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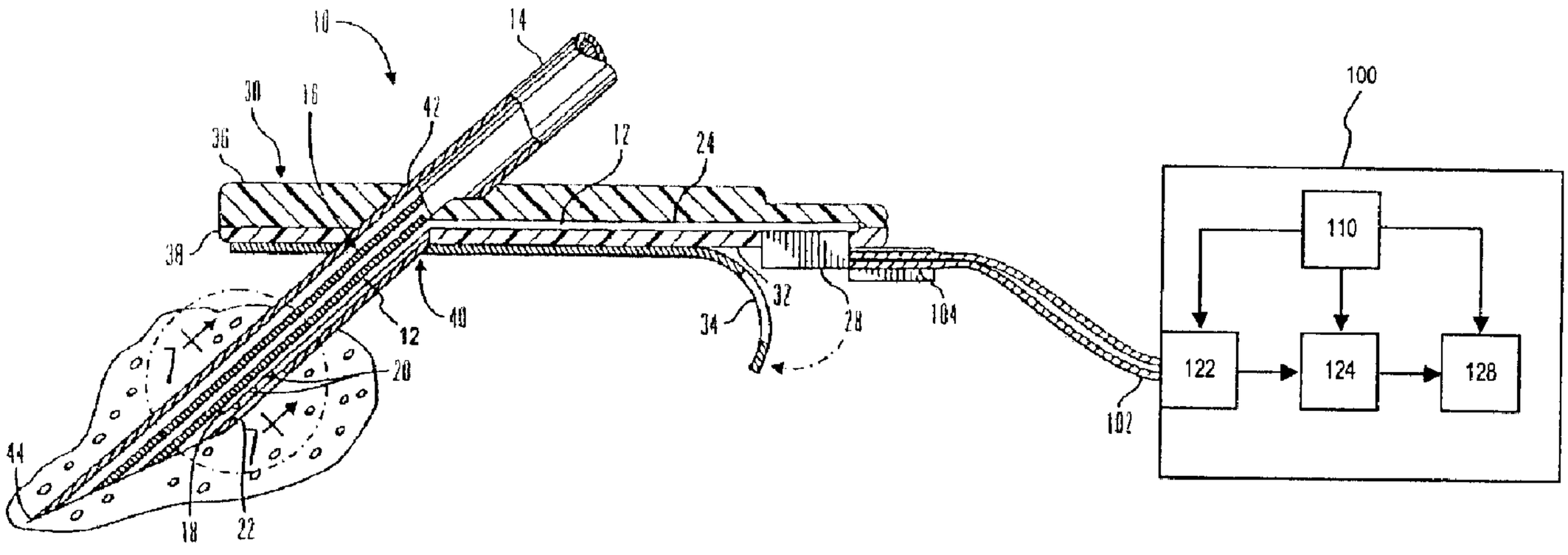


(57) Abrégé/Abstract:
A blood glucose sensing system includes a sensor and a sensor electronics device. The sensor includes a plurality of electrodes. The sensor electronics device includes stabilization circuitry. The.stabiltzation circuitry cases a first voltage to be applied to one of the electrodes for a first timeframe and causes a second voltage to be applied to one of the electrodes for a second timeframe. The stabilization circuitry repeats the application of the first voltage and the second voltage to continue the anodic - cathodic cycle. The sensor electronics device may include a power supply, a regulator, and a voltage application device, where the voltage application device receives a regulator voltage from the regulator, applies a first voltage to an electrode for the first timeframe, and applies a second voltage to an electrode for the second timeframe.

Abstract of the Disclosure

A blood glucose sensing system includes a sensor and a sensor electronics device. The sensor includes a plurality of electrodes. The sensor electronics device includes stabilization circuitry. The.stabiltzation circuitry cases a first voltage to be applied to one of the electrodes for a first timeframe and causes a second voltage to be applied to one of the electrodes for a second timeframe. The stabilization circuitry repeats the application of the first voltage and the second voltage to continue the anodic - cathodic cycle. The sensor electronics device may include a power supply, a regulator, and a voltage application device, where the voltage application device receives a regulator voltage from the regulator, applies a first voltage to an electrode for the first timeframe, and applies a second voltage to an electrode for the second timeframe.

METHOD OF AND SYSTEM FOR STABILIZATION OF SENSORS

Field of the Invention

[0001] Embodiments of this invention relate generally to methods and systems for stabilization of sensors during initial use of the sensors. More particularly, embodiments of this invention relate to systems and methods for providing an efficient way to stabilize the sensor in order for the sensor to provide accurate readings of a physiological condition of a subject.

Description of Related Art

[0002] Subjects and medical personnel wish to monitor readings of physiological conditions within the subject's body. Illustratively, subjects wish to monitor blood glucose levels in a subject's body on a continuing basis. Presently, a patient can measure his/her blood glucose (BG) using a BG measurement device, such as a test strip meter, a continuous glucose measurement system, or a hospital hemacue. BG measurement devices use various methods to measure the BG level of a patient, such as a sample of the patient's blood, a sensor in contact with a bodily fluid, an optical sensor, an enzymatic sensor, or a fluorescent sensor. When the BG measurement device has generated a BG measurement, the measurement is displayed on the BG measurement device.

[0003] Current continuous glucose measurement systems include subcutaneous (or short-term) sensors and implantable (or long-term) sensors. For each of the short-term sensors and the long-term sensors, a patient has to wait a certain amount of time in order for thee continuous glucose sensor to stabilize and to provide accurate readings. In many continuous glucose sensors, the subject must wait three hours for the continuous glucose sensor to stabilize before any glucose measurements are utilized. This is an inconvenience for the patient and in some cases may cause the patient not to utilize a continuous glucose measurement system.

[0004] Further, when a glucose sensor is first inserted into a patient's skin or subcutaneous layer, the glucose sensor does not operate in a stable state. The electrical readings from the sensor, which represent the glucose level of the patient, vary over a wide range of readings. In the past, sensor stabilization used to take several hours. A technique for sensor stabilization is detailed in U.S. Patent No. 6,809,653, ("the '653 patent") application serial No. 09/465,715, filed December 19, 1999, issued October 26, 2004, to

Mann et al., assigned to Medtronic Minimed, Inc., which is incorporated herein by reference. In the '653 patent, the initialization process for sensor stabilization may be reduced to approximately one hour. A high voltage (e.g., 1.0 – 1.2 volts) may be applied for 1 to 2 minutes to allow the sensor to stabilize and then a low voltage (e.g., between 0.5 - 0.6 volts) may be applied for the remainder of the initialization process (e.g., 58 minutes or so). Thus, even with this procedure, sensor stabilization still requires a large amount of time.

[0005] It is also desirable to allow electrodes of the sensor to be sufficiently "wetted" or hydrated before utilization of the electrodes of the sensor. If the electrodes of the sensor are not sufficiently hydrated, the result may be inaccurate readings of the patient's physiological condition. A user of current blood glucose sensors is instructed to not power up the sensors immediately. If they are utilized too early, current blood glucose sensors do not operate in an optimal or efficient fashion. No automatic procedure or measuring technique is utilized to determine when to power on the sensor. This manual process is inconvenient and places too much responsibility on the patient, who may forget to apply or turn on the power source.

BRIEF SUMMARY OF THE INVENTION

[0006] In an embodiment of the invention, a sensor is stabilized by applying a first voltage for a first time to initiate an anodic cycle in the sensor, by applying a second voltage for a second time to initiate a cathodic cycle in the sensor, and repeating the application of the first voltage and the second voltage to continue the anodic – cathodic cycle in the sensor. In an embodiment of the invention, a sensor may be stabilized by applying a first voltage for a first time, by waiting a predetermined period of time (i.e., not applying a voltage), and then cycling between the application of the first voltage and the waiting of a predetermined period of time for a number of iterations or a stabilization timeframe.

[0007] By utilizing the stabilization sequence identified above, the sensor has a faster run-in time, less background current exists in the sensor(due to suppression of background current, and the sensor has better glucose response. The first voltage may have a positive value or a negative value. The second voltage may have a positive value or negative value. Under certain operating conditions, a voltage magnitude of the first voltage for one of the iterations may have a different magnitude from a voltage magnitude of the first voltage for a second or different iteration.

[0008] In an embodiment of the invention, a voltage waveform, such as a ramp waveform, a stepped waveform, a sinusoid waveform, and a squarewave waveform, may be applied as the first voltage. Any of the above mentioned waveforms may also be applied as the second voltage. Under certain operating conditions, the voltage waveform applied as the first voltage in a first iteration of the stabilization method may differ from the voltage waveform applied as the first voltage in the second iteration. The same may hold true for the application of the second voltage. Under certain operating conditions, a voltage waveform may be applied as the first voltage to the sensor and a voltage pulse may be applied as the second voltage to the sensor.

[0009] In an embodiment of the invention, a plurality of short duration voltage pulses are applied for the first timeframe to initiate the anodic cycle in the sensor. In this embodiment, a plurality of short duration voltage pulses may be applied for the second timeframe to initiate the cathodic cycle in the sensor. The magnitude of the first plurality of short duration pulses may be different from the magnitude of the second plurality of short duration pulses. In an embodiment of the invention, the magnitude of some of the pulses in the first plurality of short duration pulses may have different values from the magnitude of other pulses in the first plurality of short duration pulses.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] A detailed description of embodiments of the invention will be made with reference to the accompanying drawings, wherein like numerals designate corresponding parts in the figures.

[0011] FIG. 1 is a perspective view of a subcutaneous sensor insertion set and block diagram of a sensor electronics device according to an embodiment of the invention;

[0012] FIG. 2(a) illustrates a substrate having two sides, a first side which contains an electrode configuration and a second side which contains electronic circuitry;

[0013] Fig. 2(b) illustrates a general block diagram of an electronic circuit for sensing an output of a sensor according to an embodiment of the present invention;

[0014] FIG. 3 illustrates a block diagram of a sensor electronics device and a sensor including a plurality of electrodes according to an embodiment of the invention;

[0015] Fig. 4 illustrates an alternative embodiment of the invention including a sensor and a sensor electronics device according to an embodiment of the present invention;

[0016] FIG. 5 illustrates an electronic block diagram of the sensor electrodes and a voltage being applied to the sensor electrodes according to an embodiment of the present invention;

[0017] Fig. 6(a) illustrates a method of applying pulses during stabilization timeframe in order to reduce the stabilization timeframe according to an embodiment of the present invention;

[0018] Fig. 6(b) illustrates a method of stabilizing sensors according to an embodiment of the present invention;

[0019] Fig. 6(c) illustrates utilization of feedback in stabilizing the sensors according to an embodiment of the present invention;

[0020] Fig. 7 illustrates an effect of stabilizing a sensor according to an embodiment of the invention;

[0021] Fig. 8 illustrates a block diagram of a sensor electronics device and a sensor including a voltage generation device according to an embodiment of the invention;

[0022] Fig. 8(b) illustrates a voltage generation device to implement this embodiment of the invention;

[0023] Fig. 8(c) illustrates a voltage generation device to generate two voltage values according in a sensor electronics device according to implement this embodiment of the invention;

[0024] Fig. 9 illustrates a sensor electronics device including a microcontroller for generating voltage pulses according to an embodiment of the present invention;

[0025] Fig. 9(b) illustrates a sensor electronics device including an analyzation module according to an embodiment of the present invention;

[0026] Fig. 10 illustrates a block diagram of a sensor system including hydration electronics according to an embodiment of the present invention;

[0027] Fig. 11 illustrates an embodiment of the invention including a mechanical switch to assist in determining a hydration time;

[0028] Fig. 12 illustrates an electrical detection of detecting hydration according to an embodiment of the invention;

[0029] Fig. 13(a) illustrates a method of hydrating a sensor according to an embodiment of the present invention;

[0030] Fig. 13(b) illustrates an additional method for verifying hydration of a sensor according to an embodiment of the present invention;

[0031] Figs. 14(a) and (b) illustrate methods of combining hydrating of a sensor with stabilizing a sensor according to an embodiment of the present invention; and

[0032] Fig. 14(c) illustrates an alternative embodiment of the invention where the stabilization method and hydration method are combined.

DETAILED DESCRIPTION OF THE INVENTION

[0033] In the following description, reference is made to the accompanying drawings which form a part hereof and which illustrate several embodiments of the present inventions. It is understood that other embodiments may be utilized and structural and operational changes may be made without departing from the scope of the present inventions.

[0034] The present invention described below with reference to flowchart illustrations of methods, apparatus, and computer program products. It will be understood that each block of the flowchart illustrations, and combinations of blocks in the flowchart illustrations, can be implemented by computer program instructions (as can any menu screens described in the Figures). These computer program instructions may be loaded onto a computer or other programmable data processing apparatus (such as a controller, microcontroller, or processor in a sensor electronics device to produce a machine, such that the instructions which execute on the computer or other programmable data processing apparatus create instructions for implementing the functions specified in the flowchart block or blocks. These computer program instructions may also be stored in a computer-readable memory that can direct a computer or other programmable data processing apparatus to function in a particular manner, such that the instructions stored in the computer-readable memory produce an article of manufacture including instructions which implement the function specified in the flowchart block or blocks. The computer program instructions may also be loaded onto a computer or other programmable data processing apparatus to cause a series of operational steps to be performed on the computer or other programmable apparatus to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide steps for implementing the functions specified in the flowchart block or blocks, and /or menus presented herein.

[0035] Fig. 1 is a perspective view of a subcutaneous sensor insertion set and a block diagram of a sensor electronics device according to an embodiment of the invention. As illustrated in Fig. 1, a subcutaneous sensor set 10 is provided for subcutaneous placement of an active portion of a flexible sensor 12 (see FIG. 2), or the like, at a selected site in the body of a user. The subcutaneous or percutaneous portion of the sensor set 10 includes a

hollow, slotted insertion needle 14, and a cannula 16. The needle 14 is used to facilitate quick and easy subcutaneous placement of the cannula 16 at the subcutaneous insertion site. Inside the cannula 16 is a sensing portion 18 of the sensor 12 to expose one or more sensor electrodes 20 to the user's bodily fluids through a window 22 formed in the cannula 16. In an embodiment of the invention, the one or more sensor electrodes 20 may include a counter electrode, a working electrode, and a reference electrode. After insertion, the insertion needle 14 is withdrawn to leave the cannula 16 with the sensing portion 18 and the sensor electrodes 20 in place at the selected insertion site.

[0036] In particular embodiments, the subcutaneous sensor set 10 facilitates accurate placement of a flexible thin film electrochemical sensor 12 of the type used for monitoring specific blood parameters representative of a user's condition. The sensor 12 monitors glucose levels in the body, and may be used in conjunction with automated or semi-automated medication infusion pumps of the external or implantable type as described in U.S Pat. Nos. 4,562,751; 4,678,408; 4,685,903 or 4,573,994, to control delivery of insulin to a diabetic patient.

[0037] Particular embodiments of the flexible electrochemical sensor 12 are constructed in accordance with thin film mask techniques to include elongated thin film conductors embedded or encased between layers of a selected insulative material such as polyimide film or sheet, and membranes. The sensor electrodes 20 at a tip end of the sensing portion 18 are exposed through one of the insulative layers for direct contact with patient blood or other body fluids, when the sensing portion 18 (or active portion) of the sensor 12 is subcutaneously placed at an insertion site. The sensing portion 18 is joined to a connection portion 24 that terminates in conductive contact pads, or the like, which are also exposed through one of the insulative layers. In alternative embodiments, other types of implantable sensors, such as chemical based, optical based, or the like, may be used.

[0038] As is known in the art, the connection portion 24 and the contact pads are generally adapted for a direct wired electrical connection to a suitable monitor or sensor electronics device 100 for monitoring a user's condition in response to signals derived from the sensor electrodes 20. Further description of flexible thin film sensors of this general type are be found in U.S. Pat. No. 5,391,250, entitled METHOD OF FABRICATING THIN FILM SENSORS. The connection portion 24 may be conveniently connected electrically to the monitor or sensor electronics device 100 or by a connector block 28 (or the like) as shown and described in U.S. Pat. No. 5,482,473, entitled FLEX CIRCUIT CONNECTOR. Thus, in

accordance with embodiments of the present invention, subcutaneous sensor sets 10 may be configured or formed to work with either a wired or a wireless characteristic monitor system.

[0039] The sensor electrodes 10 may be used in a variety of sensing applications and may be configured in a variety of ways. For example, the sensor electrodes 10 may be used in physiological parameter sensing applications in which some type of biomolecule is used as a catalytic agent. For example, the sensor electrodes 10 may be used in a glucose and oxygen sensor having a glucose oxidase enzyme catalyzing a reaction with the sensor electrodes 20. The sensor electrodes 10, along with a biomolecule or some other catalytic agent, may be placed in a human body in a vascular or non-vascular environment. For example, the sensor electrodes 20 and biomolecule may be placed in a vein and be subjected to a blood stream, or may be placed in a subcutaneous or peritoneal region of the human body.

[0040] The monitor 100 may also be referred to as a sensor electronics device 100. The monitor 100 may include a power source 110, a sensor interface 122, processing electronics 124, and data formatting electronics 128. The monitor 100 may be coupled to the sensor set 10 by a cable 102 through a connector that is electrically coupled to the connector block 28 of the connection portion 24. In an alternative embodiment, the cable may be omitted. In this embodiment of the invention, the monitor 100 may include an appropriate connector for direct connection to the connection portion 104 of the sensor set 10. The sensor set 10 may be modified to have the connector portion 104 positioned at a different location, e.g., on top of the sensor set to facilitate placement of the monitor 100 over the sensor set.

[0041] In embodiments of the invention, the sensor interface 122, the processing electronics 124, and the data formatting electronics 128 are formed as separate semiconductor chips, however alternative embodiments may combine the various semiconductor chips into a single or multiple customized semiconductor chips. The sensor interface 122 connects with the cable 102 that is connected with the sensor set 10.

[0042] The power source 110 may be a battery. The battery can include three series silver oxide 357 battery cells. In alternative embodiments, different battery chemistries may be utilized, such as lithium based chemistries, alkaline batteries, nickel metalhydride, or the like, and different number of batteries may used. The monitor 100 provides power, through the power source 110, provides power, through the cable 102 and cable connector 104 to the sensor set. In an embodiment of the invention, the power is a voltage provided to the sensor set 10. In an embodiment of the invention, the power is a current provided to the sensor set

10. In an embodiment of the invention, the power is a voltage provided at a specific voltage to the sensor set 10.

[0043] FIGS. 2(a) and 2(b) illustrates an implantable sensor and electronics for driving the implantable sensor according to an embodiment of the present invention. Fig. 2(a) shows a substrate 220 having two sides, a first side 222 of which contains an electrode configuration and a second side 224 of which contains electronic circuitry. As may be seen in FIG. 2(a), a first side 222 of the substrate comprises two counter electrode-working electrode pairs 240, 242, 244, 246 on opposite sides of a reference electrode 248. A second side 224 of the substrate comprises electronic circuitry. As shown, the electronic circuitry may be enclosed in a hermetically sealed casing 226, providing a protective housing for the electronic circuitry. This allows the sensor substrate 220 to be inserted into a vascular environment or other environment which may subject the electronic circuitry to fluids. By sealing the electronic circuitry in a hermetically sealed casing 226, the electronic circuitry may operate without risk of short circuiting by the surrounding fluids. Also shown in FIG 2(a) are pads 228 to which the input and output lines of the electronic circuitry may be connected. The electronic circuitry itself may be fabricated in a variety of ways. According to an embodiment of the present invention, the electronic circuitry may be fabricated as an integrated circuit using techniques common in the industry.

[0044] Fig. 2(b) illustrates a general block diagram of an electronic circuit for sensing an output of a sensor according to an embodiment of the present invention. At least one pair of sensor electrodes 310 may interface to a data converter 312, the output of which may interface to a counter 314. The counter 314 may be controlled by control logic 316. The output of the counter 314 may connect to a line interface 318. The line interface 318 may be connected to input and output lines 320 and may also connect to the control logic 316. The input and output lines 320 may also be connected to a power rectifier 322.

[0045] The sensor electrodes 310 may be used in a variety of sensing applications and may be configured in a variety of ways. For example, the sensor electrodes 310 may be used in physiological parameter sensing applications in which some type of biomolecule is used as a catalytic agent. For example, the sensor electrodes 310 may be used in a glucose and oxygen sensor having a glucose oxidase enzyme catalyzing a reaction with the sensor electrodes 310. The sensor electrodes 310, along with a biomolecule or some other catalytic agent, may be placed in a human body in a vascular or non-vascular environment. For example, the sensor electrodes 310 and biomolecule may be placed in a vein and be subjected to a blood stream.

[0046] FIG. 3 illustrates a block diagram of a sensor electronics device and a sensor including a plurality of electrodes according to an embodiment of the invention. The sensor set or system 350 includes a sensor 355 and a sensor electronics device 360. The sensor 355 includes a counter electrode 365, a reference electrode 370, and a working electrode 375. The sensor electronics device 360 includes a power supply 380, a regulator 385, a signal processor 390, a measurement processor 395, and a display / transmission module 397. The power supply 380 provides power (in the form of either a voltage, a current, or a voltage including a current) to the regulator 385. The regulator 385 transmits a regulated voltage to the sensor 355. In an embodiment of the invention, the regulator 385 transmits a voltage to the counter electrode 365 of the sensor 355.

[0047] The sensor 355 creates a sensor signal indicative of a concentration of a physiological characteristic being measured. For example, the sensor signal may be indicative of a blood glucose reading. In an embodiment of the invention utilizing subcutaneous sensors, the sensor signal may represent a level of hydrogen peroxide in a subject. In an embodiment of the invention where blood or cranial sensors are utilized, the amount of oxygen is being measured by the sensor and is represented by the sensor signal. In an embodiment of the invention utilizing implantable or long-term sensors, the sensor signal may represent a level of oxygen in the subject. The sensor signal is measured at the working electrode 375. In an embodiment of the invention, the sensor signal may be a current measured at the working electrode. In an embodiment of the invention, the sensor signal may be a voltage measured at the working electrode.

[0048] The signal processor 390 receives the sensor signal (e.g., a measured current or voltage) after the sensor signal is measured at the sensor 355 (e.g., the working electrode). The signal processor 390 processes the sensor signal and generates a processed sensor signal. The measurement processor 395 receives the processed sensor signal and calibrates the processed sensor signal utilizing reference values. In an embodiment of the invention, the reference values are stored in a reference memory and provided to the measurement processor 395. The measurement processor 395 generates sensor measurements. The sensor measurements may be stored in a measurement memory (not pictured). The sensor measurements may be sent to a display / transmission device to be either displayed on a display in a housing with the sensor electronics or to be transmitted to an external device.

[0049] The sensor electronics device 350 may be a monitor which includes a display to display physiological characteristics readings. The sensor electronics device 350 may also be installed in a desktop computer, a pager, a television including communications

capabilities, a laptop computer, a server, a network computer, a personal digital assistant (PDA), a portable telephone including computer functions, an infusion pump including a display, a glucose sensor including a display, and or a combination infusion pump / glucose sensor. The sensor electronics device 350may be housed in a blackberry, a network device, a home network device, or an appliance connected to a home network.

[0050] Fig. 4 illustrates an alternative embodiment of the invention including a sensor and a sensor electronics device according to an embodiment of the present invention. The sensor set or sensor system 400 includes a sensor electronics device 360 and a sensor 355. The sensor includes a counter electrode 365, a reference electrode 370, and a working electrode 375. The sensor electronics device 360 includes a microcontroller 410 and a digital-to-analog converter (DAC) 420. The sensor electronics device 360 may also include a current-to-frequency converter (I/F converter) 430.

[0051] The microcontroller 410 includes software program code, which when executed, or programmable logic which, causes the microcontroller 410 to transmit a signal to the DAC 420, where the signal is representative of a voltage level or value that is to be applied to the sensor 355. The DAC 420 receives the signal and generates the voltage value at the level instructed by the microcontroller 410. In embodiments of the invention, the microcontroller 410 may change the representation of the voltage level in the signal frequently or infrequently. Illustratively, the signal from the microcontroller 410 may instruct the DAC 420 to apply a first voltage value for one second and a second voltage value for two seconds.

[0052] The sensor 355 may receive the voltage level or value. In an embodiment of the invention, the counter electrode 365 may receive the output of an operational amplifier which has as inputs the reference voltage and the voltage value from the DAC 420. The application of the voltage level causes the sensor 355 to create a sensor signal indicative of a concentration of a physiological characteristic being measured. In an embodiment of the invention, the microcontroller 410 may measure the sensor signal (e.g., a current value) from the working electrode. Illustratively, a sensor signal measurement circuit 431 may measure the sensor signal. In an embodiment of the invention, the sensor signal measurement circuit 431 may include a resistor and the current may be passed through the resistor to measure the value of the sensor signal. In an embodiment of the invention, the sensor signal may be a current level signal and the sensor signal measurement circuit 431 may be a current-to-frequency (I/F) converter 430. The current-to-frequency converter 430 may measure the sensor signal in terms of a current reading, convert it to a frequency-based sensor signal, and

transmit the frequency-based sensor signal to the microcontroller 410. In embodiments of the invention, the microcontroller 410 may be able to receive frequency-based sensor signals easier than non-frequency-based sensor signals. The microcontroller 410 receives the sensor signal, whether frequency-based or non frequency-based, and determines a value for the physiological characteristic of a subject, such as a blood glucose level. The microcontroller 410 may include program code, which when executed or run, is able to receive the sensor signal and convert the sensor signal to a physiological characteristic value. In an embodiment of the invention, the microcontroller 410 may convert the sensor signal to a blood glucose level. In an embodiment of the invention, the microcontroller 410 may utilize measurements stored within an internal memory in order to determine the blood glucose level of the subject. In an embodiment of the invention, the microcontroller 410 may utilize measurements stored within a memory external to the microcontroller 410 to assist in determining the blood glucose level of the subject.

[0053] After the physiological characteristic value is determined by the microcontroller 410, the microcontroller 410 may store measurements of the physiological characteristic values for a number of time periods. For example, a blood glucose value may be sent to the microcontroller 410 from the sensor every second or five seconds, and the microcontroller may save sensor measurements for five minutes or ten minutes of BG readings. The microcontroller 410 may transfer the measurements of the physiological characteristic values to a display on the sensor electronics device 450. For example, the sensor electronics device 450 may be a monitor which includes a display that provides a blood glucose reading for a subject. In an embodiment of the invention, the microcontroller 410 may transfer the measurements of the physiological characteristic values to an output interface of the microcontroller 410. The output interface of the microcontroller 410 may transfer the measurements of the physiological characteristic values, e.g., blood glucose values, to an external device, e.g., such as an infusion pump, a combined infusion pump / glucose meter, a computer, a personal digital assistant, a pager, a network appliance, a server, a cellular phone, or any computing device.

[0054] FIG. 5 illustrates an electronic block diagram of the sensor electrodes and a voltage being applied to the sensor electrodes according to an embodiment of the present invention. In the embodiment of the invention illustrated in FIG. 5, an op amp 530 or other servo controlled device may connect to sensor electrodes 510 through a circuit/electrode interface 538. The op amp 530, utilizing feedback through the sensor electrodes, attempts to maintain a prescribed voltage (what the DAC may desire the applied voltage to be) between a

reference electrode 532 and a working electrode 534 by adjusting the voltage at a counter electrode 536. Current may then flow from a counter electrode 536 to a working electrode 534. Such current may be measured to ascertain the electrochemical reaction between the sensor electrodes 510 and the biomolecule of a sensor that has been placed in the vicinity of the sensor electrodes 510 and used as a catalyzing agent. The circuitry disclosed in Fig. 5 may be utilized in a long-term or implantable sensor or may be utilized in a short-term or subcutaneous sensor.

[0055] In a long-term sensor embodiment, where a glucose oxidase enzyme is used as a catalytic agent in a sensor, current may flow from the counter electrode 536 to a working electrode 534 only if there is oxygen in the vicinity of the enzyme and the sensor electrodes 10. Illustratively, if the voltage set at the reference electrode 532 is maintained at about 0.5 volts, the amount of current flowing from a counter electrode 536 to a working electrode 534 has a fairly linear relationship with unity slope to the amount of oxygen present in the area surrounding the enzyme and the electrodes. Thus, increased accuracy in determining an amount of oxygen in the blood may be achieved by maintaining the reference electrode 532 at about 0.5 volts and utilizing this region of the current-voltage curve for varying levels of blood oxygen. Different embodiments of the present invention may utilize different sensors having biomolecules other than a glucose oxidase enzyme and may, therefore, have voltages other than 0.5 volts set at the reference electrode.

[0056] As discussed above, during initial implantation or insertion of the sensor 510, a sensor 510 may provide inaccurate readings due to the adjusting of the subject to the sensor and also electrochemical byproducts caused by the catalyst utilized in the sensor. A stabilization period is needed for many sensors in order for the sensor 510 to provide accurate readings of the physiological parameter of the subject. During the stabilization period, the sensor 510 does not provide accurate blood glucose measurements. Users and manufacturers of the sensors may desire to improve the stabilization timeframe for the sensor so that the sensors can be utilized quickly after insertion into the subject's body or a subcutaneous layer of the subject.

[0057] In previous sensor electrode systems, the stabilization period or timeframe was one hour to three hours. In order to decrease the stabilization period or timeframe and increase the timeliness of accuracy of the sensor, a sensor (or electrodes of a sensor) may be subjected to a number of pulses rather than the application of one pulse followed by the application of another voltage. Fig. 6(a) illustrates a method of applying pulses during stabilization timeframe in order to reduce the stabilization timeframe according to an

embodiment of the present invention. In this embodiment of the invention, a voltage application device applies 600 a first voltage to an electrode for a first time or time period. In an embodiment of the invention, the first voltage may be a DC constant voltage. This results in an anodic current being generated. In an alternative embodiment of the invention, a digital-to-analog converter or another voltage source may supply the voltage to the electrode for a first time period. The anodic current means that electrons are being driven away from electrode to which the voltage is applied. In an embodiment of the invention, an application device may apply a current instead of a voltage. In an embodiment of the invention where a voltage is applied to a sensor, after the application of the first voltage to the electrode, the voltage regulator may not apply 605 a voltage for a second time, timeframe, or time period. In other words, the voltage application device waits until a second time period elapses. The non-application of voltage results in a cathodic current, which results in the gaining of electrons by the electrode to which the voltage is not applied. The application of the first voltage to the electrode for a first time period followed by the non-application of voltage for a second time period is repeated 610 for a number of iterations. This may be referred to as an anodic and cathodic cycle. In an embodiment of the invention, the number of total iterations of the stabilization method is three, i.e., three applications of the voltage for the first time period, each followed by no application of the voltage three times for the second time period. In an embodiment of the invention, the first voltage may be 1.07 volts. In an embodiment of the invention, the first voltage may be 0.535 volts. In an embodiment of the invention, the first voltage may be approximately 0.7 volts.

[0058] The result of the repeated application of the voltage and the non-application of the voltage results in the sensor (and thus the electrodes) being subjected to an anodic - cathodic cycle. The anodic - cathodic cycle results in the reduction of electrochemical byproducts which are generated by a patient's body reacting to the insertion of the sensor or the implanting of the sensor. In an embodiment of the invention, the electrochemical byproducts cause generation of a background current, which results in inaccurate measurements of the physiological parameter of the subject. In an embodiment of the invention, the electrochemical byproduct may be eliminated. Under other operating conditions, the electrochemical byproducts may be reduced or significantly reduced. A successful stabilization method results in the anodic-cathodic cycle reaching equilibrium, electrochemical byproducts being significantly reduced, and background current being minimized.

[0059] In an embodiment of the invention, the first voltage being applied to the electrode of the sensor may be a positive voltage. In an embodiment of the invention, the first voltage being applied may be a negative voltage. In an embodiment of the invention, the first voltage may be applied to a working electrode. In an embodiment of the invention, the first voltage may be applied to the counter electrode or the reference electrode.

[0060] In embodiments of the invention, the duration of the voltage pulse and the no application of voltage may be equal, e.g., such as three minutes each. In embodiments of the invention, the duration of the voltage application or voltage pulse may be different values, e.g., the first time and the second time may be different. In an embodiment of the invention, the first time period may be five minutes and the waiting period may be two minutes. In an embodiment of the invention, the first time period may be two minutes and the waiting period (or second timeframe) may be five minutes. In other words, the duration for the application of the first voltage may be two minutes and there may be no voltage applied for five minutes This timeframe is only meant to be illustrative and should not be limiting. For example, a first timeframe may be two, three, five or ten minutes and the second timeframe may be five minutes, ten minutes, twenty minutes, or the like. The timeframes (e.g., the first time and the second time) may depend on unique characteristics of different electrodes, the sensors, and/or the patient's physiological characteristics.

[0061] In embodiments of the invention, more or less than three pulses may be utilized to stabilize the glucose sensor. In other words, the number of iterations may be greater than 3 or less than three. For example, four voltage pulses (e.g., a high voltage followed by no voltage) may be applied to one of the electrodes or six voltage pulses may be applied to one of the electrodes.

[0062] Illustratively, three consecutive pulses of 1.07 volts (followed by three pulses of no volts) may be sufficient for a sensor implanted subcutaneously. In an embodiment of the invention, three consecutive voltage pulses of 0.7 volts may be utilized. The three consecutive pulses may have a higher or lower voltage value, either negative or positive, for a sensor implanted in blood or cranial fluid, e.g., the long-term or permanent sensors. In addition, more than three pulses (e.g., five, eight, twelve) may be utilized to create the anodic-cathodic cycling between anodic and cathodic currents in any of the subcutaneous, blood, or cranial fluid sensors.

[0063] Fig. 6(b) illustrates a method of stabilizing sensors according to an embodiment of the present invention. In the embodiment of the invention illustrated in Fig. 6(b), a voltage application device may apply 630 a first voltage to the sensor for a first time

to initiate an anodic cycle at an electrode of the sensor. The voltage application device may be a DC power supply, a digital-to-analog converter, or a voltage regulator. After the first time period has elapsed, a second voltage is applied 635 to the sensor for a second time to initiate an cathodic cycle at an electrode of the sensor. Illustratively, rather than no voltage being applied, as is illustrated in the method of Fig. 6(a), a different voltage (from the first voltage) is applied to the sensor during the second timeframe. In an embodiment of the invention, the application of the first voltage for the first time and the application of the second voltage for the second time are applied 640 for a number of iterations. In an embodiment of the invention, the application of the first voltage for the first time and the application of the second voltage for the second time may each be applied for a stabilization timeframe, e.g., 10 minutes, 15 minutes, or 20 minutes rather than for a number of iterations. This stabilization timeframe is the entire timeframe for the stabilization sequence, e.g., until the sensor (and electrodes) are stabilized. The benefit of this stabilization methodology is a faster run-in of the sensors, less background current (in other words a suppression of some the background current), and a better glucose response.

[0064] In an embodiment of the invention, the first voltage may be 0.535 volts applied for five minutes, the second voltage may be 1.070 volts applied for two minutes, the first voltage of 0.535 volts may be applied for five minutes, the second voltage of 1.070 volts may be applied for two minutes, the first voltage of 0.535 volts may be applied for five minutes, and the second voltage of 1.070 volts may be applied for two minutes. In other words, in this embodiment, there are three iterations of the voltage pulsing scheme. The pulsing methodology may be changed in that the second timeframe, e.g., the timeframe of the application of the second voltage may be lengthened from two minutes to five minutes, ten minutes, fifteen minutes, or twenty minutes. In addition, after the three iterations are applied in this embodiment of the invention, a nominal working voltage of 0.535 volts may be applied.

[0065] The 1.08 and 0.535 volts are illustrative values. Other voltage values may be selected based on a variety of factors. These factors may include the type of enzyme utilized in the sensor, the membranes utilized in the sensor, the operating period of the sensor, the length of the pulse, and/or the magnitude of the pulse. Under certain operating conditions, the first voltage may be in a range of 1.00 to 1.09 volts and the second voltage may be in a range of 0.510 to 0.565 volts. In other operating embodiments, the ranges that bracket the first voltage and the second voltage may have a higher range, e.g., 0.3 volts, 0.6 volts, 0.9 volts, depending on the voltage sensitivity of the electrode in the sensor. Under

other operating conditions, the voltage may be in a range of 0.8 volts to 1.34 volts and the other voltage may be in a range of 0.335 to 0.735. Under other operating conditions, the range of the higher voltage may be smaller than the range of the lower voltage. Illustratively, the higher voltage may be in a range of 0.9 to 1.09 volts and the lower voltage may be in a range of 0.235 to 0.835.

[0066] In an embodiment of the invention, the first voltage and the second voltage may be positive voltages, or alternatively in other embodiments of the invention, negative voltages. In an embodiment of the invention, the first voltage may be positive and the second voltage may be negative, or alternatively, the first voltage may be negative and the second voltage may be positive. The first voltage may be different voltage levels for each of the iterations. In an embodiment of the invention, the first voltage may be a D.C. constant voltage. In other embodiments of the invention, the first voltage may be a ramp voltage, a sinusoid-shaped voltage, a stepped voltage, a squarewave, or other commonly utilized voltage waveforms. In an embodiment of the invention, the second voltage may be a D.C. constant voltage, a ramp voltage, a sinusoid-shaped voltage, a stepped voltage, a squarewave, or other commonly utilized voltage waveforms. In an embodiment of the invention, the first voltage or the second voltage may be an AC signal riding on a DC waveform. In an embodiment of the invention, the first voltage may be one type of voltage, e.g., a ramp voltage, and the second voltage may be a second type of voltage, e.g., a sinusoid-shaped voltage. In an embodiment of the invention, the first voltage (or the second voltage) may have different waveform shapes for each of the iterations. For example, if there are three cycles in a stabilization method, in a first cycle, the first voltage may be a ramp voltage, in the second cycle, the first voltage may be a constant voltage, and in the third cycle, the first voltage may be a sinusoidal voltage.

[0067] In an embodiment of the invention, a duration of the first timeframe and a duration of the second timeframe may have the same value, or alternatively, the duration of the first timeframe and the second timeframe may have different values. For example, the duration of the first timeframe may be two minutes and the duration of the second timeframe may be five minutes and the number of iterations may be three. As discussed above, the stabilization method may include a number of iterations. In embodiments of the invention, during different iterations of the stabilization method, the duration of each of the first timeframes may change and the duration of each of the second timeframes may change. Illustratively, during the first iteration of the anodic-cathodic cycling, the first timeframe may be 2 minutes and the second timeframe may be 5 minutes. During the second iteration, the

first timeframe may be 1 minute and the second timeframe may be 3 minutes. During the third iteration, the first timeframe may be 3 minutes and the second timeframe may be 10 minutes.

[0068] In an embodiment of the invention, a first voltage of 0.535 volts is applied to an electrode in a sensor for two minutes to initiate an anodic cycle, then a second voltage of 1.07 volts is applied to the electrode to the sensor for five minutes to initiate a cathodic cycle. The first voltage of 0.535 volts is then applied again for two minutes to initiate the anodic cycle and a second voltage of 1.07 volts is applied to the sensor for five minutes. In a third iteration, 0.535 volts is applied for two minutes to initiate the anodic cycle and then 1.07 volts is applied for five minutes. The voltage applied to the sensor is then 0.535 during the actual working timeframe of the sensor, e.g., when the sensor provides readings of a physiological characteristic of a subject.

[0069] Shorter duration voltage pulses may be utilized in the embodiment of Figs 6(a) and 6(b). The shorter duration voltage pulses may be utilized to apply the first voltage, the second voltage, or both. In an embodiment of the present invention, the magnitude of the shorter duration voltage pulse for the first voltage is -1.07 volts and the magnitude of the shorter duration voltage pulse for the second voltage is approximately half of the high magnitude, e.g., - .535 volts. Alternatively, the magnitude of the shorter duration pulse for the first voltage may be 0.535 volts and the magnitude of the shorter duration pulse for the second voltage is 1.07 volts.

[0070] In embodiments of the invention utilizing short duration pulses, the voltage may not be applied continuously for the entire first time period. Instead, in the first time period, the voltage application device may transmit a number of short duration pulses during the first time period. In other words, a number of mini-width or short duration voltage pulses may be applied to the electrodes of the sensors over the first time period. Each mini-width or short duration pulse may a width of a number of milliseconds. Illustratively, this pulse width may be 30 milliseconds, 50 milliseconds, 70 milliseconds or 200 milliseconds. These values are meant to be illustrative and not limiting. In an embodiment of the invention, such as the embodiment illustrated in Fig. 6(a), these short duration pulses are applied to the sensor (electrode) for the first time period and then no voltage is applied for the second time period.

[0071] In an embodiment of the invention, each short duration pulse may have the same time duration within the first time period. For example, each short duration voltage pulse may have a time width of 50 milliseconds and each pulse delay between the pulses may be 950 milliseconds. In this example, if two minutes is the measured time for the first

timeframe, then 120 short duration voltage pulses may be applied to the sensor. In an embodiment of the invention, each of the short duration voltage pulses may have different time durations. In an embodiment of the invention, each of the short duration voltage pulses may have the same amplitude values. In an embodiment of the invention, each of the short duration voltage pulses may have different amplitude values. By utilizing short duration voltage pulses rather than a continuous application of voltage to the sensors, the same anodic and cathodic cycling may occur and the sensor (e.g., electrodes) is subjected to less total energy or charge over time. The use of short duration voltage pulses utilizes less power as compared to the application of continuous voltage to the electrodes because there is less energy applied to the sensors (and thus the electrodes).

[0072] Fig. 6(c) illustrates utilization of feedback in stabilizing the sensors according to an embodiment of the present invention. The sensor system may include a feedback mechanism to determine if additional pulses are needed to stabilize a sensor. In an embodiment of the invention, a sensor signal generated by an electrode (e.g., a working electrode) may be analyzed to determine is the sensor signal is stabilized. A first voltage is applied 630 to an electrode for a first timeframe to initiate an anodic cycle. A second voltage is applied 635 to an electrode for a second timeframe to initiate a cathodic cycle. In an embodiment of the invention, an analyzation module may analyze a sensor signal (e.g., the current emitted by the sensor signal, a resistance at a specific point in the sensor, an impedance at a specific node in the sensor) and determine if a threshold measurement has been reached 637 (e.g., determining if the sensor is providing accurate readings by comparing against the threshold measurement). Under other operating conditions, the measurement may be compared to set measurement criteria. If the sensor readings are determined to be accurate, (because they are above a threshold, below a threshold, or meet measurement criteria) which represents that the electrode (and thus the sensor) is stabilized 642 , no additional application of the first voltage and / or the second voltage may be generated. If the stability was not achieved, in an embodiment of the invention, then an additional anodic / cathodic cycle is initiated by the application 630 of a first voltage to an electrode for a first time period and then the application 635 of the second voltage to the electrode for a second time period.

[0073] In embodiments of the invention, the analyzation module may be employed after an anodic / cathodic cycle of three applications of the first voltage and the second voltage to an electrode of the sensor. In an embodiment of the invention, an analyzation

module may be employed after one application of the first voltage and the second voltage, as is illustrated in Fig. 6(c).

[0074] In an embodiment of the invention, the analyzation module may be utilized to measure a voltage emitted after a current has been introduced across an electrode or across two electrodes. The analyzation module may monitor a voltage level at the electrode or at the receiving level. In an embodiment of the invention, if the voltage level is above a certain threshold, this may mean that the sensor is stabilized. In an embodiment of the invention, if the voltage level falls below a threshold level, this may indicate that the sensor is stabilized and ready to provide readings. In an embodiment of the invention, a current may be introduced to an electrode or across a couple of electrodes. The analyzation module may monitor a current level emitted from the electrode. In this embodiment of the invention, the analyzation module may be able to monitor the current if the current is different by an order of magnitude from the sensor signal current. If the current is above or below a current threshold, this may signify that the sensor is stabilized. Instead of comparing the monitored or measured current to a threshold, the monitored or measured current (or voltage, resistance, or impedance) may be compared to a set measurement criteria. If the measured reading matches or meets the set measurement criteria, timeframes for the first voltage and/or the second voltage may be modified or altered, magnitudes for the first voltage and/or the second voltage may be modified or altered, or the application of the first voltage and/or the second voltage may be terminated.

[0075] In an embodiment of the invention, the analyzation module may measure an impedance between two electrodes of the sensor. The analyzation module may compare the impedance against a threshold or target impedance value and if the measured impedance is lower than the target or threshold impedance, the sensor (and hence the sensor signal) may be stabilized. In an embodiment of the invention, the analyzation module may measure a resistance between two electrodes of the sensor. In this embodiment of the invention, if the analyzation module compares the resistance against a threshold or target resistance value and the measured resistance value is less than the threshold or target resistance value, then the analyzation module may determine that the sensor is stabilized and that the sensor signal may be utilized.

[0076] Fig. 7 illustrates an effect of stabilizing a sensor according to an embodiment of the invention. Line 705 represents blood glucose sensor readings for a glucose sensor where a previous single pulse stabilization method was utilized. Line 710 represents blood glucose readings for a glucose sensor where three voltage pulses are applied (e.g., 3 voltage

pulses having a duration of 2 minutes each followed by 5 minutes of no voltage being applied). The x-axis 715 represents an amount of time. The dots 720 725 730 and 735 represent measured glucose readings, taken utilizing a fingerstick and then input into a glucose meter. As illustrated by the graph, the previous single pulse stabilization method took approximately 1 hour and 30 minutes in order to stabilize to the desired glucose reading, e.g., 100 units. In contrast, the three pulse stabilization method took only approximately 15 minutes to stabilize the glucose sensor and results in a drastically improved stabilization timeframe.

[0077] Fig. 8 illustrates a block diagram of a sensor electronics device and a sensor including a voltage generation device according to an embodiment of the invention. The voltage generation or application device 810 includes electronics, logic, or circuits which generate voltage pulses. The sensor electronics device 360 may also include a input device 820 to receive reference values and other useful data. In an embodiment of the invention, the sensor electronics device may include a measurement memory 830 to store sensor measurements. In this embodiment of the invention, the power supply 380 may supply power to the sensor electronics device. The power supply 380 may supply power to a regulator 385, which supplies a regulated voltage to the voltage generation or application device 810. The connection terminals 811 represent that in the illustrated embodiment of the invention, the connection terminal couples or connects the sensor 355 to the sensor electronics device 360.

[0078] In an embodiment of the invention illustrated in Fig. 8, the voltage generation or application device 810 supplies a voltage, e.g., the first voltage or the second voltage, to an input terminal of an operational amplifier 840. The voltage generation or application device 810 may also supply the voltage to a working electrode 375 of the sensor 355. Another input terminal of the operational amplifier 840 is coupled to the reference electrode 370 of the sensor. The application of the voltage from the voltage generation or application device 810 to the operational amplifier 840 drives a voltage measured at the counter electrode 365 to be close to or equal the voltage applied at the working electrode 375. In an embodiment of the invention, the voltage generation or application device 810 could be utilized to apply the desired voltage between the counter electrode and the working electrode. This may occur by the application of the fixed voltage to the counter electrode directly.

[0079] In an embodiment of the invention as illustrated in Figs. 6(a) and 6(b), the voltage generation device 810 generates a first voltage that is to be applied to the sensor during a first timeframe. The voltage generation device 810 transmits this first voltage to an op amp 840 which drives the voltage at a counter electrode 365 of the sensor 355 to the first

voltage. In an embodiment of the invention, the voltage generation device 810 also could transmit the first voltage directly to the counter electrode 365 of the sensor 355. In the embodiment of the invention illustrated in Fig. 6(a), the voltage generation device 810 then does not transmit the first voltage to the sensor 355 for a second timeframe. In other words, the voltage generation device 810 is turned off or switched off. The voltage generation device 810 may be programmed to continue cycling between applying the first voltage and not applying a voltage for either a number of iterations or for a stabilization timeframe, e.g., for twenty minutes. Fig. 8(b) illustrates a voltage generation device to implement this embodiment of the invention. The voltage regulator 385 transfers the regulated voltage to the voltage generation device 810. A control circuit 860 controls the closing and opening of a switch 850. If the switch 850 is closed, the voltage is applied. If the switch 850 is opened, the voltage is not applied. The timer 865 provides a signal to the control circuit 860 to instruct the control circuit 860 to turn on and off the switch 850. The control circuit 860 includes logic which can instruct the circuit to open and close the switch 850 a number of times (to match the necessary iterations). In an embodiment of the invention, the timer 865 may also transmit a stabilization signal to identify that the stabilization sequence is completed, i.e. that a stabilization timeframe has elapsed.

[0080] In an embodiment of the invention, the voltage generation device generates a first voltage for a first timeframe and generates a second voltage for a second timeframe. Fig. 8(c) illustrates a voltage generation device to generate two voltage values according in a sensor electronics device according to implement this embodiment of the invention. In this embodiment of the invention, a two position switch 870 is utilized. Illustratively, if the first switch position 871 is turned on or closed by the timer 865 instructing the control circuit 860, then the voltage generation device 810 generates a first voltage for the first timeframe. After the first voltage has been applied for the first timeframe, timer sends a signal to the control circuit 860 indicating the first timeframe has elapsed and the control circuit 860 directs the switch 870 to move to the second position 872. When the switch 870 is at the second position 872, the regulated voltage is directed to a voltage step-down or buck converter 880 to reduce the regulated voltage to a lesser value. The lesser value is then delivered to the op amp 840 for the second timeframe. After the timer 865 has sent a signal to the control circuit 860 that the second timeframe has elapsed, then the control circuit 860 moves the switch 870 back to the first position. This continues until the desired number of iterations has been completed or the stabilization timeframe has elapsed. In an embodiment of the invention,

after the sensor stabilization timeframe has elapsed, the sensor transmits a sensor signal 350 to the signal processor 390.

[0081] Fig. 8(d) illustrates a voltage application device 810 utilized to perform more complex applications of voltage to the sensor. The voltage application device 810 may include a control device 860, a switch 890, a sinusoid generation device 891, a ramp voltage generation device 892, and a constant voltage generation device 893. In other embodiments of the invention, the voltage application may generate an AC wave on top of a DC signal or other various voltage pulse waveforms. In the embodiment of the invention illustrated in Fig. 8(d), the control device 860 may cause the switch to move to one of the three voltage generation systems 891 (sinusoid), 892 (ramp), 893 (constant DC). This results in each of the voltage regulation systems generating the identified voltage waveform. Under certain operating conditions, e.g., where a sinusoidal pulse is to be applied for three pulses, the control device 860 may cause the switch 890 to connect the voltage from the voltage regulator 385 to the sinusoid voltage generator 891 in order for the voltage application device 810 to generate a sinusoidal voltage. Under other operating conditions, e.g., when a ramp voltage is applied to the sensor as the first voltage for a first pulse of three pulses, a sinusoid voltage is applied to the sensor as the first voltage for a second pulse of the three pulses, and a constant DC voltage is applied to the sensor as the first voltage for a third pulse of the three pulses, the control device 860 may cause the switch 890, during the first timeframes in the anodic / cathodic cycles, to move between connecting the voltage from the voltage generation or application device 810 to the ramp voltage generation system 891, then to the sinusoidal voltage generation system 892, and then to the constant DC voltage generation system 893. In this embodiment of the invention, the control device 860 may also be directing or controlling the switch to connect certain ones of the voltage generation subsystems to the voltage from the regulator 385 during the second timeframe, e.g., during application of the second voltage.

[0082] Fig. 9 illustrates a sensor electronics device including a microcontroller for generating voltage pulses according to an embodiment of the present invention. The advanced sensor electronics device may include a microcontroller 410 (see Fig. 4), a digital-to-analog converter (DAC) 420, an op amp 840, and a sensor signal measurement circuit 431. In an embodiment of the invention, the sensor signal measurement circuit may be a current-to-frequency (I/F) converter 430. In the embodiment of the invention illustrated in Fig. 9, software or programmable logic in the microcontroller 410 provides instructions to transmit signals to the DAC 420, which in turn instructs the DAC 420 to output a specific voltage to

the operational amplifier 840. The microcontroller 410 may also be instructed to output a specific voltage to the working electrode 375, as is illustrated by line 911 in Fig. 9. As discussed above, the application of the specific voltage to operational amplifier 840 and the working electrode 375 may drive the voltage measured at the counter electrode to the specific voltage magnitude. In other words, the microcontroller 410 outputs a signal which is indicative of a voltage or a voltage waveform that is to be applied to the sensor 355 (e.g., the operational amplifier 840 coupled to the sensor 355). In an alternative embodiment of the invention, a fixed voltage may be set by applying a voltage directly from the DAC 420 between the reference electrode and the working electrode 375. A similar result may also be obtained by applying voltages to each of the electrodes with the difference equal to the fixed voltage applied between the reference and working electrode. In addition, the fixed voltage may be set by applying a voltage between the reference and the counter electrode. Under certain operating conditions, the microcontroller 410 may generates a pulse of a specific magnitude which the DAC 420 understands represents that a voltage of a specific magnitude is to be applied to the sensor. After a first timeframe, the microcontroller 410 (via the program or programmable logic) outputs a second signal which either instructs the DAC 420 to output no voltage (for a sensor electronics device 360 operating according to the method described in Fig. 6(a)) or to output a second voltage (for a sensor electronics device 360 operating according to the method described in Fig. 6(b)). The microcontroller 410, after the second timeframe has elapsed, then repeats the cycle of sending the signal indicative of a first voltage to apply, (for the first timeframe) and then sending the signal to instruct no voltage is to be applied or that a second voltage is to be applied (for the second timeframe).

[0083] Under other operating conditions, the microcontroller 410 may generate a signal to the DAC 420 which instructs the DAC to output a ramp voltage. Under other operating conditions, the microcontroller 410 may generate a signal to the DAC 420 which instructs the DAC 420 to output a voltage simulating a sinusoidal voltage. These signals could be incorporated into any of the pulsing methodologies discussed above in the preceding paragraph or earlier in the application. In an embodiment of the invention, the microcontroller 410 may generate a sequence of instructions and/or pulses, which the DAC 420 receives and understands to mean that a certain sequence of pulses is to be applied. For example, the microcontroller 410 may transmit a sequence of instructions (via signals and/or pulses) that instruct the DAC 420 to generate a constant voltage for a first iteration of a first timeframe, a ramp voltage for a first iteration of a second timeframe, a sinusoidal voltage for

a second iteration of a first timeframe, and a squarewave having two values for a second iteration of the second timeframe.

[0084] The microcontroller 410 may include programmable logic or a program to continue this cycling for a stabilization timeframe or for a number of iterations. Illustratively, the microcontroller 410 may include counting logic to identify when the first timeframe or the second timeframe has elapsed. Additionally, the microcontroller 410 may include counting logic to identify that a stabilization timeframe has elapsed. After any of the preceding timeframes have elapsed, the counting logic may instruct the microcontroller to either send a new signal or to stop transmission of a signal to the DAC 420.

[0085] The use of the microcontroller 410 allows a variety of voltage magnitudes to be applied in a number of sequences for a number of time durations. In an embodiment of the invention, the microcontroller 410 may include control logic or a program to instruct the digital-to-analog converter 420 to transmit a voltage pulse having a magnitude of approximately 1.0 volt for a first time period of 1 minute, to then transmit a voltage pulse having a magnitude of approximately 0.5 volts for a second time period of 4 minutes, and to repeat this cycle for four iterations. In an embodiment of the invention, the microcontroller 410 may be programmed to transmit a signal to cause the DAC 420 to apply the same magnitude voltage pulse for each first voltage in each of the iterations. In an embodiment of the invention, the microcontroller 410 may be programmed to transmit a signal to cause the DAC to apply a different magnitude voltage pulse for each first voltage in each of the iterations. In this embodiment of the invention, the microcontroller 410 may also be programmed to transmit a signal to cause the DAC 420 to apply a different magnitude voltage pulse for each second voltage in each of the iterations. Illustratively, the microcontroller 410 may be programmed to transmit a signal to cause the DAC 420 to apply a first voltage pulse of approximately one volt in the first iteration, to apply a second voltage pulse of approximately .5 volts in the first iteration, to apply a first voltage of 0.7 volts and a second voltage of 0.4 volts in the second iteration, and to apply a first voltage of 1.2 and a second voltage of 0.8 in the third iteration.

[0086] The microcontroller 410 may also be programmed to instruct the DAC 420 to provide a number of short duration voltage pulses for a first timeframe. In this embodiment of the invention, rather than one voltage being applied for the entire first timeframe (e.g., two minutes), a number of shorter duration pulses may be applied to the sensor. In this embodiment, the microcontroller 410 may also be programmed to program the DAC 420 to provide a number of short duration voltage pulses for the second timeframe to

the sensor. Illustratively, the microcontroller 410 may send a signal to cause the DAC to apply a number of short duration voltage pulses where the short duration is 50 milliseconds or 100 milliseconds. In between these short duration pulses the DAC may apply no voltage or the DAC may apply a minimal voltage. The DAC 420 may cause the microcontroller to apply the short duration voltage pulses for the first timeframe, e.g., two minutes. The microcontroller 410 may then send a signal to cause the DAC to either not apply any voltage or to apply the short duration voltage pulses at a magnitude of a second voltage for a second timeframe to the sensor, e.g., the second voltage may be 0.75 volts and the second timeframe may be 5 minutes. In an embodiment of the invention, the microcontroller 410 may send a signal to the DAC 420 to cause the DAC 420 to apply a different magnitude voltage for each of short duration pulses in the first timeframe and/or in the second timeframe. In an embodiment of the invention, the microcontroller 410 may send a signal to the DAC 420 to cause the DAC 420 to apply a pattern of voltage magnitudes to the short durations voltage pulses for the first timeframe or the second timeframe. For example, the microcontroller may transmit a signal or pulses instructing the DAC 420 to apply thirty 20 millisecond pulses to the sensor during the first timeframe. Each of the thirty 20 millisecond pulses may have the same magnitude or may have a different magnitude. In this embodiment of the invention, the microcontroller 410 may instruct the DAC 420 to apply short duration pulses during the second timeframe or may instruct the DAC 420 to apply another voltage waveform during the second timeframe.

[0087] Although the disclosures in Figs. 6 – 8 disclose the application of a voltage, a current may also be applied to the sensor to initiate the stabilization process. Illustratively, in the embodiment of the invention illustrated in Fig. 6(b), a first current may be applied during a first timeframe to initiate an anodic or cathodic response and a second current may be applied during a second timeframe to initiate the opposite anodic or cathodic response. The application of the first current and the second current may continue for a number of iterations or may continue for a stabilization timeframe. In an embodiment of the invention, a first current may be applied during a first timeframe and a first voltage may be applied during a second timeframe. In other words, one of the anodic or cathodic cycles may be triggered by a current being applied to the sensor and the other of the anodic or cathodic cycles may be triggered by a voltage being applied to the sensor. As described above, a current applied may be a constant current, a ramp current, a stepped pulse current, or a sinusoidal current. Under certain operating conditions, the current may be applied as a sequence of short duration pulses during the first timeframe.

[0088] Fig. 9(b) illustrates a sensor and sensor electronics utilizing an analyzation module for feedback in a stabilization period according to an embodiment of the present invention. Fig. 9(b) introduces an analyzation module 950 to the sensor electronics device 360. The analyzation module 950 utilizes feedback from the sensor to determine whether or not the sensor is stabilized. In an embodiment of the invention, the microcontroller 410 may include instructions or commands to control the DAC 420 so that the DAC 420 applies a voltage or current to a part of the sensor 355. Fig. 9(b) illustrates that a voltage or current could be applied between a reference electrode 370 and a working electrode 375. However, the voltage or current can be applied in between electrodes or directly to one of the electrodes and the invention should not be limited by the embodiment illustrated in Fig. 9(b). The application of the voltage or current is illustrated by dotted line 955. The analyzation module 950 may measure a voltage, a current, a resistance, or an impedance in the sensor 355. Fig. 9(b) illustrates that the measurement occurs at the working electrode 375, but this should not be limit the invention because other embodiments of the invention may measure a voltage, a current, a resistance, or an impedance in between electrodes of the sensor or direct at either the reference electrode 370 or the counter electrode 365. The analyzation module 950 may receive the measured voltage, current, resistance, or impedance and may compare the measurement to a stored value (e.g., a threshold value or set measurement criteria). Dotted line 956 represents the analyzation module 950 reading or taking a measurement of the voltage, current, resistance, or impedance. Under certain operating conditions, if the measured voltage, current, resistance, or impedance is above the threshold, (or matches the set measurement criteria) the sensor is stabilized and the sensor signal is providing accurate readings of a physiological condition of a patient. Under other operating conditions, if the measured voltage, current, resistance, or impedance is below the threshold, the sensor is stabilized. Under other operating conditions, the analyzation module 950 may verify that the measured voltage, current, resistance, or impedance is stable for a specific timeframe, e.g., one minute or two minutes. This may represent that the sensor 355 is stabilized and that the sensor signal is transmitting accurate measurements of a subject's physiological parameter, e.g., blood glucose level. After the analyzation module 950 has determined that the sensor is stabilized and the sensor signal is providing accurate measurements, the analyzation module 950 may transmit a signal (e.g., a sensor stabilization signal) to the microcontroller 410 indicating that the sensor is stabilized and that the microcontroller 410 can start using or receiving the sensor signal from the sensor 355. This is represented by dotted line 957. Under other operating conditions, the microcontroller may receive a sensor stabilization

signal and may either terminate the stabilization sequence (because the sensor is stabilized), modify or alter the application of the pulses, or modify or alter the timing of the pulses.

[0089] Fig. 10 illustrates a block diagram of a sensor system including hydration electronics according to an embodiment of the present invention. The sensor system includes a connector 1010, a sensor 1012, and a monitor or sensor electronics device 1025. The sensor 1010 includes electrodes 1020 and a connection portion 1024. In an embodiment of the invention, the sensor 1012 may be connected to the sensor electronics device 1025 via a connector 1010 and a cable. In other embodiments of the invention, the sensor 1012 may be directly connected to the sensor electronics device 1025. In other embodiments of the invention, the sensor 1012 may be incorporated into the same physical device as the sensor electronics device 1025. The monitor or sensor electronics device 1025 may include a power supply 1030, a regulator 1035, a signal processor 1040, a measurement processor 1045, and a processor 1050. The monitor or sensor electronics device 1025 may also include a hydration detection circuit 1060. The hydration detection circuit 1060 interfaces with the sensor 1012 to determine if the electrodes 1020 of the sensor 1012 are sufficiently hydrated. If the electrodes 1020 are not sufficiently hydrated, the electrodes 1020 do not provide accurate glucose readings, so it is important to know when the electrodes 1020 are sufficiently hydrated. Once the electrodes 1020 are sufficiently hydrated, accurate glucose readings may be obtained.

[0090] In an embodiment of the invention illustrated in Fig. 10, the hydration detection circuit 1060 may include a delay or timer module 1065 and a connection detection module 1070. In an embodiment of the invention utilizing the short term sensor or the subcutaneous sensor, after the sensor 1012 has been inserted into the subcutaneous tissue, the sensor electronics device or monitor 1025 is connected to the sensor 1012 utilizing the cable 1015. The connection detection module 1070 identifies that the sensors electronics device or monitor 1025 has been connected to the sensor 1012 and sends a signal to the timer module 1065. This is illustrated in Fig. 10 by the arrow 1084 which represents a detector 1083 detecting a connection and sending a signal to the connection detection module 1070 indicating the sensor 1012 has been connected to the sensor electronics device or monitor 1025. In an embodiment of the invention where implantable or long-term sensors are utilized, a connection detection module 1070 identifies that the implantable sensor has been inserted into the body. The timer module 1065 receives the connection signal and waits a set or established hydration time. Illustratively, the hydration time may be two minutes, five minutes, ten minutes, or 20 minutes. These examples are meant to be illustrative and not to

be limiting. The timeframe does not have to be a set number of minutes and can include any number of seconds. In an embodiment of the invention, after the timer module 1065 has waited for the set hydration time, the timer module 1065 may notify the processor 1050 that the sensor 1012 is hydrated by sending a hydration signal, which is illustrated by dotted line 1086.

[0091] In this embodiment of the invention, the processor 1050 may receive the hydration signal and only start utilizing the sensor signal (e.g., sensor measurements) after the hydration signal has been received. In another embodiment of the invention, the hydration detection circuit 1060 may be coupled between the sensor (the sensor electrodes 1020) and the signal processor 1040. In this embodiment of the invention, the hydration detection circuit 1060 may prevent the sensor signal from being sent to signal processor 1040 until the timer module 1065 has notified the hydration detection circuit 1060 that the set hydration time has elapsed. This is illustrated by the dotted lines labeled with reference numerals 1080 and 1081. Illustratively, the timer module 1065 may transmit a connection signal to a switch (or transistor) to turn on the switch and let the sensor signal proceed to the signal processor 1040. In an alternative embodiment of the invention, the timer module 1065 may transmit a connection signal to turn on a switch 1088 (or close the switch 1088) in the hydration detection circuit 1060 to allow a voltage from the regulator 1035 to be applied to the sensor 1012 after the hydration time has elapsed. In other words, in this embodiment of the invention, the voltage from the regulator 1035 will not be applied to the sensor 1012 until after the hydration time has elapsed.

[0092] Fig. 11illustrates an embodiment of the invention including a mechanical switch to assist in determining a hydration time. In an embodiment of the invention, a single housing 1100 may include a sensor assembly 1120 and a sensor electronics device 1125. In an embodiment of the invention, the sensor assembly 1120 may be in one housing and the sensor electronics device 1125 may be in a separate housing, but the sensor assembly 1120 and the sensor electronics device 1125 may be connected together. In this embodiment of the invention, a connection detection mechanism 1160 may include be a mechanical switch. The mechanical switch may detect that the sensor 1120 is physically connected to the sensor electronics device 1125. In an embodiment of the invention, a timer circuit 1135 may also be activated when the mechanical switch 1160 detects that the sensor 1120 is connected to the sensor electronics device 1125. In other words, the mechanical switch may close and a signal may be transferred to a timer circuit 1135. Once a hydration time has elapsed, the timer circuit 1135 transmits a signal to the switch 1140 to allow the regulator 1035 to apply a

voltage to the sensor 1120. In other words, no voltage is applied until the hydration time has elapsed. In an embodiment of the invention, current may replace voltage as what is being applied to the sensor once the hydration time elapses. In an alternative embodiment of the invention, when the mechanical switch 1160 identifies that a sensor 1120 has been physically connected to the sensor electronics device 1125, power may initially be applied to the sensor 1120. Power being sent to the sensor 1120 results in a sensor signal being output from the working electrode in the sensor 1120. The sensor signal may be measured and sent to and may be input to a processor 1175. The processor 1175 may include a counter input. Under certain operating conditions, after a set hydration time has elapsed from when the sensor signal was input into the processor 1175, the processor 1175 may start processing the sensor signal as an accurate measurement of the glucose in a subject's body. In other words, the processor 1170 has received the sensor signal from the potentiostat circuit 1170 for a certain amount of time, but will not process the signal until receiving an instruction from the counter input of the processor identifying that a hydration time has elapsed. In an embodiment of the invention, the potentiostat circuit 1170 may include a current-to-frequency converter 1180. In this embodiment of the invention, the current-to-frequency converter 1180, may receive the sensor signal as a current value and may convert the current value into a frequency value, which is easier for the processor 1175 to handle.

[0093] In an embodiment of the invention, the mechanical switch 1160 may also notify the processor 1170 when the sensor 1120 has been disconnected from the sensor electronics device 1125. This is represented by dotted line 1176 in Fig. 11. This may result in the processor 1170 powering down or reducing power to a number of components of the sensor electronics device 1125. If the sensor 1120 is not connected, the battery or power source may be drained if the components or circuits of the sensor electronics device 1125 are in a power on stated. Accordingly, if the mechanical switch 1160 detects that the sensor 1120 has been disconnected from the sensor electronics device 1125, the mechanical switch may indicate this to the processor 1175, and the processor 1175 may power down or reduce power to one or more of the electronic circuits or components of the sensor electronics device 1125.

[0094] Fig. 12 illustrates an electrical method of detection of hydration according to an embodiment of the invention. In an embodiment of the invention, an electrical detecting mechanism for detecting connection of a sensor may be utilized. In this embodiment of the invention, the hydration detection electronics 1250 may include an AC source 1255 and a detection circuit 1260. The hydration detection electronics 1250 may be located in the sensor electronics device 1225. The sensor 1220 may include a counter electrode 1221, a reference

electrode 1222, and a working electrode 1223. As illustrated in Fig. 12, the AC source 1255 is coupled to a voltage setting device 1275, the reference electrode 1222, and the detection circuit 1260. In this embodiment of the invention, an AC signal from the AC source is applied to the reference electrode connection, as illustrated by dotted line 1291 in Fig. 12. In an embodiment of the invention, the AC signal is coupled to the sensor 1220 through an impedance and the coupled signal is attenuated significantly if the sensor 1220 is connected to the sensor electronics device 1225. Thus, a low level AC signal is present at an input to the detection circuit 1260. This may also be referred to as a highly attenuated signal or a signal with a high level of attenuation. Under certain operating conditions, the voltage level of the AC signal may be Vapplied *(Ccoupling) / (Ccoupling + Csensor). If the detection circuit 1260 detects that the a high level AC signal (lowly attenuated signal) is present at an input terminal of the detection circuit 1260, no interrupt is sent to the microcontroller 410 because the sensor 1220 has not been sufficiently hydrated or activated. For example, the input of the detection circuit 1260 may be a comparator. If the sensor 1220 is sufficiently hydrated (or wetted), an effective capacitance forms between the counter electrode and the reference electrode, (e.g., capacitance C_{r-c} in Fig. 12) and an effective capacitance forms between the reference electrode and the working electrode (e.g., capacitance C_{w-r} in Fig. 12). In other words, an effective capacitance relates to capacitance being formed between two nodes and does not represent that an actual capacitor is placed in a circuit between the two electrodes. In an embodiment of the invention, the AC signal from the AC source 1255 is sufficiently attenuated by capacitances C_{r-c} and C_{w-r} and the detection circuit 1260 detects the presence of a low level or highly attenuated AC signal from the AC source 1255 at the input terminal of the detection circuit 1260. This embodiment of the invention is significant because the utilization of the existing connections between the sensor 1120 and the sensor electronics device 1125 reduces the number of connections to the sensor. In other words, the mechanical switch, disclosed in Fig. 11, requires a switch and associated connections between the sensor 1120 and the sensor electronics device 1125. It is advantageous to eliminate the mechanical switch because the sensor 1120 is continuously shrinking in size and the elimination of components helps achieve this size reduction. In alternative embodiments of the invention, the AC signal may be applied to different electrodes (e.g., the counter electrode or the working electrode) and the invention may operate in a similar fashion.

[0095] As noted above, after the detection circuit 1260 has detected that a low level AC signal is present at the input terminal of the detection circuit 1260, the detection circuit

1260 may later detect that a high level AC signal, with low attenuation, is present at the input terminal. This represents that the sensor 1220 has been disconnected from the sensor electronics device 1225 or that the sensor is not operating properly. If the sensor has been disconnected from the sensor electronics device 1225, the AC source may be coupled with little or low attenuation to the input of the detection circuit 1260. As noted above, the detection circuit 1260 may generate an interrupt to the microcontroller. This interrupt may be received by the microcontroller and the microcontroller may reduce or eliminate power to one or a number of components or circuits in the sensor electronics device 1225. This may be referred to as the second interrupt. Again, this helps reduce power consumption of the sensor electronics device 1225, specifically when the sensor 1220 is not connected to the sensor electronics device 1225.

[0096] In an alternative embodiment of the election illustrated in Fig. 12, the AC signal may be applied to the reference electrode 1222, as is illustrated by reference numeral 1291, and an impedance measuring device 1277 may measure the impedance of an area in the sensor 1220. Illustratively, the area may be an area between the reference electrode and the working electrode, as illustrated by dotted line 1292 in Fig. 12. Under certain operating conditions, the impedance measuring device 1277 may transmit a signal to the detection circuit 1260 if a measured impedance has decreased to below an impedance threshold or other set criteria. This represents that the sensor is sufficiently hydrated. Under other operating conditions, the impedance measuring device 1277 may transmit a signal to the detection circuit 1260 once the impedance is above an impedance threshold. The detection circuit 1260 then transmits the interrupt to the microcontroller 410. In another embodiment of the invention, the detection circuit 1260 may transmit an interrupt or signal directly to the microcontroller.

[0097] In an alternative embodiment of the invention, the AC source 1255 may be replaced by a DC source. If a DC source is utilized, then a resistance measuring element may be utilized in place of an impedance measuring element 1277. In an embodiment of the invention utilizing the resistance measuring element, once the resistance drops below a resistance threshold or a set criteria, the resistance measuring element may transmit a signal to the detection circuit 1260 (represented by dotted line 1293) or directly to the microcontroller indicating that the sensor is sufficiently hydrated and that power may be applied to the sensor.

[0098] In the embodiment of the invention illustrated in Fig. 12, if the detection circuit 1260 detects a low level or highly attenuated AC signal from the AC source, an

interrupt is generated to the microcontroller 410. This interrupt indicates that sensor is sufficiently hydrated. In this embodiment of the invention, in response to the interrupt, the microcontroller 410 generates a signal that is transferred to a digital-to-analog converter 420 to instruct or cause the digital-to-analog converter 420 to apply a voltage or current to the sensor 1220. Any of the different sequence of pulses or short duration pulses described above in Figs. 6(a), 6(b), or 6(c) or the associated text describing the application of pulses, may be applied to the sensor 1220. Illustratively, the voltage from the DAC 420 may be applied to an op-amp 1275, the output of which is applied to the counter electrode 1221 of the sensor 1220. This results in a sensor signal being generated by the sensor, e.g., the working electrode 1223 of the sensor. Because the sensor is sufficiently hydrated, as identified by the interrupt, the sensor signal created at the working electrode 1223 is accurately measuring glucose. The sensor signal is measured by a sensor signal measuring device 431 and the sensor signal measuring device 431 transmits the sensor signal to the microcontroller 410 where a parameter of a subject's physiological condition is measured. The generation of the interrupt represents that a sensor is sufficiently hydrated and that the sensor 1220 is now supplying accurate glucose measurements. In this embodiment of the invention, the hydration period may depend on the type and/or the manufacturer of the sensor and on the sensor's reaction to insertion or implantation in the subject. Illustratively, one sensor 1220 may have a hydration time of five minutes and one sensor 1220 may have a hydration time of one minute, two minutes, three minutes, six minutes, or 20 minutes. Again, any amount of time may be an acceptable amount of hydration time for the sensor, but smaller amounts of time are preferable.

[0099] If the sensor 1220 has been connected, but is not sufficiently hydrated or wetted, the effective capacitances $C_{r\text{-}c}$ and $C_{w\text{-}r}$ may not attenuate the AC signal from the AC source 1255. The electrodes in the sensor 1120 are dry before insertion and because the electrodes are dry, a good electrical path (or conductive path) does not exist between the two electrodes. Accordingly, a high level AC signal or lowly attenuated AC signal may still be detected by the detection circuit 1260 and no interrupt may be generated. Once the sensor has been inserted, the electrodes become immersed in the conductive body fluid. This results in a leakage path with lower DC resistance. Also, boundary layer capacitors form at the metal / fluid interface. In other words, a rather large capacitance forms between the metal / fluid interface and this large capacitance looks like two capacitors in series between the electrodes of the sensor. This may be referred to as an effective capacitance. In practice, a conductivity of an electrolyte above the electrode is being measured. In some embodiments

of the invention, the glucose limiting membrane (GLM) also illustrates impedance blocking electrical efficiency. An unhydrated GLM results in high impedance, whereas a high moisture GLM results in low impedance. Low impedance is desired for accurate sensor measurements.

[00100] Fig. 13(a) illustrates a method of hydrating a sensor according to an embodiment of the present invention. In an embodiment of the invention, the sensor may be physically connected 1310 to the sensor electronics device. After the connection, in one embodiment of the invention, a timer or counter may be initiated to count 1320 a hydration time. After the hydration time has elapsed, a signal may be transmitted 1330 to a subsystem in the sensor electronics device to initiate the application of a voltage to the sensor. As discussed above, in an embodiment of the invention, a microcontroller may receive the signal and instruct the DAC to apply a voltage to the sensor or in another embodiment of the invention, a switch may receive a signal which allows a regulator to apply a voltage to the sensor. The hydration time may be five minutes, two minutes, ten minutes and may vary depending on the subject and also on the type of sensor

[00101] In an alternative embodiment of the invention, after the connection of the sensor to the sensor electronics device, an AC signal (e.g., a low voltage AC signal) may be applied 1340 to the sensor, e.g., the reference electrode of the sensor. The AC signal may be applied because the connection of the sensor to the sensor electronics device allows the AC signal to be applied to the sensor. After application of the AC signal, an effective capacitance forms 1350 between the electrode in the sensor that the voltage is applied to and the other two electrodes. A detection circuit determines 1360 what level of the AC signal is present at the input of the detection circuit. If a low level AC signal (or highly attenuated AC signal) is present at the input of the detection circuit, due to the effective capacitance forming a good electrical conduit between the electrodes and the resulting attenuation of the AC signal, an interrupt is generated 1370 by the detection circuit and sent to a microcontroller.

[00102] The microcontroller receives the interrupt generated by the detection circuit and transmits 1380 a signal to a digital-to-analog converter instructing or causing the digital-to-analog converter to apply a voltage to an electrode of the sensor, e.g., the counter electrode. The application of the voltage to the electrode of the sensor results in the sensor creating or generating a sensor signal 1390. A sensor signal measurement device 431 measures the generated sensor signal and transmits the sensor signal to the microcontroller. The microcontroller receives 1395 the sensor signal from the sensor signal measurement

device, i.e., which is coupled to the working electrode, and processes the sensor signal to extract a measurement of a physiological characteristic of the subject or patient.

[00103] Fig. 13(b) illustrates an additional method for verifying hydration of a sensor according to an embodiment of the present invention. In the embodiment of the invention illustrated in Fig. 13(b), the sensor is physically connected 1310 to the sensor electronics device. In an embodiment of the invention, an AC signal is applied 1341 to an electrode, e.g., a reference electrode, in the sensor. Alternatively, in an embodiment of the invention, a DC signal is applied 1341 to an electrode in the sensor. If an AC signal is applied, an impedance measuring element measures 1351 an impedance at a point within the sensor. Alternatively, if a DC signal is applied a resistance measuring element measures 1351 a resistance at a point within the sensor. If the resistance or impedance is lower than an resistance threshold or impedance threshold, respectively, then the impedance (or resistance) measuring element transmits 1361 (or allows a signal to be transmitted) to the detection circuit, and the detection circuit transmits an interrupt identifying that the sensor is hydrated to the microcontroller.

[00104] The microcontroller receives the interrupt and transmits 1380 a signal to a digital-to-analog converter to apply a voltage to the sensor. In an alternative embodiment of the invention, the digital-to-analog converter can apply a current to the sensor, as discussed above. The sensor, e.g., the working electrode, creates 1390 a sensor signal, which represents a physiological parameter of a patient. The microcontroller receives 1395 the sensor signal from a sensor signal measuring device, which measures the sensor signal at an electrode in the sensor, e.g., the working electrode. The microcontroller processes the sensor signal to extract a measurement of the physiological characteristic of the subject or patient, e.g., the blood glucose level of the patient.

[00105] Figs. 14(a) and (b) illustrate methods of combining hydrating of a sensor with stabilizing of a sensor according to an embodiment of the present invention. In an embodiment of the invention illustrated in Fig. 14(a), the sensor is connected 1405 to the sensor electronics device. The AC signal is applied 1410 to an electrode of the sensor. The detection circuit determines 1420 what level of the AC signal is present at an input of the detection circuit. If the detection circuit determines that a low level of the AC signal is present at the input, (representing a high level of attenuation to the AC signal), an interrupt is sent 1430 to microcontroller. Once the interrupt is sent to the microcontroller, the microcontroller knows to begin or initiate 1440 a stabilization sequence, i.e., the application of a number of voltage pulses to an electrode of the sensors, as described above. For

example, the microcontroller may cause a digital-to-analog converter to apply three voltage pulses (having a magnitude of + 0.535 volts) to the sensor with each of the three voltage pulses followed by a period of three voltage pulses (having a magnitude of 1.07 volts to be applied). This may be referred to transmitting a stabilization sequence of voltages. The microcontroller may cause this by the execution of a software program in a read-only memory (ROM) or a random access memory. After the stabilization sequence has finished executing, the sensor may generate 1450 a sensor signal, which is measured and transmitted to a microcontroller.

[00106] In an embodiment of the invention, the detection circuit may determine 1432 that a high level AC signal has continued to be present at the input of the detection circuit (e.g., an input of a comparator), even after a hydration time threshold has elapsed. For example, the hydration time threshold may be 10 minutes. After 10 minutes has elapsed, the detection circuit may still be detecting that a high level AC signal is present. At this point in time, the detection circuit may transmit 1434 a hydration assist signal to the microcontroller. If the microcontroller receives the hydration assist signal, the microcontroller may transmit 1436 a signal to cause a DAC to apply a voltage pulse or a series of voltage pulses to assist the sensor in hydration. In an embodiment of the invention, the microcontroller may transmit a signal to cause the DAC to apply a portion of the stabilization sequence or other voltage pulses to assist in hydrating the sensor. In this embodiment of the invention, the application of voltage pulses may result in the low level AC signal (or highly attenuated signal) being detected 1438 at the detection circuit. At this point, the detection circuit may transmit an interrupt, as is disclosed in step 1430, and the microcontroller may initiate a stabilization sequence.

[00107] Fig. 14(b) illustrates a second embodiment of a combination of a hydration method and a stabilization method where feedback is utilized in the stabilization process. A sensor is connected 1405 to a sensor electronics device. An AC signal (or a DC signal) is applied 1411 to the sensor. In an embodiment of the invention, the AC signal (or the DC signal) is applied to an electrode of the sensor, e.g. the reference electrode. A impedance measuring device (or resistance measuring device) measures 1416 the impedance (or resistance) within a specified area of the sensor. In an embodiment of the invention, the impedance (or resistance) may be measured between the reference electrode and the working electrode. The measured impedance (or resistance) may be compared 1421 to an impedance or resistance value to see if the impedance (or resistance) is low enough in the sensor, which indicates the sensor is hydrated. If the impedance (or resistance) is below the impedance (or

resistance) value or other set criteria, (which may be a threshold value), an interrupt is transmitted 1431 to the microcontroller. After receiving the interrupt, the microcontroller transmits 1440 a signal to the DAC instructing the DAC to apply a stabilization sequence of voltages (or currents) to the sensor. After the stabilization sequence has been applied to the sensor, a sensor signal is created in the sensor (e.g., at the working electrode), is measured by a sensor signal measuring device, is transmitted by the sensor signal measuring device, and is received 1450 by the microcontroller. Because the sensor is hydrated and the stabilization sequence of voltages has been applied to the sensor, the sensor signal is accurately measuring a physiological parameter (i.e., blood glucose)

[00108] Fig. 14(c) illustrates a third embodiment of the invention where a stabilization method and hydration method are combined. In this embodiment of the invention, the sensor is connected 1500 to the sensor electronics device. After the sensor is physically connected to the sensor electronics device, an AC signal (or DC signal) is applied 1510 to an electrode (e.g., reference electrode) of the sensor. At the same time, or around the same time, the microcontroller transmits a signal to cause the DAC to apply 1520 a stabilization voltage sequence to the sensor. In an alternative embodiment of the invention, a stabilization current sequence may be applied to the sensor instead of a stabilization voltage sequence. The detection circuit determines 1530 what level of an AC signal (or DC signal) is present at an input terminal of the detection circuit. If there is a low level AC signal (or DC signal), representing a highly attenuated AC signal (or DC signal), present at the input terminal of the detection circuit, an interrupt is transmitted 1540 to the microcontroller. Because the microcontroller has already initiated the stabilization sequence, the microcontroller receives the interrupt and sets 1550 a first indicator that the sensor is sufficiently hydrated. After the stabilization sequence is complete, the microcontroller sets 1555 a second indicator indicating the completion of the stabilization sequence. The application of the stabilization sequence voltages results in the sensor, e.g., the working electrode, creating 1560 a sensor signal, which is measured by a sensor signal measuring circuit, and sent to the microcontroller. If the second indicator that the stabilization sequence is complete is set and the first indicator that the hydration is complete is set, the microcontroller is able to utilize 1570 the sensor signal. If one or both of the indicators are not set, the microcontroller may not utilize the sensor signal because the sensor signal may not represent accurate measurements of the physiological measurements of the subject.

[00109] The scope of the claims should not be limited by the preferred embodiments set forth herein, but should be given the broadest interpretation consistent with the description as a whole.

WHAT IS CLAIMED IS:

1. A method of stabilizing a sensor in physiological parameter sensing applications during initialization of the sensor, comprising:

(a) applying a first voltage to an electrode in a sensor for a first timeframe;

(b) applying a second voltage to an electrode in a sensor for a second timeframe;

(c) making a measurement of an electrical characteristic of the sensor; and

(d) based on the measurement, determining whether the sensor is stabilized.

2. A blood glucose sensing system, comprising:

a sensor, the sensor including a plurality of electrodes; and

a sensor electronics device, the sensor electronics device including circuitry configured

(a) to provide a first voltage to one of the plurality of electrodes for a first timeframe,

(b) to provide a second voltage to the one of the plurality of electrodes for a second timeframe,

(c) to make a measurement of an electrical characteristic of the sensor and,

(d) based on the measurement, to determine whether the sensor is stabilized.

3. A program code storage device, comprising:

computer-readable storage medium; and

computer-readable program code, the computer-readable program code being stored on the computer-readable storage medium and having instructions, which when executed cause a glucose sensing system according to claim 2 to:

(a) transmit a first signal to a digital-to-analogue converter (DAC), the DAC being coupled to an electrode of a sensor in physiological parameter sensing applications, the first signal representative of a first voltage that the DAC is to apply to the electrode for a first predetermined time;

(b) transmit a second signal instructing the DAC to apply a second voltage to the electrode for a second predetermined time;

(c) transmit a measurement signal to an analyzation module to cause the analyzation module to measure an electrical characteristic of the sensor; and

(d) receive a third signal from the analyzation module indicating whether the sensor is stabilized based on the measurement.

4. A method according to claim 1, the system according to claim 2 or the device according to claim 3 wherein the second voltage is zero.

5. The method of claim 1 or 4; the device of claim 3 or 4; or the system of claim 2 or 4, wherein the sensor is determined to be stabilized if the measured electrical characteristic exceeds a threshold value.

6. The method, the device or the system of claim 5 wherein the electrical characteristic is one of voltage, current, resistance or impedance.

7. The method of claim 1 or 4; the device of claim 3 or 4; or the system of claim 2 or 4, further repeating steps (a) to (d) if the sensor is determined not to be stabilized.

8. The method, device or the system of claim 7, wherein the duration of at least one of the first timeframe and the second timeframe is modified for the repetition of steps (a) to (d).

9. The method of claim 1 or 4; the device of claim 3 or 4; or the system of claim 2 or 4, wherein if the sensor is determined not to be stabilized, repeating steps (a) and (b) for a plurality of iterations prior to proceeding to steps (c) and (d).

10. The method of claim 1; the system of claim 2; or the device of claim 3, wherein at least one of the first and second voltages is a ramp voltage, a sinusoid-shaped voltage, a stepped voltage or a squarewave or the at least one of the first and second voltages includes a plurality of voltage pulses.

11. The method, device or system of claim 4 wherein the first voltage is a ramp voltage, a sinusoid-shaped voltage, a stepped voltage or a squarewave.

12. The method, device or system of claim 4 wherein the first voltage includes a plurality of voltage pulses.

13. The method, device or the system of claim 12 further including modifying the number of the plurality of voltage pulses and repeating steps (a)-(d) if the sensor is determined not to be stabilized.

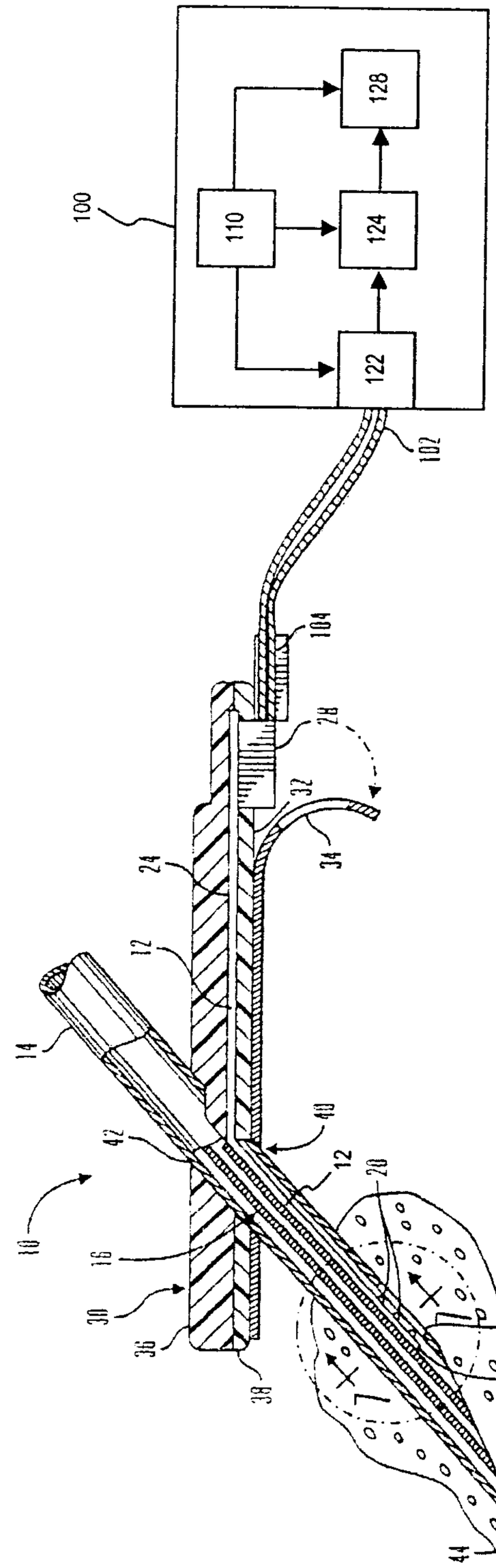
14. A blood glucose sensing system, comprising:

a sensor, the sensor including a plurality of electrodes; and

a sensor electronics device, the sensor electronics device including stabilization circuitry to provide a first voltage to one of the plurality of electrodes to initiate an anodic cycle within the sensor, to provide a second voltage to the one of the plurality of electrodes to initiate a cathodic cycle within the sensor, and to repeat the application of the first voltage and the second voltage to continue the anodic - cathodic cycle;

wherein the stabilization circuitry includes a microcontroller, the microcontroller transmitting a first signal indicative of the first voltage to be applied to a sensor and also transmitting a second signal indicative of the second voltage, and

wherein the stabilization circuitry further includes analyzation circuitry to measure an electrical characteristic of the sensor and to transmit a reading indicating the electrical characteristic measurement to the microcontroller.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124
128
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Fig. 1

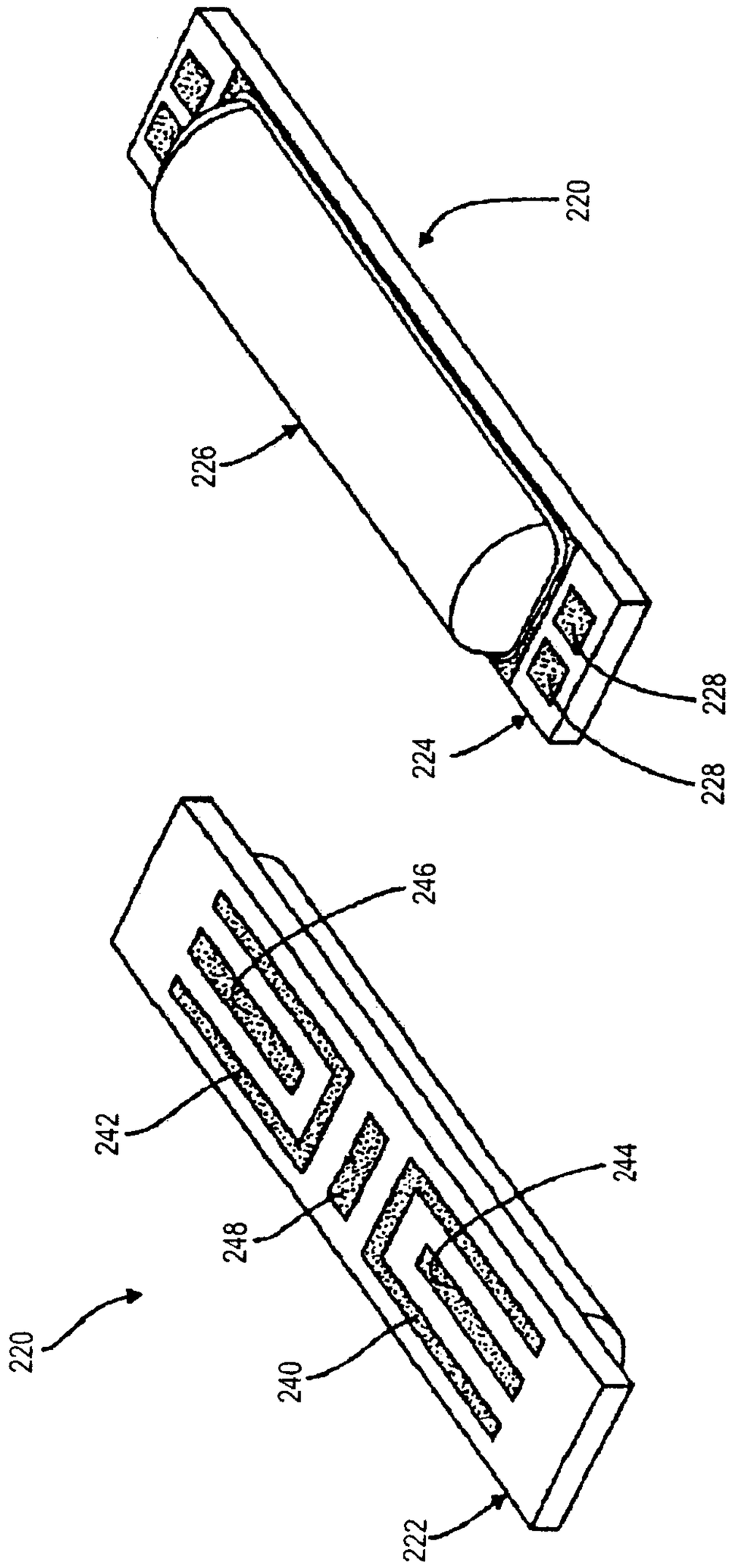
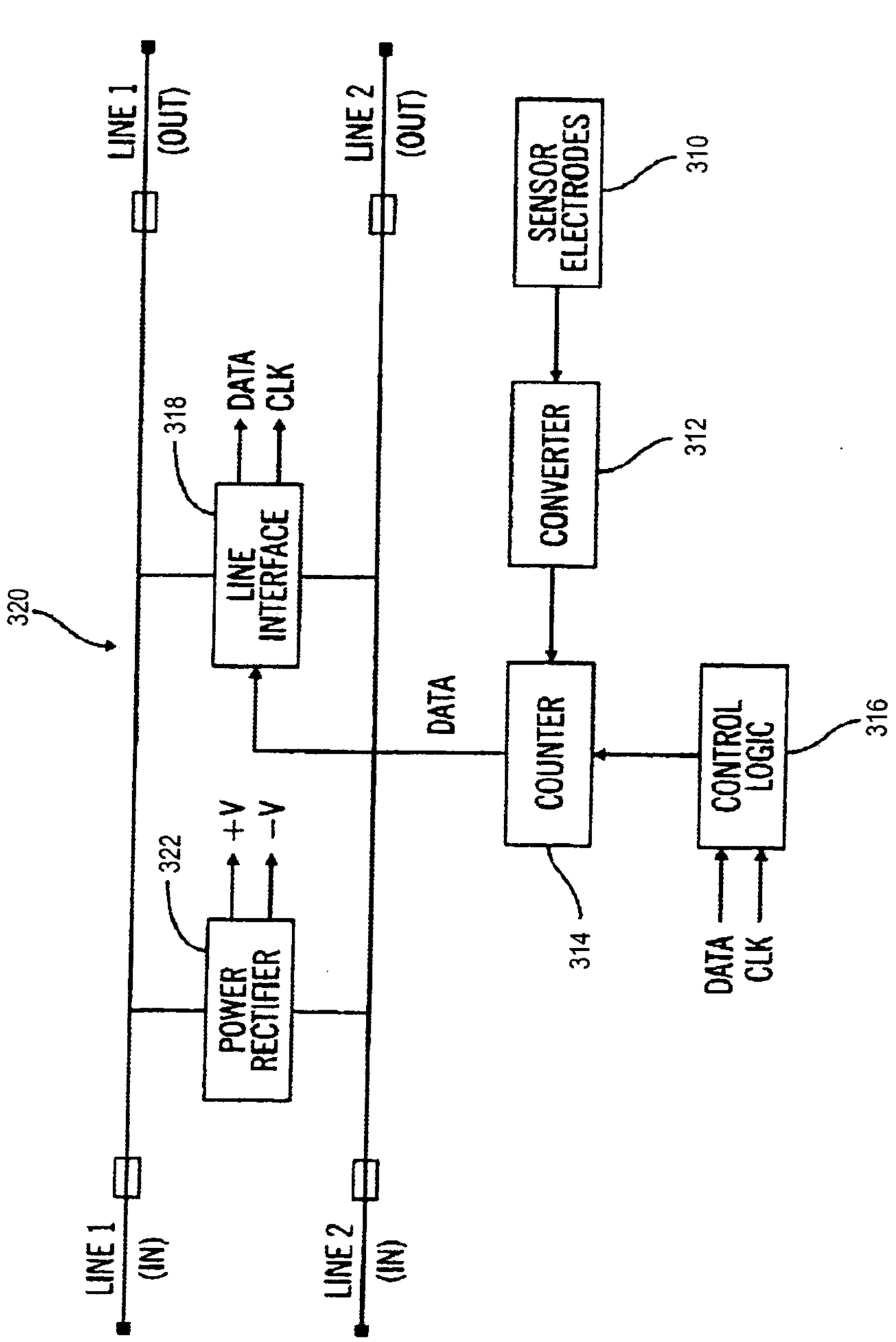


Fig. 2(a)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(OUT)
LINE 2
(OUT)
SENSOR ELECTRODES
310
320
318
DATA
CLK
LINE INTERFACE
CONVERTER
312
DATA
COUNTER
CONTROL LOGIC
316
322
+V
-V
POWER RECTIFIER
314
DATA
CLK
LINE 1
(IN)
LINE 2
(IN)

Fig. 2(b)

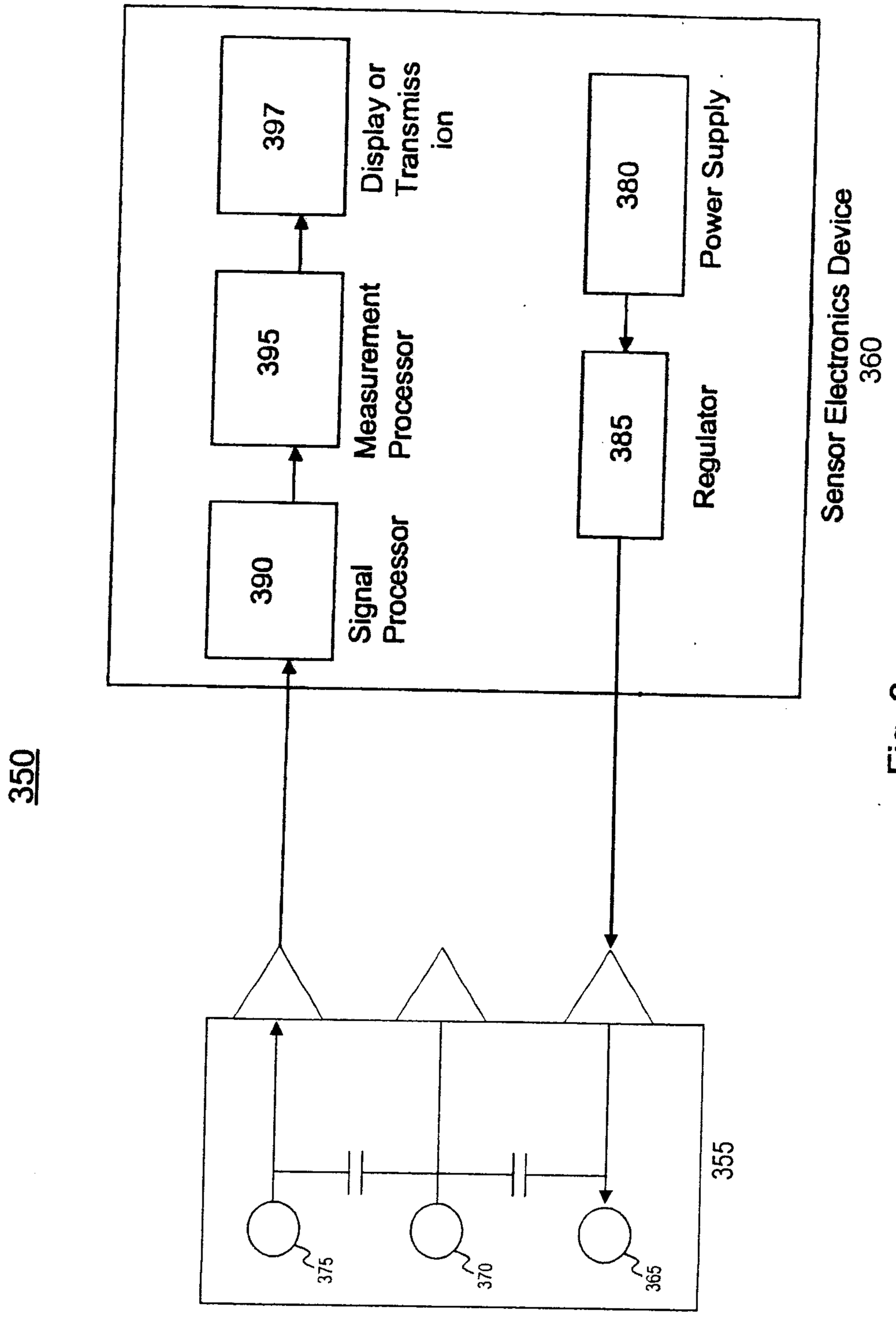
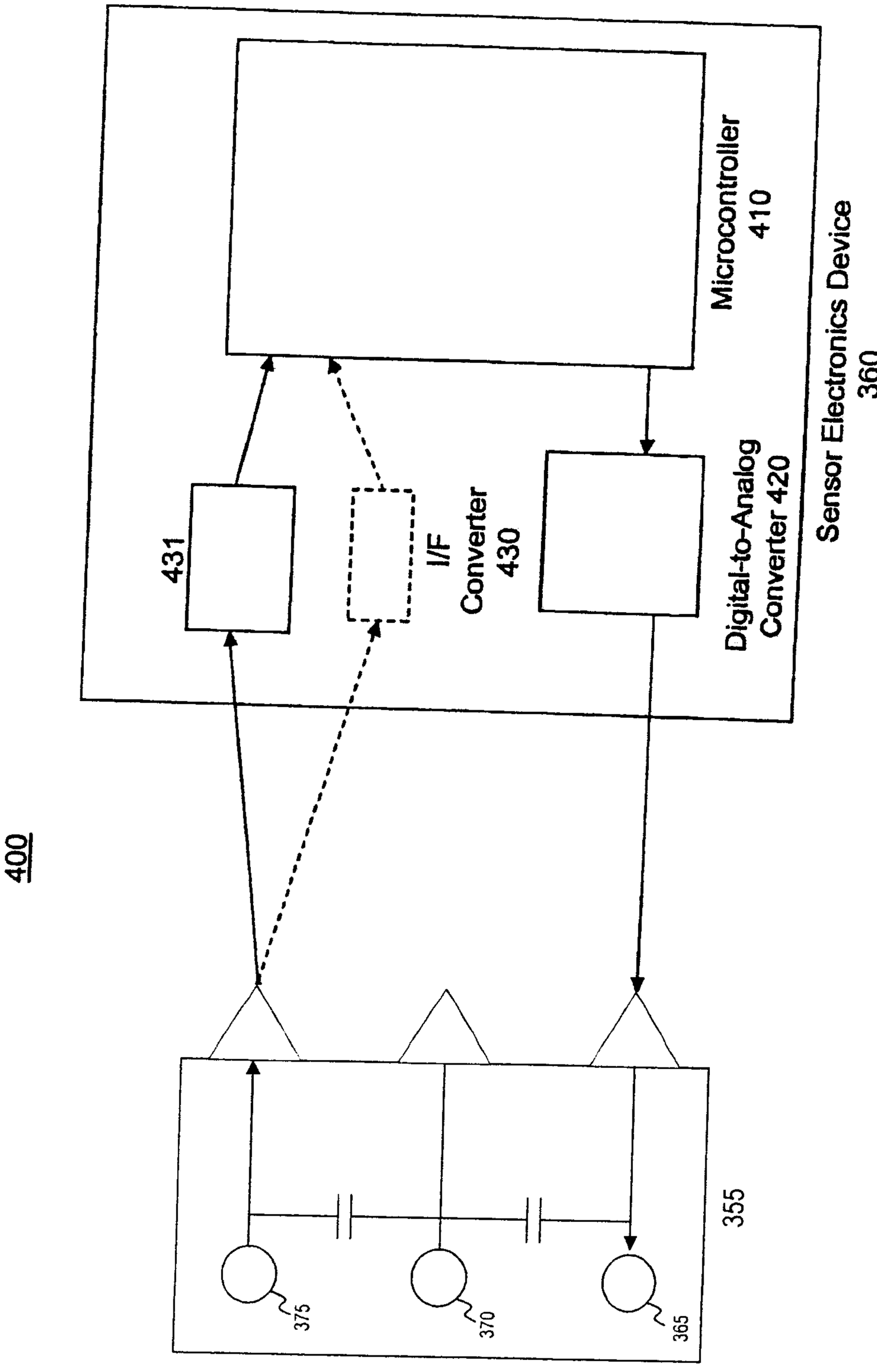

350
Sensor Electronics Device
360
397
Display or Transmiss ion
395
Measurement Processor
390
Signal Processor
380
Power Supply
385
Regulator
355
375
370
365

Fig. 3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Sensor Electronics Device
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Microcontroller
410
Digital-to-Analog
Converter 420
I/F
Converter
430
431
355
375
370
365

Fig. 4

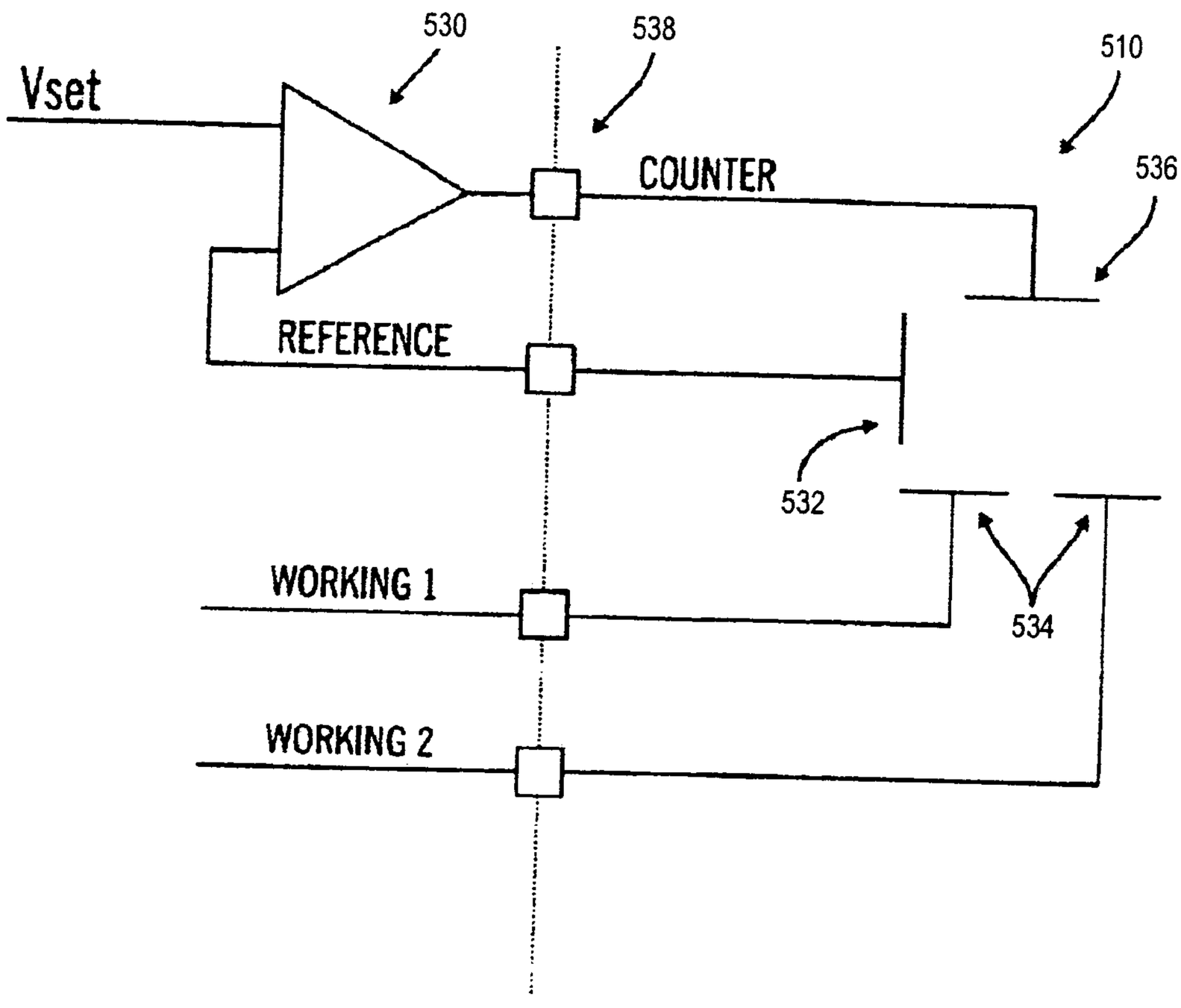

530
538
510
Vset
COUNTER
536
REFERENCE
532
WORKING 1
534
WORKING 2

Fig. 5

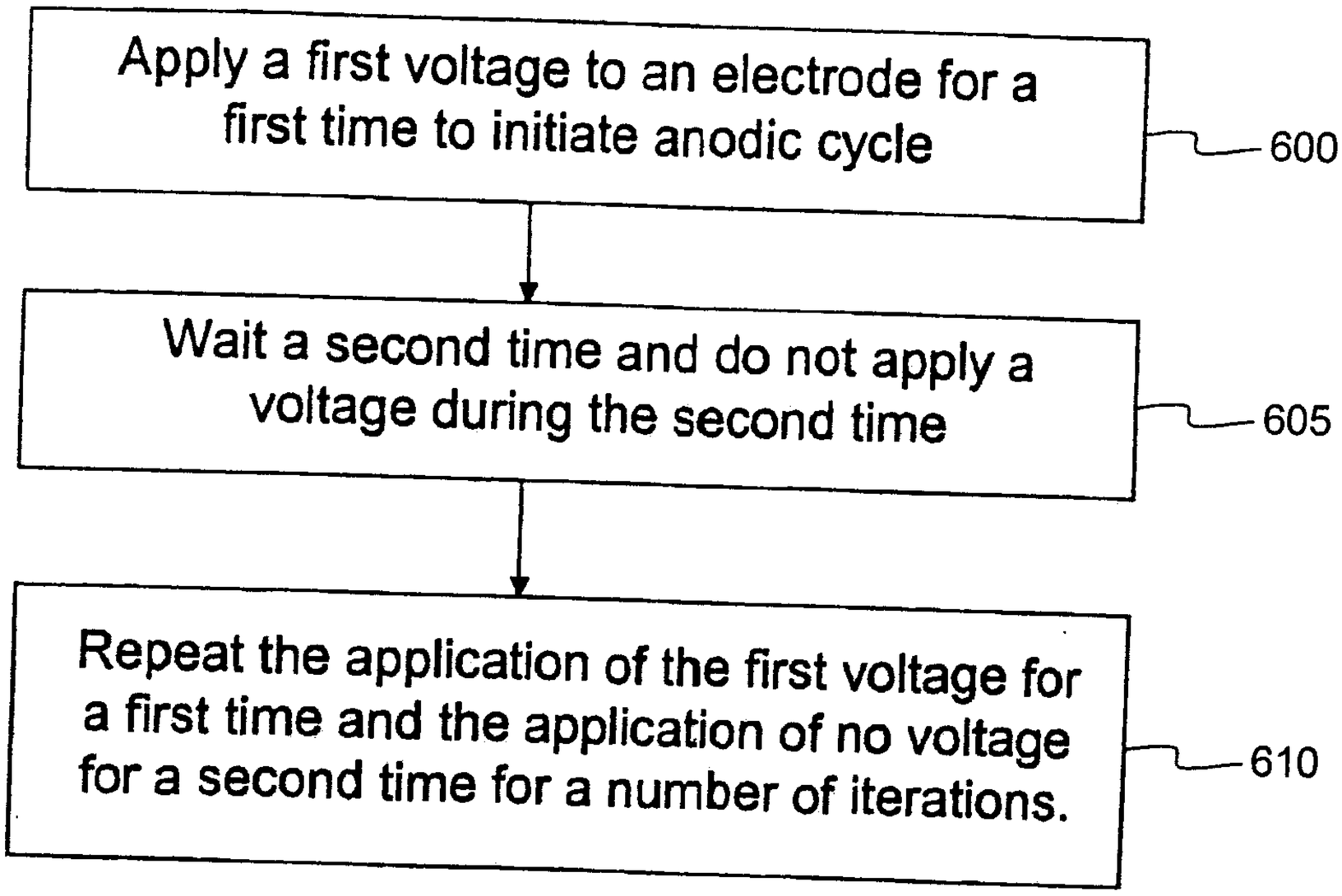

Apply a first voltage to an electrode for a first time to initiate anodic cycle
600
Wait a second time and do not apply a voltage during the second time
605
Repeat the application of the first voltage for a first time and the application of no voltage for a second time for a number of iterations.
610

Fig. 6(a)

Fig. 6(b)

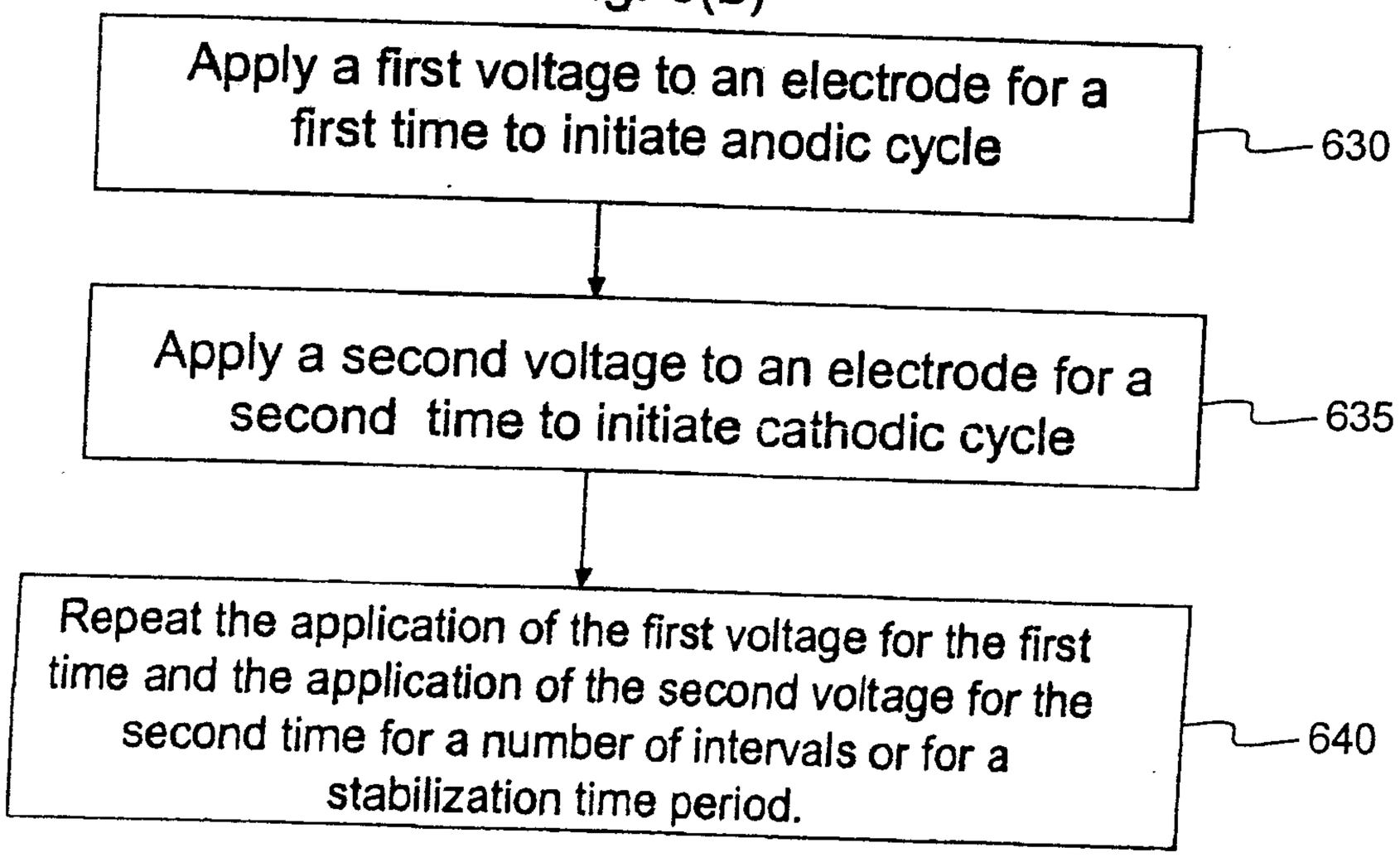
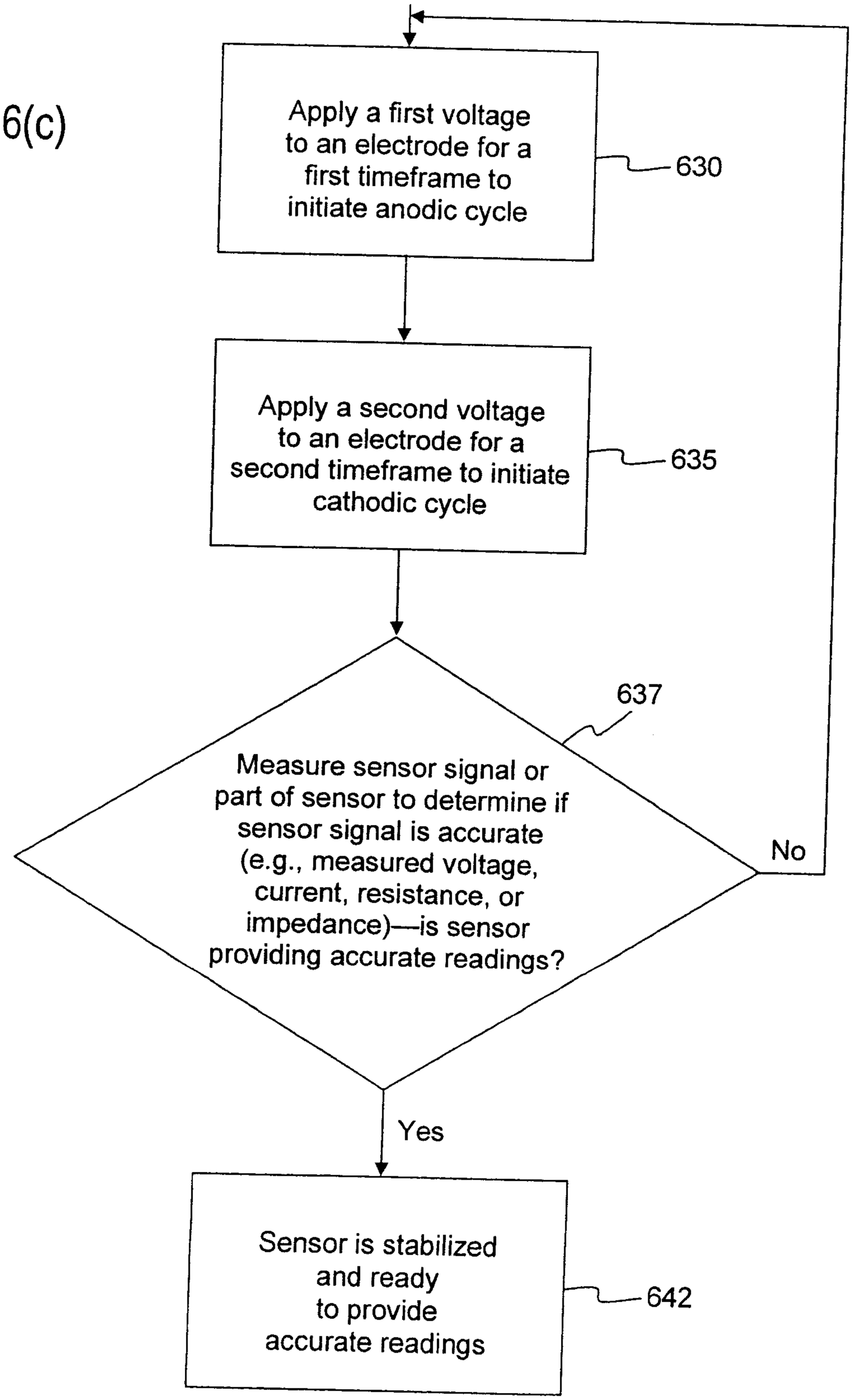

Apply a first voltage to an electrode for a first time to initiate anodic cycle
630
Apply a second voltage to an electrode for a second time to initiate cathodic cycle
635
Repeat the application of the first voltage for the first time and the application of the second voltage for the second time for a number of intervals or for a stabilization time period.
640

Fig. 6(c)


Apply a first voltage to an electrode for a first timeframe to initiate anodic cycle
630
Apply a second voltage to an electrode for a second timeframe to initiate cathodic cycle
635
637
Measure sensor signal or part of sensor to determine if sensor signal is accurate (e.g., measured voltage, current, resistance, or impedance)—is sensor providing accurate readings?
No
Yes
Sensor is stabilized and ready to provide accurate readings
642

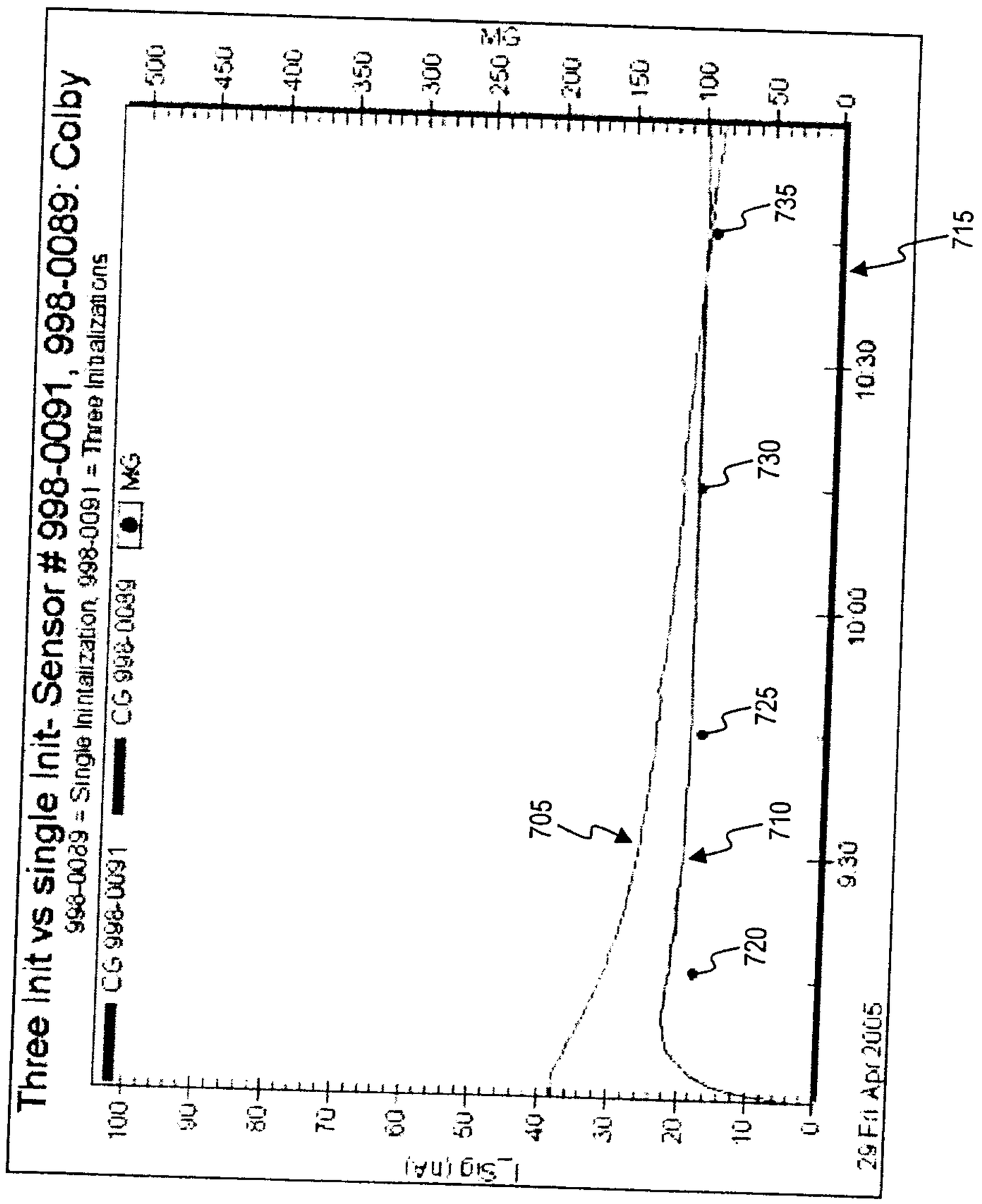

Three Init vs single Init- Sensor # 998-0091, 998-0089: Colby
998-0089 = Single Initialization, 998-0091 = Three Initializations
CG 998-0091
CG 998-0089
MG
mg/dL
MG
500
450
400
350
300
250
200
150
100
50
0
100
90
80
70
60
50
40
30
20
10
0
705
710
715
720
725
730
735
9:30
10:00
10:30
29 Fri Apr 2005

Fig. 7

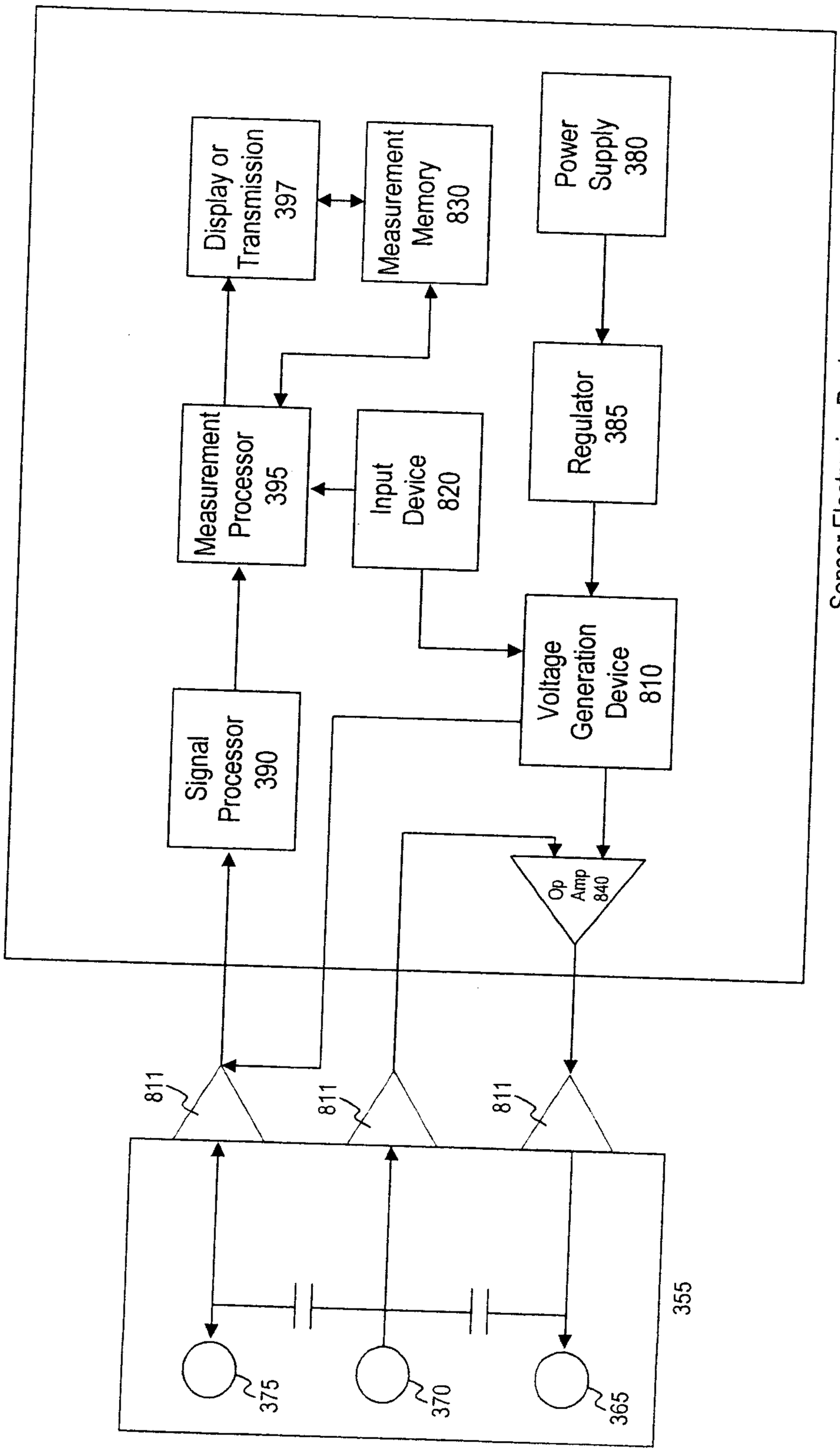

Sensor Electronics Device
360
Power Supply
380
Regulator
385
Voltage Generation Device
810
Op Amp
840
Display or Transmission
397
Measurement Memory
830
Measurement Processor
395
Input Device
820
Signal Processor
390
811
811
811
355
375
370
365

Fig. 8

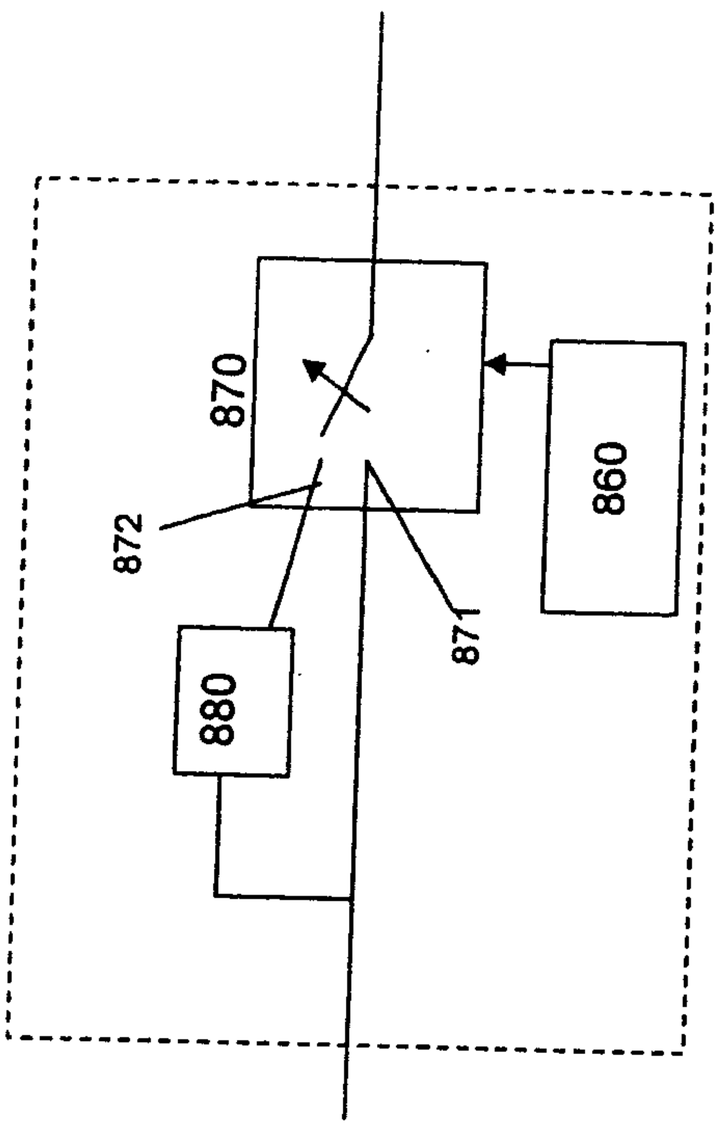


Fig. 8(c)

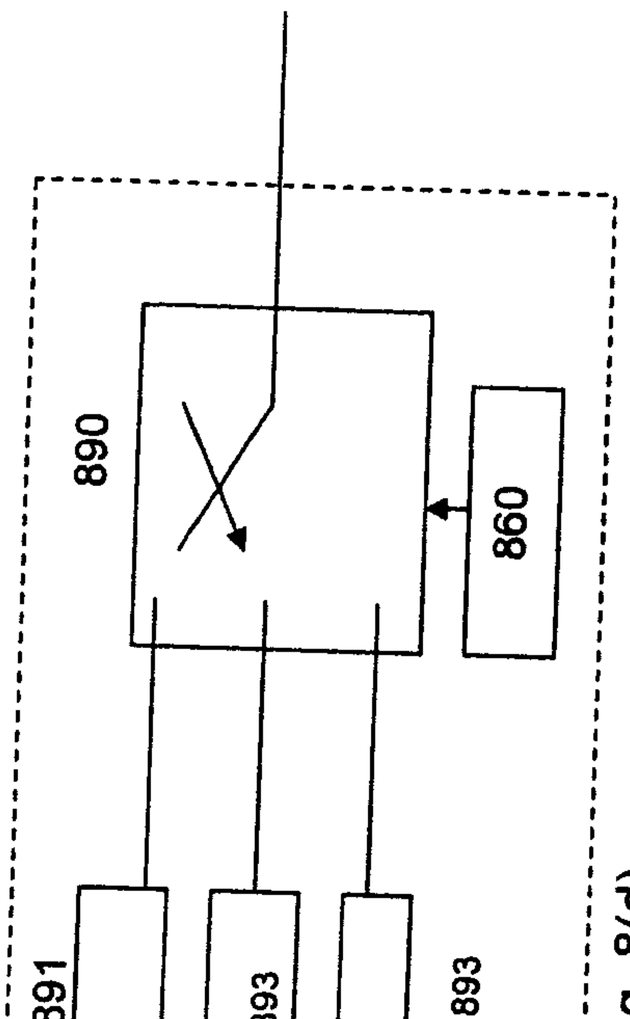


Fig. 8(d)

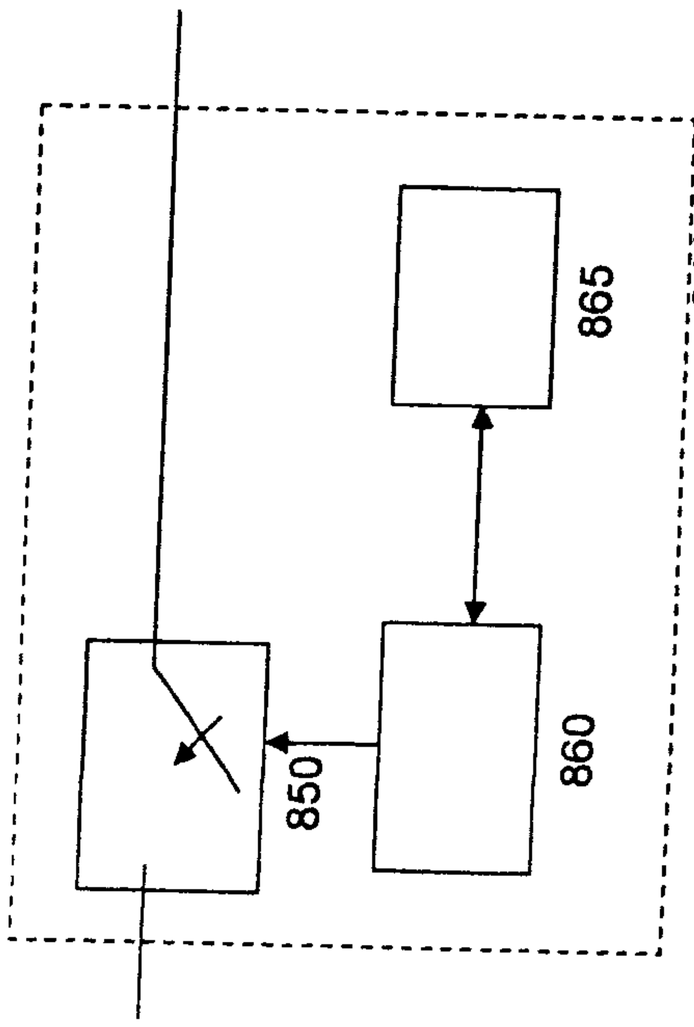


Fig. 8(b)

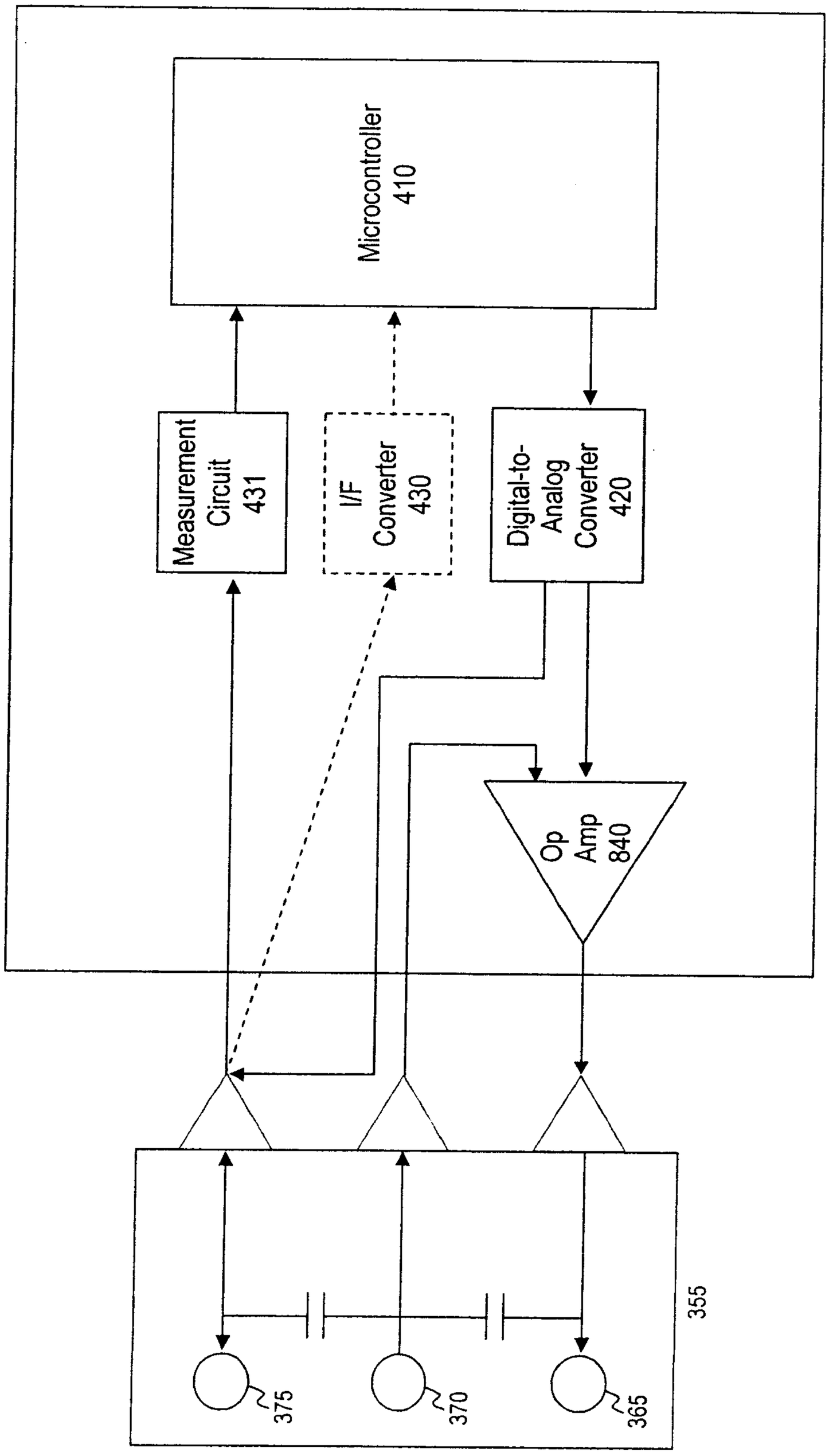

Microcontroller
410
Measurement
Circuit
431
I/F
Converter
430
Digital-to-
Analog
Converter
420
Op
Amp
840
Sensor Electronics Device
360
355
375
370
365

Fig. 9

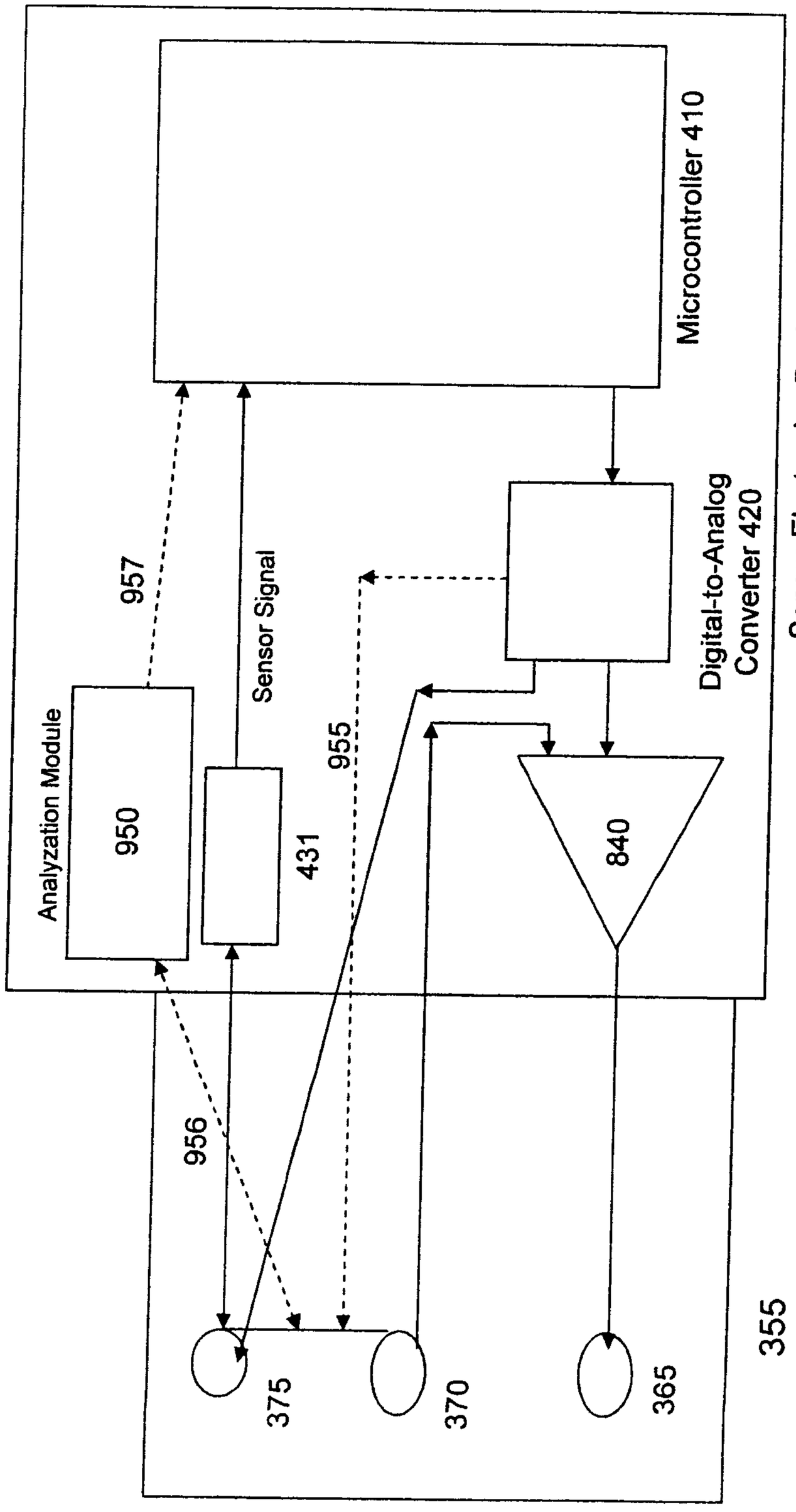

Sensor Electronics Device 360
Microcontroller 410
Digital-to-Analog Converter 420
Sensor Signal
957
955
956
Analyzation Module
950
431
840
375
370
365
355

Fig. 9(b)

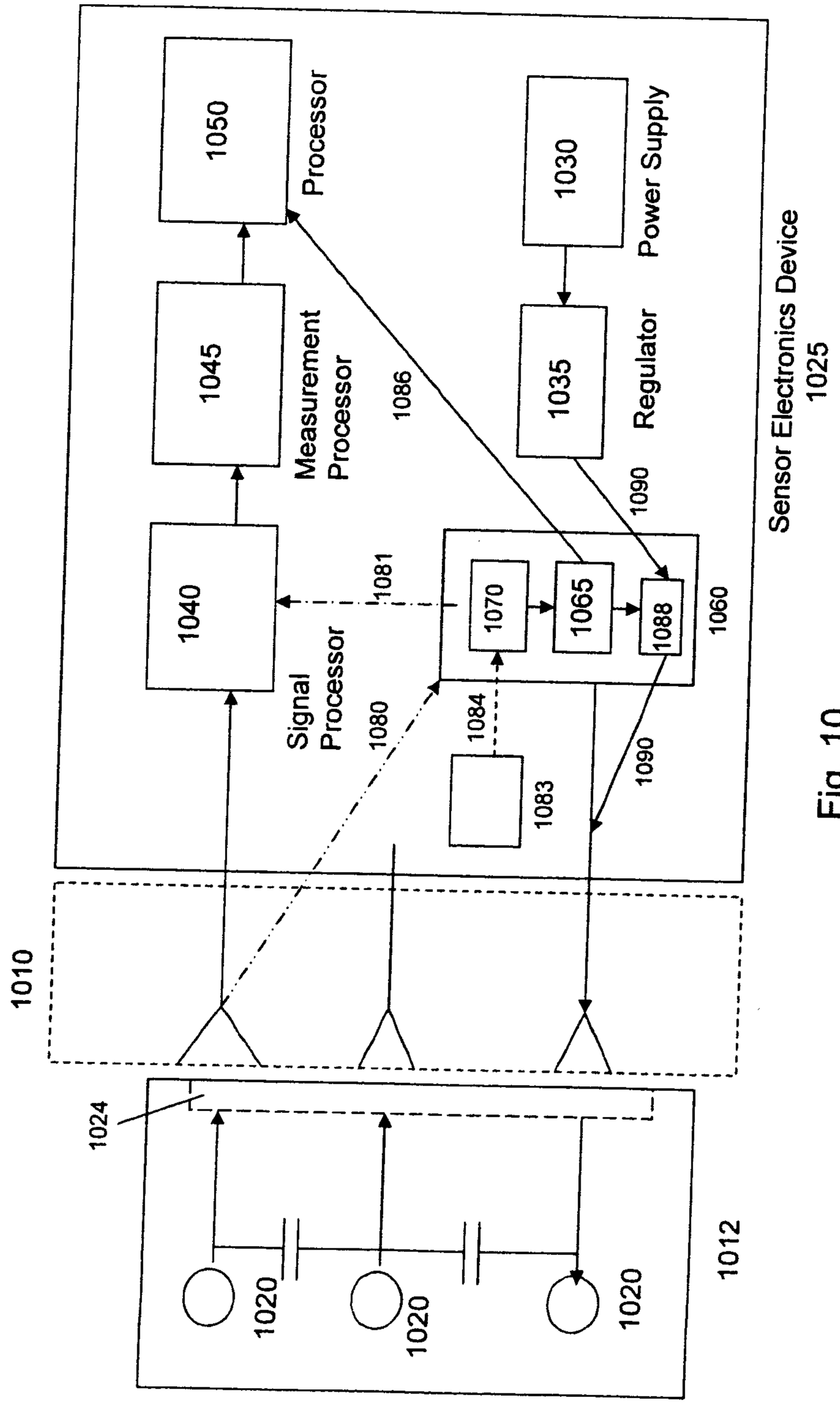

Sensor Electronics Device
1025
1050
Processor
1030
Power Supply
1045
Measurement
Processor
1086
1035
Regulator
1090
1040
1081
1070
1065
1088
1060
Signal
Processor
1080
1084
1083
1090
1010
1024
1020
1020
1020
1012

Fig. 10

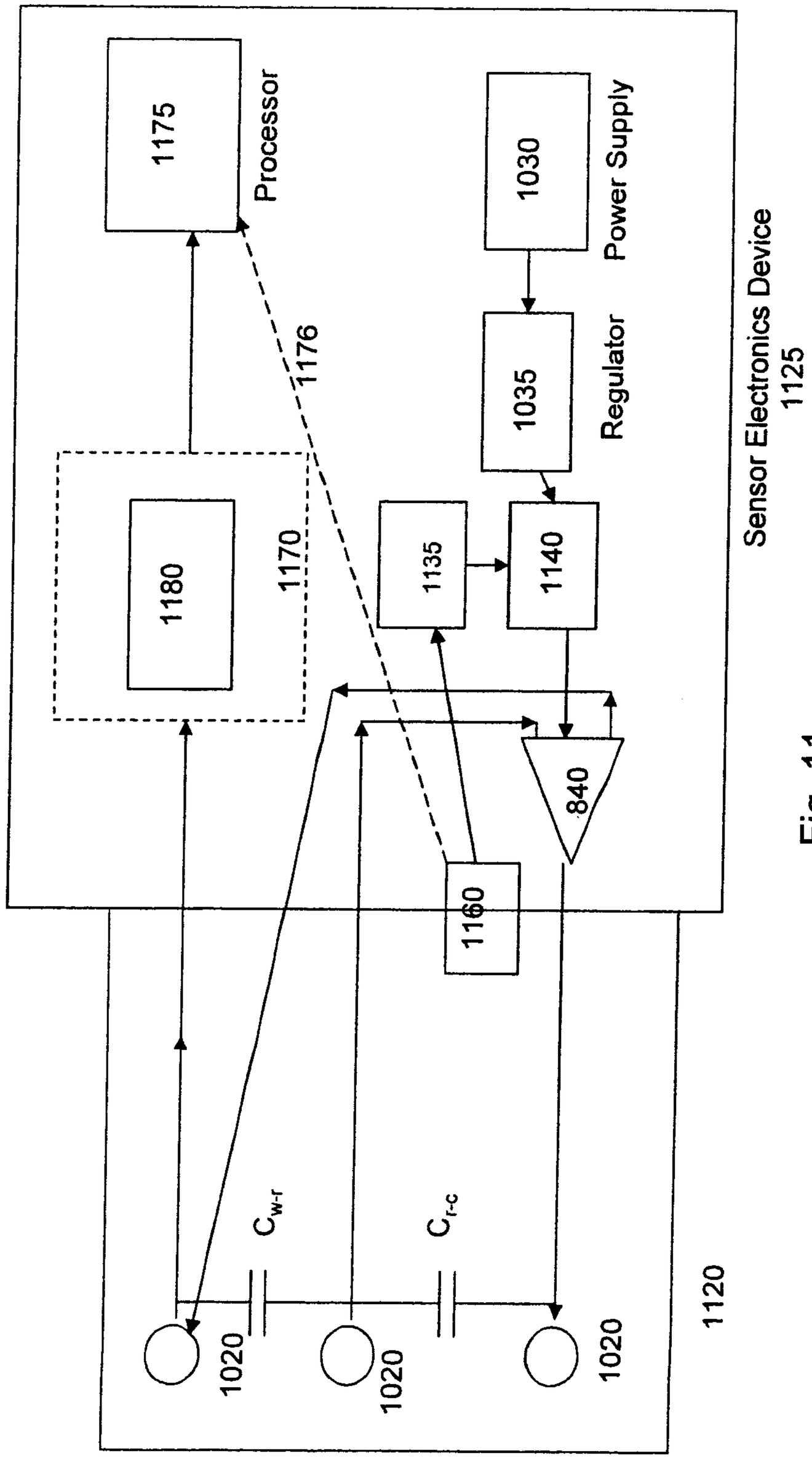

Sensor Electronics Device
1125
1175
Processor
1176
1030
Power Supply
1035
Regulator
1180
1170
1135
1140
840
1160
C_{w-r}
C_{r-c}
1020
1020
1020
1120

Fig. 11

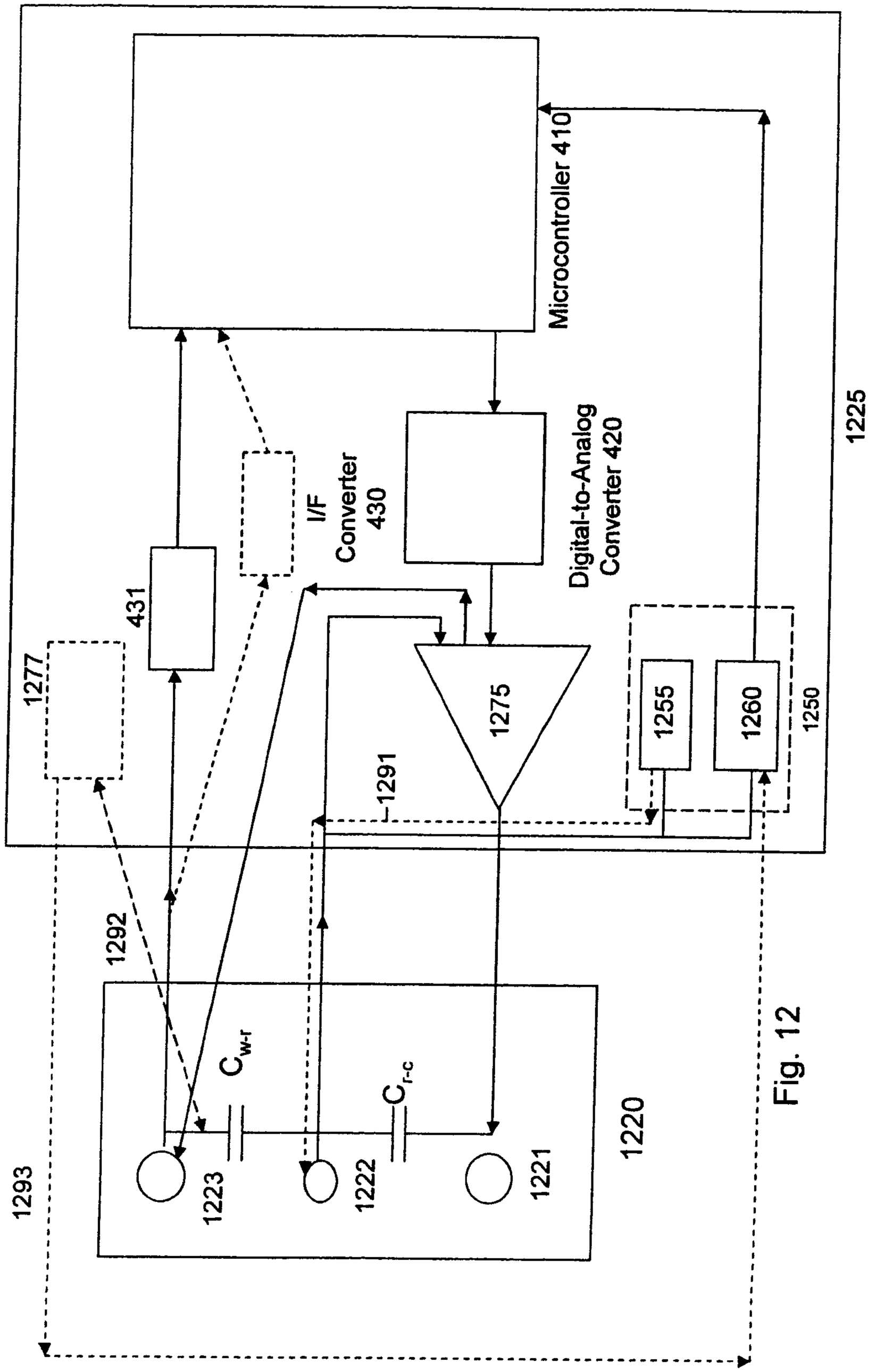

Microcontroller 410
Digital-to-Analog Converter 420
I/F Converter 430
431
1277
1275
1291
1255
1260
1250
1292
1293
1223
1222
1221
1220
1225
C_{w-r}
C_{r-c}

Fig. 12

Fig. 13(a)

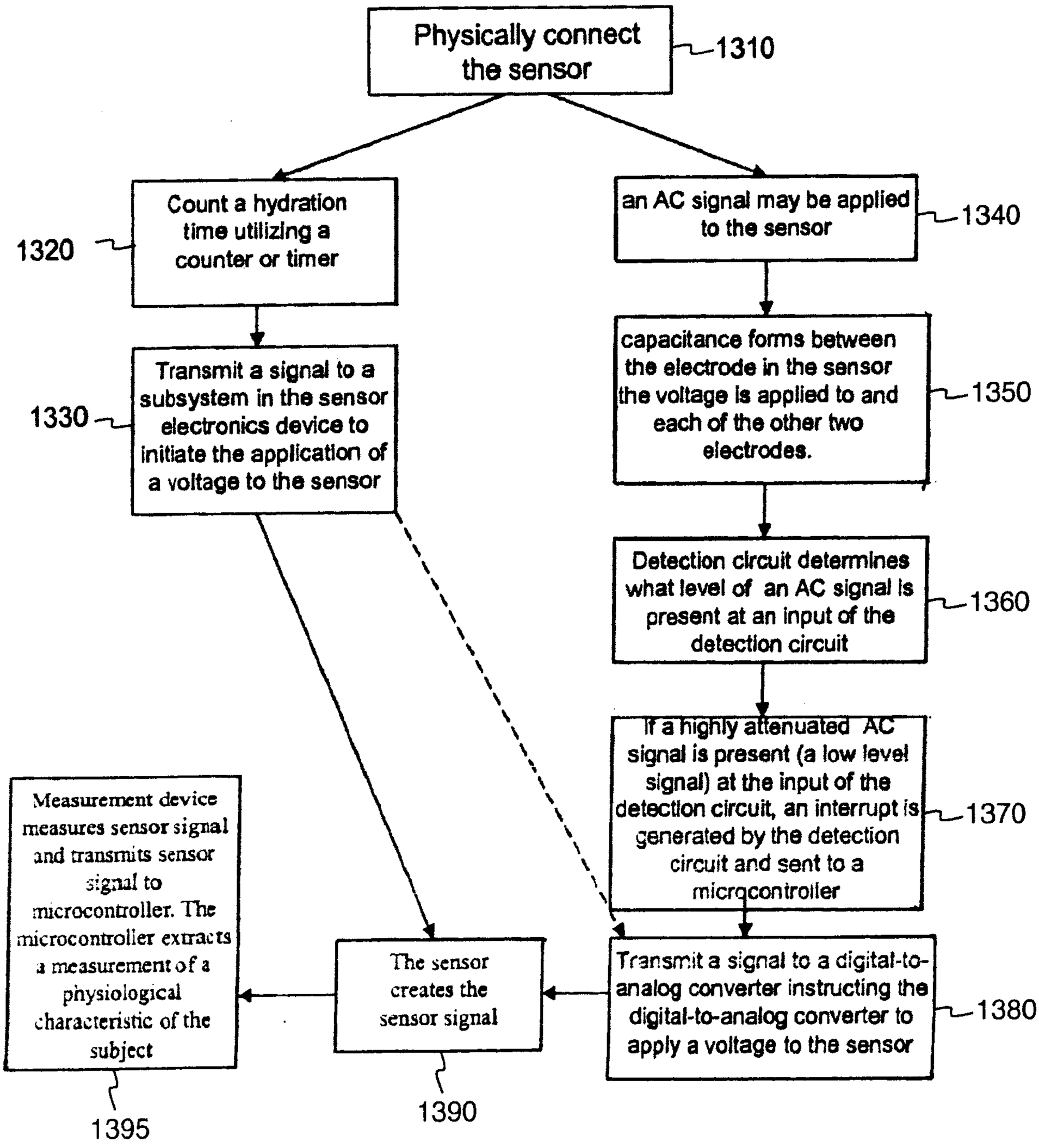
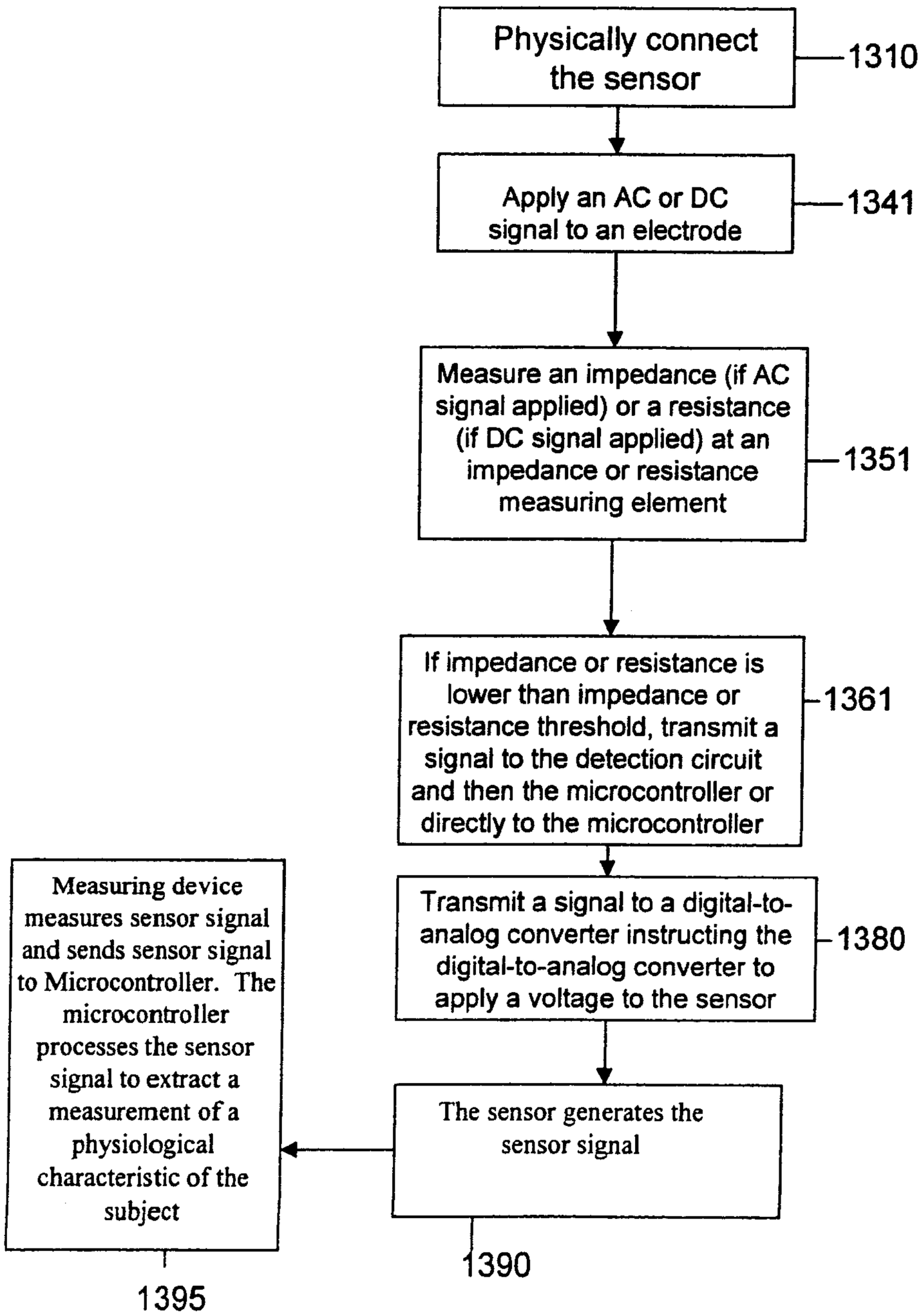

Physically connect the sensor
1310
Count a hydration time utilizing a counter or timer
1320
Transmit a signal to a subsystem in the sensor electronics device to initiate the application of a voltage to the sensor
1330
an AC signal may be applied to the sensor
1340
capacitance forms between the electrode in the sensor the voltage is applied to and each of the other two electrodes.
1350
Detection circuit determines what level of an AC signal is present at an input of the detection circuit
1360
If a highly attenuated AC signal is present (a low level signal) at the input of the detection circuit, an interrupt is generated by the detection circuit and sent to a microcontroller
1370
Transmit a signal to a digital-to-analog converter instructing the digital-to-analog converter to apply a voltage to the sensor
1380
The sensor creates the sensor signal
1390
Measurement device measures sensor signal and transmits sensor signal to microcontroller. The microcontroller extracts a measurement of a physiological characteristic of the subject
1395

Fig. 13(b)


Physically connect the sensor
1310
Apply an AC or DC signal to an electrode
1341
Measure an impedance (if AC signal applied) or a resistance (if DC signal applied) at an impedance or resistance measuring element
1351
If impedance or resistance is lower than impedance or resistance threshold, transmit a signal to the detection circuit and then the microcontroller or directly to the microcontroller
1361
Transmit a signal to a digital-to-analog converter instructing the digital-to-analog converter to apply a voltage to the sensor
1380
The sensor generates the sensor signal
1390
Measuring device measures sensor signal and sends sensor signal to Microcontroller. The microcontroller processes the sensor signal to extract a measurement of a physiological characteristic of the subject
1395

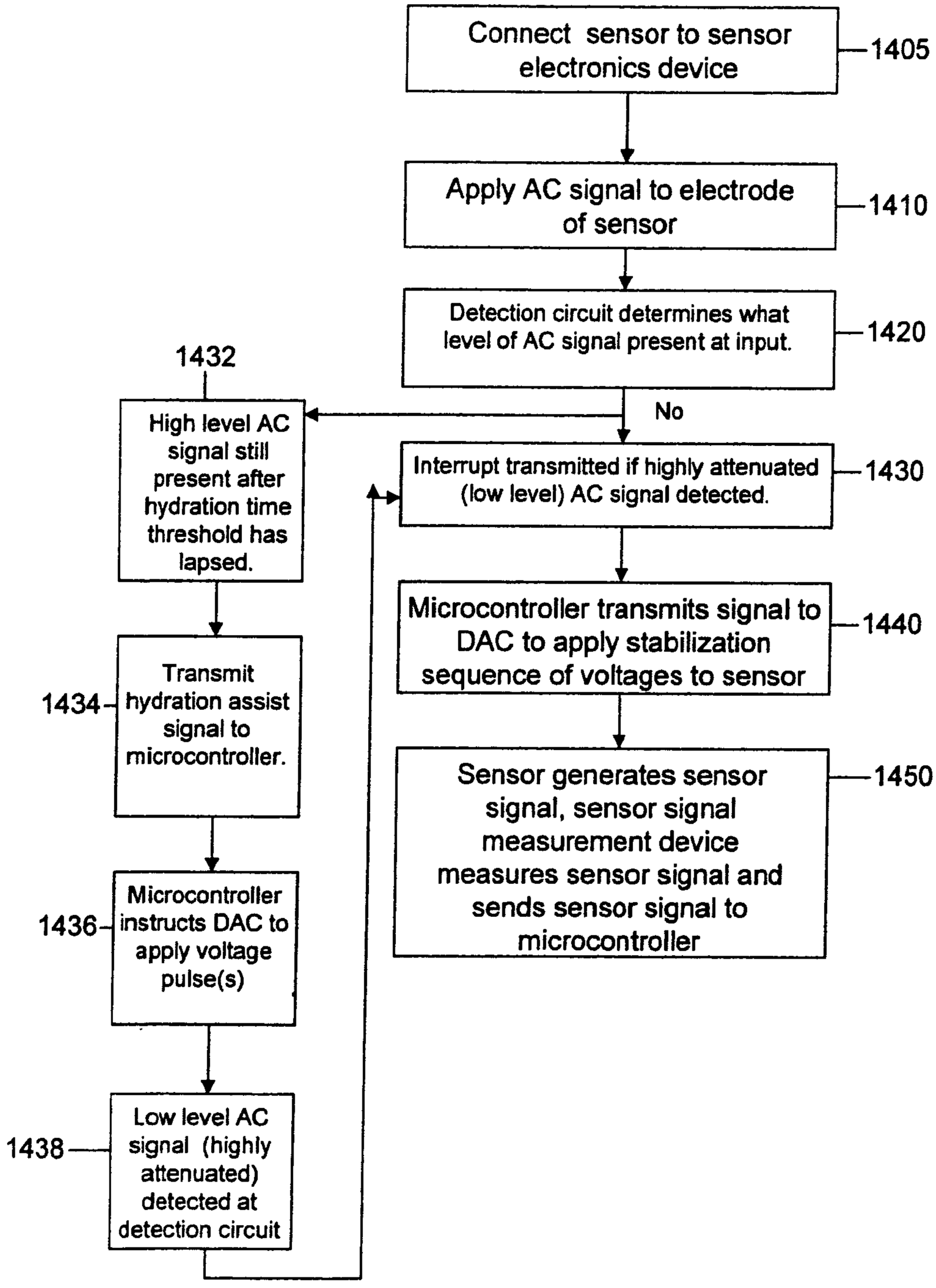

Connect sensor to sensor electronics device
1405
Apply AC signal to electrode of sensor
1410
Detection circuit determines what level of AC signal present at input.
1420
No
1432
High level AC signal still present after hydration time threshold has lapsed.
Interrupt transmitted if highly attenuated (low level) AC signal detected.
1430
Microcontroller transmits signal to DAC to apply stabilization sequence of voltages to sensor
1440
Sensor generates sensor signal, sensor signal measurement device measures sensor signal and sends sensor signal to microcontroller
1450
1434
Transmit hydration assist signal to microcontroller.
1436
Microcontroller instructs DAC to apply voltage pulse(s)
1438
Low level AC signal (highly attenuated) detected at detection circuit

Fig. 14(a)

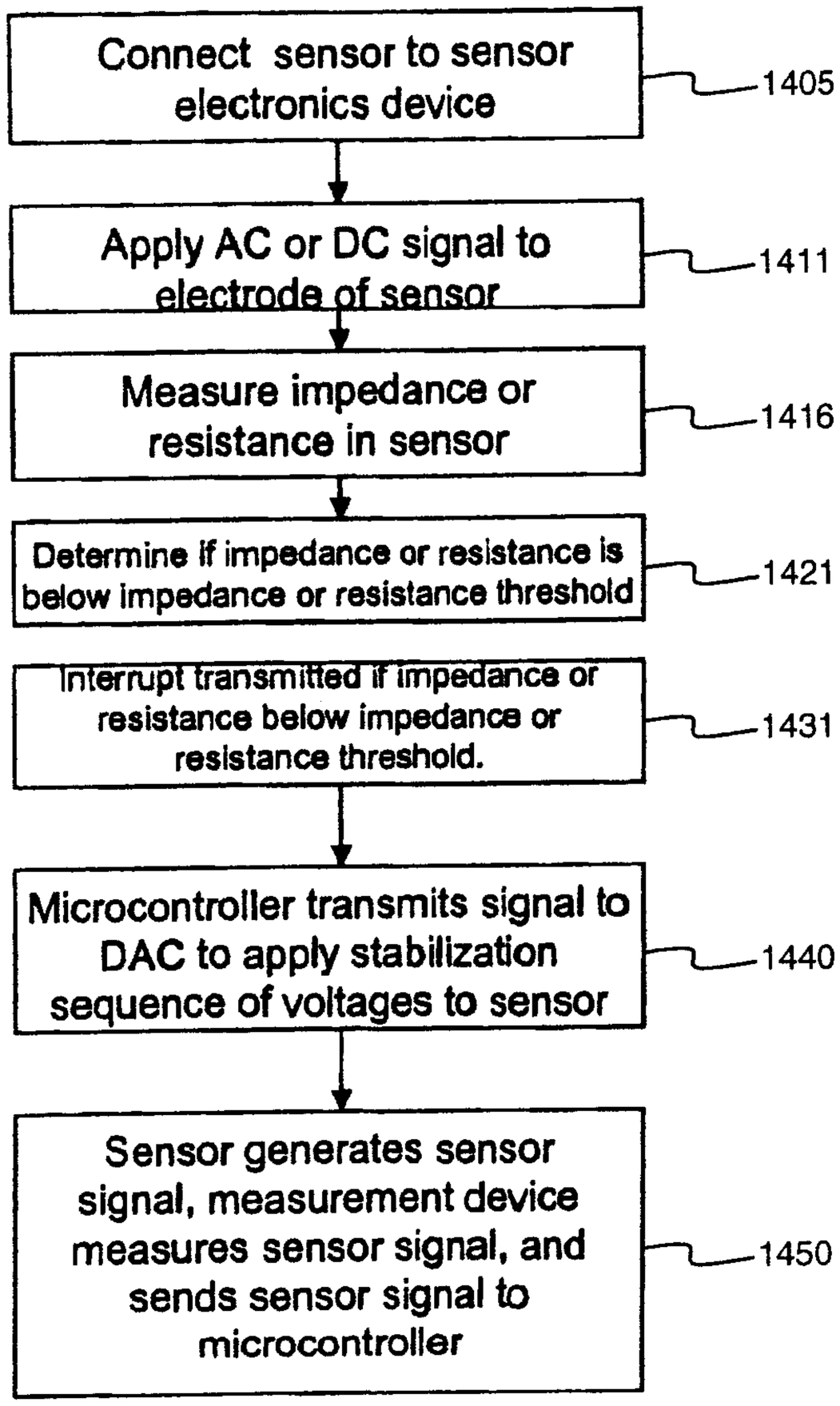

Connect sensor to sensor electronics device
1405
Apply AC or DC signal to electrode of sensor
1411
Measure impedance or resistance in sensor
1416
Determine if impedance or resistance is below impedance or resistance threshold
1421
Interrupt transmitted if impedance or resistance below impedance or resistance threshold.
1431
Microcontroller transmits signal to DAC to apply stabilization sequence of voltages to sensor
1440
Sensor generates sensor signal, measurement device measures sensor signal, and sends sensor signal to microcontroller
1450

Fig. 14(b)

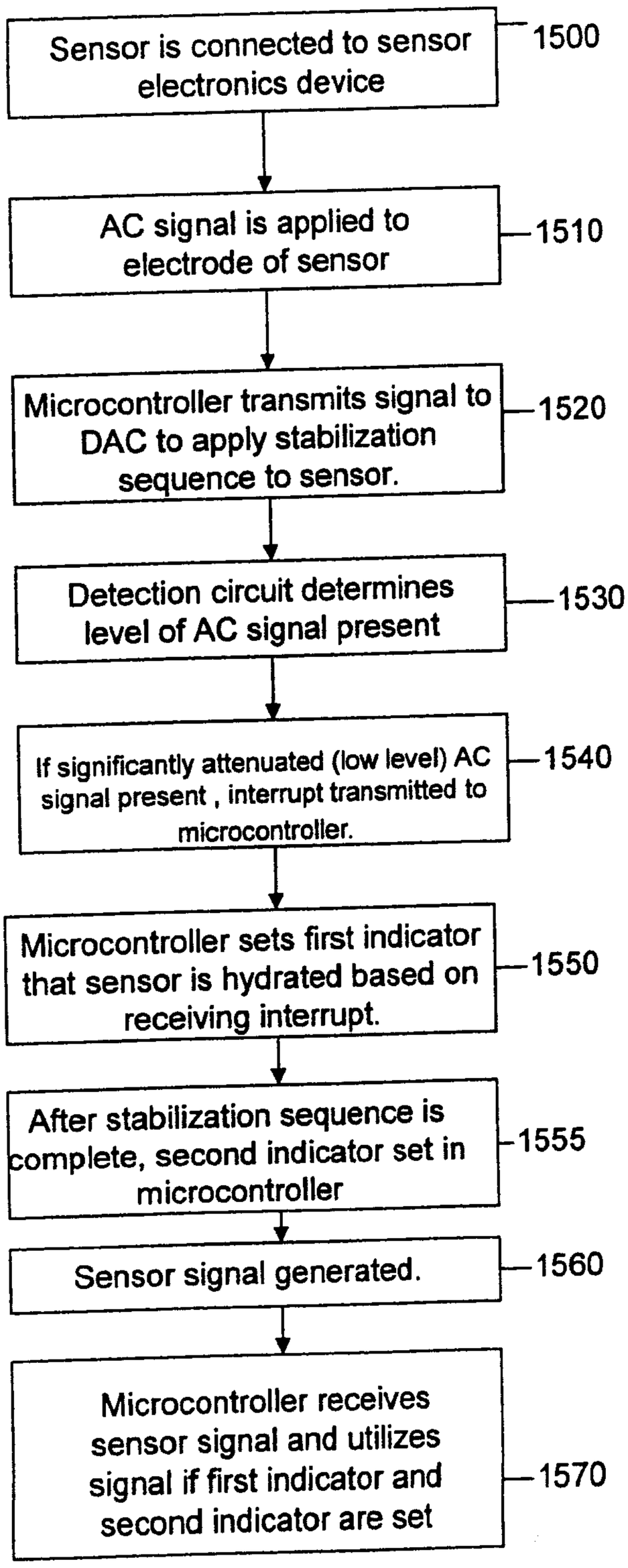
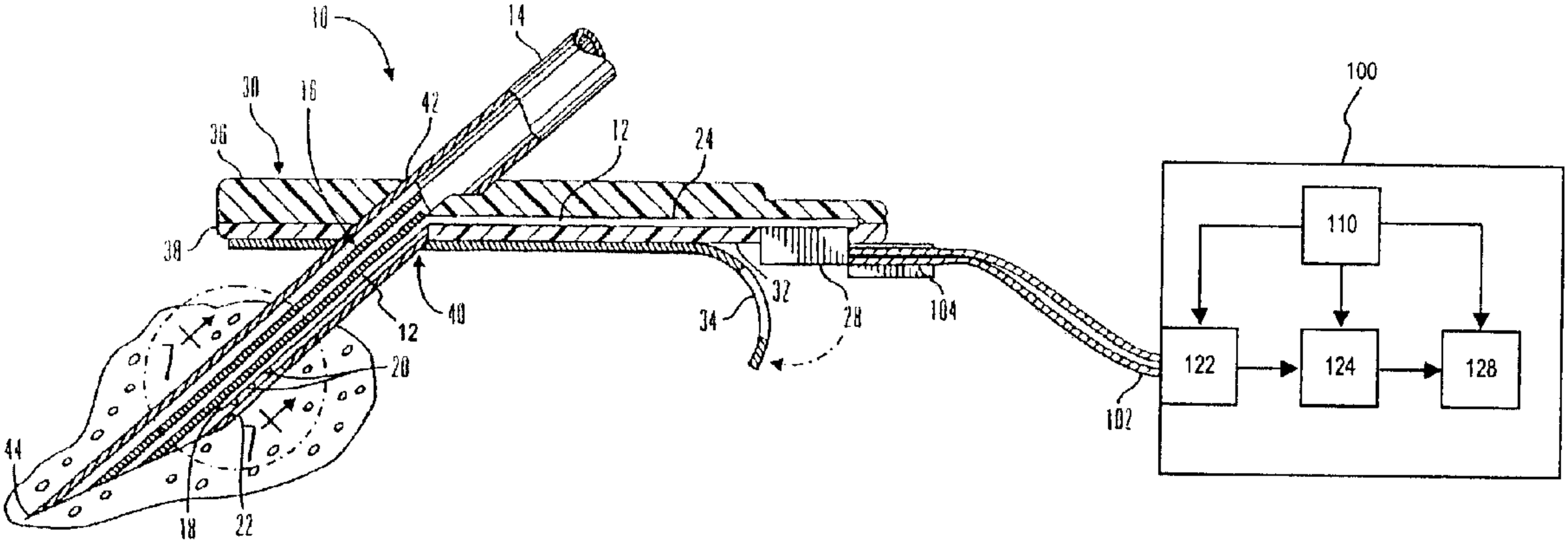

Sensor is connected to sensor electronics device
1500
AC signal is applied to electrode of sensor
1510
Microcontroller transmits signal to DAC to apply stabilization sequence to sensor.
1520
Detection circuit determines level of AC signal present
1530
If significantly attenuated (low level) AC signal present , interrupt transmitted to microcontroller.
1540
Microcontroller sets first indicator that sensor is hydrated based on receiving interrupt.
1550
After stabilization sequence is complete, second indicator set in microcontroller
1555
Sensor signal generated.
1560
Microcontroller receives sensor signal and utilizes signal if first indicator and second indicator are set
1570

Fig. 14(c)


10
14
30
16
42
36
12
24
38
40
12
32
34
28
104
20
44
18
22
102
100
110
122
124
128