor **307**.

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

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

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

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

In a further embodiment, the one or more of the transmitter unit **102**, the primary receiver unit **104**, secondary receiver unit **106**, or the data processing terminal/infusion section **105** may be configured to receive the blood glucose value wirelessly over a communication link from, for example, a glucose meter. In still a further embodiment, the user or patient manipulating or using the analyte monitoring system **100** (FIG. **1**) may manually input the blood glucose value using, for example, a user interface (for example, a keyboard, keypad, and the like) incorporated in the one or more of the transmitter unit **102**, the primary receiver unit **104**, secondary receiver unit **106**, or the data processing terminal/infusion section **105**.

FIG. **4** is a schematic of the dynamic multi-stage signal amplification in the transmitter unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **4**, there is provided in one embodiment a transimpedance amplifier **420** whose output terminal **423** is coupled to a first input terminal **411** of the analog to digital converter (ADC) **410** in the analog interface **201** (FIG. **2**) of the transmitter unit **102**. Further shown in FIG. **4**, the monitored analyte sensor signal from the sensor **101** is provided to an inverting input terminal **421** of the transimpedance amplifier **420**. The sensor signal in FIG. **4** is shown as a signal source **440**. Furthermore, a noninverting input terminal **422** of the transimpedance amplifier **420** is provided with a reference voltage signal from a reference signal source Vref **450**. In one embodiment, the reference voltage signal may be

approximately 1.012 volts. However, based upon the component tolerance, and design configuration, other suitable reference voltage signals may be used.

In one aspect, based on the input analyte sensor signal from the signal source **440** and the reference signal Vref **450**, the transimpedance amplifier **420** may be in one embodiment configured to convert the received current signal representing the monitored or detected analyte level, and to convert the current signal to a corresponding voltage signal which is provided to the output terminal **423** of the transimpedance amplifier **420**. Further, as shown in FIG. **4** the monitored analyte voltage signal from the output terminal **423** of the transimpedance amplifier **420** is provided to the first input terminal **411** (Channel 1) of the ADC **410**.

Referring again to FIG. **4**, a second amplifier **430** is provided in one embodiment whose noninverting input terminal **431** is coupled to the output terminal **423** of the transimpedance amplifier **420** to receive the output voltage signal corresponding to the monitored analyte level, while an inverting input terminal **432** of the second amplifier **430** is coupled in one embodiment to the reference signal Vref source **450**. Moreover, output terminal **433** of the second amplifier is coupled in one embodiment to a second input terminal **412** (Channel 2) of the ADC **410**. In operation, the second amplifier **430** may be configured to step up the output signal of the transimpedance amplifier **410** by a predetermined factor (for example, a factor of 2), and to provide the stepped up signal to the analog to digital converter (ADC) **410**.

Referring back to FIG. **4**, the analog to digital converter (ADC) **410** of the analog interface **201** (FIG. **2**) of the transmitter unit **102** (FIG. **1**) in one embodiment may be configured to detect signals at both the first and second input terminals or channels **411**, **412**, and based on one or more predetermined process or routine, the voltage signal at one of the first or the second input terminals or channels **411**, **412** is used by the ADC **410** for further processing as corresponding to the monitored analyte level from the sensor **101** (FIG. **1**). That is, in one embodiment, depending upon the signal resolution corresponding to the analyte level monitored, the ADC **410** may be configured to select one of the output signals from the transimpedance amplifier **420** or the second amplifier **430** for further processing.

For example, when the signal received at the second input terminal **412** of the ADC **410** exceeds a predetermined threshold value, the input signal at the first input terminal **411** may be used. More specifically, in one embodiment, the ADC **410** may be configured to process the signals at the second input terminal **412** (Channel 2) since it has a higher resolution compared to the signal at the first input terminal **411** received from the transimpedance amplifier **420**. When the signal received at the second input terminal **412** exceeds a predetermined threshold level (for example, based on the tolerance level of the analog to digital converter (ADC) **410**), the voltage signal received at the first input terminal **411** from the transimpedance amplifier **420** may be used to convert to a corresponding digital signal representing the monitored analyte level detected by the sensor **101** (FIG. **1**).

Referring back to FIG. **4**, in one embodiment, the analog to digital converter (ADC) **410** may include a 12 bit A/D converter configured to support up to approximately 4,096 bits or ADC counts. In this case, in one embodiment, when the signal at the second input terminal **412** of the ADC **410** approaches approximately 4,000 bits or ADC counts, for example, the processor **204** (FIG. **2**) of the transmitter unit **102** may be configured to switch from the second input terminal **412** to the first input terminal **411**, to use the output signal from the transimpedance amplifier **420**. In this manner, in one embodiment, the processor **204** of the transmitter unit **102** may be configured to monitor the signal levels at the two input terminals **411**, **412** of the ADC **410**, and when the signal level or ADC count associated with the output signal from the second amplifier **430** provided at the second input terminal **412** of the ADC **410** exceeds the predetermined threshold (for example, 4,000 bits or ADC count), the processor **204** may be configured to switch over to the output signal of the transimpedance amplifier **410** provided on the first input terminal **411** of the ADC **410** for further processing.

In the manner described above, the dynamic multi-stage amplifier configuration in one embodiment may be configured to support variations in the analyte sensor sensitivities due to, for example, manufacturing variations, among others, while maintaining an acceptable or desirable sensor signal resolution. For example, in one embodiment, high sensitivity sensors may be configured for use with the full scale or range (for example, up to approximately 150 nA corresponding to the supported approximately 500 mg/dL glucose level) associated with the transimpedance amplifier **420** output signal provided to the first input terminal **411** (Channel 1) of the analog to digital converter (ADC) **410**, while low sensitivity sensors may be associated with the second amplifier **430** output signal (for example, full scale current signal level of approximately 75 nA corresponding to the supported approximately 500 mg/dL glucose level) provided to the second input terminal **412** (Channel 2) of the analog to digital converter (ADC) **410**.

For example, as discussed above, in one embodiment, the processor **204** of the transmitter unit **102** may be configured to monitor the signals at the two input terminals **411**, **412** of the ADC **410**, and determine, that if the received signal level does not have sufficient resolution to convert to the desired resolution of the digital signal (for example, 12 bits for the ADC **410**) corresponding to the monitored analyte level associated with the sensor **101**, the processor **204** may be configured to dynamically toggle or switch from using the voltage signal received from one of the two input terminals **411**, **412**, to using the voltage signal from the other one of the two input terminals **411**, **412** to provide a dynamic range of tolerance level for the sensor sensitivities.

Accordingly, an apparatus in one embodiment includes a first amplifier having at least one input terminal and an output terminal, the at least one input terminal coupled to a signal source, the output terminal configured to provide a first output signal, a second amplifier having at least one input terminal and an output terminal, the at least one input terminal coupled to the output terminal of the first amplifier, the output terminal of the second amplifier configured to provide a second output signal, a processor operatively coupled to receive the first output signal and the second output signal, where the first output signal is a predetermined ratio of the second output signal, and further, where the first output signal and the second output signal are associated with a monitored analyte level of a user.

In one aspect, the first amplifier may include a transimpedance amplifier.

The monitored analyte level may include glucose level.

Also, the at least one input terminal of the first amplifier may include an inverting input terminal, and, also may include a reference signal source coupled to a noninverting input terminal of the first amplifier.

In a further aspect, the second amplifier may include a gain of approximately two.

In still another aspect, the first output signal may be associated with a signal level from the signal source.

The apparatus may also include an analog to digital converter coupled to the output terminals of the first and second amplifiers, where the analog to digital (A/D) converter may include a 12 bit A/D converter.

The apparatus in another embodiment may include a processor operatively coupled to the A/D converter for processing the one or more signals received at the one or more first amplifier output terminal and the second amplifier output terminal.

Moreover, the processor may be configured to compare the one or more signals received at the one or more first amplifier output terminal and the second amplifier output terminal to a predetermined threshold value, which, in one embodiment may include approximately 4,000 bits (or analog to digital converter (ADC) counts).

Still further, the processor may be configured to process a signal associated with one of the one or more signals received at the one or more first amplifier output terminal and the second amplifier output terminal when another signal associated with the other one of the one or more signals received at the one or more first amplifier output terminal and the second amplifier output terminal exceeds the predetermined threshold value.

A method in accordance with another embodiment includes receiving a first signal having a first signal resolution and associated with a monitored analyte level of a user, receiving a second signal having a second signal resolution and associated with the monitored analyte level of the user, comparing the received first signal to a predetermined threshold level, and processing one of the received first or second signals based on the comparing step.

When the received first signal does not exceed the predetermined threshold level, further including processing the first signal. On the other hand, when the received first signal exceeds the predetermined threshold level, further including processing the second signal.

A data processing device in accordance with still another embodiment includes a multi stage amplifier unit configured to receive a signal and to generate a plurality of amplifier unit output signals each corresponding to a monitored analyte level of a patient, an analog to digital (A/D) conversion unit operatively coupled to the multi-stage amplifier unit configured to digitally convert the plurality of amplifier unit output signals, and a processor unit operatively coupled to the A/D conversion unit, the processor unit configured to process one of the plurality of digitally converted amplifier unit output signals.

The device in another aspect may include a data communication unit operatively coupled to the processor unit, and configured to transmit the digitally converted and processed amplifier unit output signal.

The data communication unit may include an RF transmitter for wireless data transmission to a remote device such as, for example, a data receiver unit, data processing terminal, an infusion device or the like configured for RF communication.

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 apparatus, comprising:

an analyte sensor having a portion in fluid contact with bodily fluid under a skin surface to monitor an analyte level in the bodily fluid;

a processor operatively coupled to the analyte sensor; and

a memory operatively coupled to the processor for storing instructions which, when executed by the processor, causes the processor to:

receive a first signal having a first signal resolution generated by the analyte sensor and associated with the monitored analyte level;

receive a second signal having a second signal resolution generated by the analyte sensor and associated with the monitored analyte level;

compare the received second signal to a predetermined threshold level; and

process one of the received first or the second signals based on the comparison of the received second signal to the predetermined threshold level.

2. The apparatus of claim **1**, wherein the predetermined threshold level includes approximately 4,000 bits or ADC counts.

3. The apparatus of claim **1**, wherein the second signal has a higher resolution compared to the first signal.

4. The apparatus of claim **1**, wherein the second signal is processed based on the comparison of the received second signal to the predetermined threshold level when the received second signal does not exceed the predetermined threshold level.

5. The apparatus of claim **1**, wherein the first signal is processed based on the comparison of the received second signal to the predetermined threshold level when the received second signal exceeds the predetermined threshold level.

6. The apparatus of claim **1**, further comprising a high sensitivity sensor associated with the first signal and a low sensitivity sensor associated with the second signal.

7. The apparatus of claim **6**, wherein the high sensitivity sensor is configured for use with a current signal level of up to approximately 150 nA, and wherein the low sensitivity sensor is configured for use with a current signal level of approximately 75 nA.

8. The apparatus of claim **1**, wherein the analyte sensor comprises a plurality of electrodes including a working electrode comprising an analyte-responsive enzyme bonded to a polymer disposed on the working electrode.

9. The apparatus of claim **8**, wherein the working electrode comprises a mediator crosslinked with the polymer disposed on the working electrode.

10. The apparatus of claim **1**, wherein the analyte sensor comprises a plurality of electrodes including a working electrode comprising a mediator bonded to a polymer disposed on the working electrode.

11. A method, comprising:

receiving a first signal having a first signal resolution and associated with a monitored analyte level, the first signal generated by an analyte sensor having a portion in fluid contact with bodily fluid under a skin surface to monitor an analyte level in the bodily fluid;

receiving a second signal having a second signal resolution generated by the analyte sensor and associated with the monitored analyte level;

comparing the received second signal to a predetermined threshold level; and

processing one of the received first or the second signals based on the comparison of the received second signal to the predetermined threshold level.

12. The method of claim **11**, wherein the predetermined threshold level includes approximately 4,000 bits or ADC counts.

13. The method of claim **11**, wherein the second signal has a higher resolution compared to the first signal.

14. The method of claim **11**, wherein the second signal is processed based on the comparison of the received second signal to the predetermined threshold level when the received second signal does not exceed the predetermined threshold level.

15. The method of claim **11**, wherein the first signal is processed based on the comparison of the received second signal to the predetermined threshold level when the received second signal exceeds the predetermined threshold level.

16. The method of claim **11**, further comprising providing a high sensitivity sensor associated with the first signal and a low sensitivity sensor associated with the second signal.

17. The method of claim **16**, wherein the high sensitivity sensor is configured for use with a current signal level of up to approximately 150 nA, and wherein the low sensitivity sensor is configured for use with a current signal level of approximately 75 nA.

18. The method of claim **11**, wherein the analyte sensor comprises a plurality of electrodes including a working electrode comprising an analyte-responsive enzyme bonded to a polymer disposed on the working electrode.

19. The method of claim **18**, wherein the working electrode comprises a mediator crosslinked with the polymer disposed on the working electrode.

20. The method of claim **11**, wherein the analyte sensor comprises a plurality of electrodes including a working electrode comprising a mediator bonded to a polymer disposed on the working electrode.

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专利名称(译)	用于在医疗设备中提供动态多级信号放大的方法和装置		
公开(公告)号	US9743866	公开(公告)日	2017-08-29
申请号	US15/209741	申请日	2016-07-13
[标]申请(专利权)人(译)	雅培糖尿病护理公司		
申请(专利权)人(译)	雅培糖尿病INC.		
当前申请(专利权)人(译)	雅培糖尿病INC.		
[标]发明人	FENNELL MARTIN J		
发明人	FENNELL, MARTIN J.		
IPC分类号	G08B29/00 A61M5/172 A61B5/00 A61B5/145 A61B5/1486		
CPC分类号	A61B5/14532 A61B5/002 A61B5/0004 A61B5/14546 A61B5/14865 A61B5/7225 A61B5/7246 A61B5/7475 A61M5/1723 A61B2560/0209 A61B2560/0252 A61B2560/045		
优先权	14/188659 2015-01-20 US 13/867948 2014-04-15 US 13/437894 2013-04-23 US 13/114029 2012-04-03 US 12/849004 2011-05-24 US 12/102836 2010-08-03 US 60/911866 2007-04-14 US		
其他公开文献	US20160317071A1		
外部链接	Espacenet USPTO		

摘要(译)

提供了用于在医疗遥测系统中提供多级信号放大的方法和装置。