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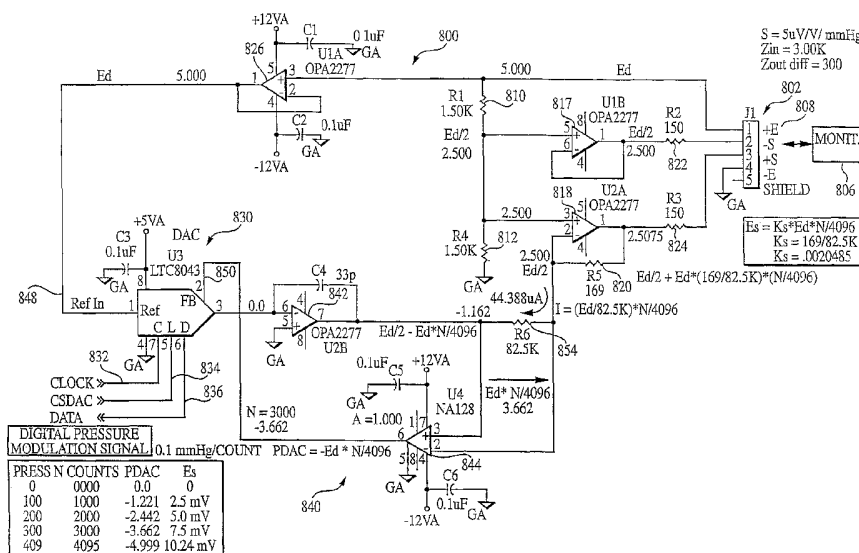
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(54) Title: APPARATUS AND METHOD FOR INTERFACING TIME-VARIANT SIGNALS



(57) Abstract: An improvement apparatus and method for interfacing a time variant waveform between two hardware environments. In one aspect, the invention comprises a circuit for accurately simulating the output of one or more types of sensing device (e.g., passive bridge pressure transducer) for use with a plurality of different monitoring and/or analysis devices, thereby obviating the need for specialized interface circuitry adapted to each different monitor/analyser. In one exemplary embodiment, the sensing device comprises a non-invasive blood pressure monitor (NIBPM), which universally interfaces with prior art patient monitors via the interface circuit of the invention. In a second aspect of the invention, an improved NIBPM device incorporating the interface circuit is disclosed. An improved disconnect circuit adapted to sense the status of the electrical connection between the sensing device and monitor is also described.

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## APPARATUS AND METHOD FOR INTERFACING TIME-VARIANT SIGNALS

### Background of the Invention

#### 1. Field of the Invention

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This invention relates generally to apparatus and methods for interfacing time-variant signals, and specifically to the conditioning/simulation of waveforms (such as, for example, blood pressure waveforms) on monitoring equipment.

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#### 2. Description of Related Technology

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Slowly time-variant waveforms or signals have broad application in many fields, including industry, research, and medicine. Within the medical field, one application of particular interest relates to the monitoring of arterial blood pressure within living subjects (such as human beings and canines). As part of so-called “invasive” arterial blood pressure monitoring, a disposable pressure transducer is commonly utilized to measure the blood pressure of the subject via an invasive arterial line that infuses normal saline at a “KVO” rate into an appropriate blood vessel. KVO (or “keep vein open”) refers to the minimum flow rate required to keep an IV needle from clotting off in the vein. The disposable pressure transducer (DPT) is a passive resistive bridge implemented typically from silicon strain beam technology. The DPT electrically interfaces to a patient monitor available from any number of different vendors such as Hewlett Packard/Agilent/Philips, General Electric/Marquette, Datex–Ohmeda, Datascope/Fakuda-Denshi, Welch Allyn/Protocol, Space Labs, Criticare, Critikon, and Valley Medical, as well as others. The patient monitor supplies the excitation signal to energize the bridge circuit of the DPT, and also provides the signal conditioning of the output derived from the DPT in order to display the subject’s blood pressure waveform on the display device of the patient monitor.

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The various monitors described above utilize varying methods to energize the bridge and recover the output signal. In one simple scheme (shown as Fig. 1), the bridge **101** of the DPT **100** is driven by a constant direct current (DC) voltage source **102**. The value of the DC voltage produced by the source **102** can be any value between 1V and 10V, but is typically set at 5V. This voltage value minimizes the self-heating effect that occurs when resistors R1 **104**, R2 **106**,

R3 108, R4 110, R5 112, and R6 114 dissipate power. This power dissipation changes the temperature of the bridge sensor resistors R3 108, R4 110, R5 112, and R6 114, and causes their electrical resistance values to change. This change in resistance causes an error in the output of the bridge 101 which is not desired. Usually the manufacturer of the DPT will add additional resistors (not shown) to compensate for such temperature effects, and to calibrate the output of the DPT to a particular value (such as 5 uV /V/ mmHg). None-the-less, minimizing the self-heating of the components limits the magnitude of the error, since such electrical compensation is never perfect.

As shown in Fig. 1, the drive signal to the DPT 100 is applied across the +E 120 and -E 122 terminals. Resistors R1 104 and R2 106 limit bridge current, and provide temperature compensation for span. When pressure is applied to the transducer, the geometry of the silicon strain beam is arranged so that resistors R3 108 and R6 114 decrease in value, and the values of resistors R4 110 and R5 112 increase in value by the same amount. This change is typically on the order of 1% of the resistor's resistance value, and is commonly referred to as "Delta R" or  $\Delta R$ . In a typical configuration, resistors R3 108, R4 110, R5 112, and R6 114 all have the same nominal value referred to as  $R_b$ . Resistors R1 and R2 are usually chosen to have equal resistance so that the nominal voltage at terminals +S 130 and -S 132 will be equal to one-half of the drive voltage  $E_d$ . For these conditions, the output impedance of the bridge 101 will be  $R_b$ , and the input impedance will be given by Eqn. 1:

$$Z_{in} = R1 + R2 + R_b \quad (\text{Eqn. 1})$$

Typical values for  $Z_{in}$  and  $Z_{out}$  ( $R_b$ ) are 3K ohms and 300 ohms, respectively. Given these definitions, it can be readily demonstrated that the bridge output voltage across terminals +S 130 and -S 132 can be described by Eqn. 2 as follows:

$$E_s = +S - (-S) = E_d \times \frac{dR}{Z_{in}} \quad (\text{Eqn. 2})$$

Derivation of Eqn. 2 is conducted by analyzing an equivalent balanced bridge configuration

200 (Fig. 2) based on the following six assumptions: (i) Resistor R1 202 = R2 202; (ii) Resistors R3 204, R4 206, R5 208, and R6 210 are all equal in resistance when the bridge 200 is in balance, and are equal to R<sub>b</sub>; (iii) when the bridge unbalances, resistors R3, R4, R5, and R6 all change by an equal amount (dR) as shown in Fig. 3; (iv) the load across terminals +S 230 and -S 232 is an infinite differential impedance; (v) there are no loads between +S and +E or -E; and (vi) there are no loads between -S and +E or -E.

When the bridge in Fig. 2 is in balance, the resistance between terminal 1 240 and terminal 2 242 is given by R<sub>b</sub> (i.e., 2 x R<sub>b</sub> placed in parallel with 2 x R<sub>b</sub> yields an effective impedance of R<sub>b</sub>). In the unbalanced configuration of Fig. 3, the resistance between terminal 1 340 and terminal 2 342 is also given by R<sub>b</sub>, since the quantity (R3 + R4 +dR - dR) = 2R<sub>b</sub>, which, when placed in parallel with (R5 + R6 +dR - dR) = 2R<sub>b</sub>, yields an effective impedance of R<sub>b</sub>. Similarly, the bridge output impedance Z<sub>out</sub> = R<sub>b</sub>.

The unbalanced circuit of Fig. 3 can be simplified to an equivalent circuit 400 shown as Fig. 4 herein. The input impedance seen by the excitation source E<sub>d</sub> is therefore given by Eqn. 3:

$$Z_{in} = R1 + R2 + Rb \tag{Eqn. 3}$$

20 The relationship between E<sub>b</sub> (i.e., the equivalent voltage across the bridge) and the excitation voltage E<sub>d</sub> is given by Eqn. 4:

$$Eb = Ed \times \left[ \frac{Rb}{R1 + R2 + Rb} \right] \tag{Eqn. 4}$$

25 Note, however, that (R1 + R2 + Rb) = Z<sub>in</sub>. Hence, E<sub>b</sub> can be represented as shown in Eqn. 5:

$$Eb = Ed \times \left[ \frac{Rb}{Zin} \right] \tag{Eqn. 5}$$

30 The bridge may be analyzed alone, since the voltage E<sub>b</sub> across the bridge is constant (and hence R<sub>b</sub> is constant). This un-balanced circuit equivalent 500 is shown in Fig.5 herein. The voltage at node +S 502 is given by Eqn. 6:

$$\begin{aligned}
 E(+S) &= Eb \times \left[ \frac{Rb + dR}{Rb + dR + Rb - dR} \right] \\
 &= E(+S) = Eb \times \left[ \frac{Rb + dR}{2 \times Rb} \right] \\
 &= E(+S) = Eb \times \left[ \frac{1}{2} + \frac{dR}{2 \times Rb} \right]. \tag{Eqn. 6}
 \end{aligned}$$

A similar expression can be developed for the voltage at node -S 504 (Eqn. 7):

$$E(-S) = Eb \times \left[ \frac{1}{2} - \frac{dR}{2 \times Rb} \right] \tag{Eqn. 7}$$

The differential output E(s) is simply E(+s) - E(-s), as follows:

$$\begin{aligned}
 E(S) &= Eb \times \left\{ \left[ \frac{1}{2} + \frac{dR}{2 \times Rb} \right] - \left[ \frac{1}{2} - \frac{dR}{2 \times Rb} \right] \right\} = \\
 E(S) &= Eb \times \left[ \frac{dR}{Rb} \right] \tag{Eqn. 8}
 \end{aligned}$$

Finally, substituting the result of Eqn. 5 into Eqn. 8 yields Eqn. 2 above:

$$E(s) = Ed \times \left[ \frac{dR}{Zin} \right]$$

In order for all DPT's to function similarly, they are typically calibrated during manufacture to a standard sensitivity of 5 uV /V/ mmHg. This means that for an applied pressure of 100 mmHg, and a drive voltage ( $E_d$ ) of 5V, the output  $E_s$  will be 2.5 mV. This requires that the resistance difference (dR) be 1.5 ohms, according to Eqn. 2 above. For a  $Zin$  of 3 kohms, the full-scale pressure specification for such DPTs is 300 mmHg, which would require a resistance difference (dR) value of 4.5 ohms, and yield an output voltage of 7.5 mV.

It can be shown that the differential resistance dR is a function of pressure:

$$dR = Ks \times Zin \times P \tag{Eqn. 9}$$

where:

$K_s$  = scaling factor of 5 uV / V / mmHg, and

P = sensed pressure.

Substituting this result into Eqn. 2 results in the transfer function for the bridge, Eqn. 10:

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$$E_s = E_d \times K_s \times P \quad (\text{Eqn. 10})$$

Note that the output voltage  $E_s$  is a function of both pressure (P), the input variable, and the drive voltage ( $E_d$ ) provided by the monitor.

10 For the 5 VDC drive condition, the signal processing of the output is typically quite limited in scope; e.g., amplifying the bridge output with an instrumentation amplifier, and filtering the output with a 2-pole low pass filter whose cutoff frequency is above any frequency components of interest in the blood pressure signal. A typical value for such filter cutoff frequency is 45 Hz.

15 When a user wishes to supply the monitor with and display a waveform other than that derived from the aforementioned DPT (such as that from a digital non-invasive blood pressure monitor such as that manufactured by the Assignee hereof), the DPT must be disconnected from the monitor, and the new signal source electrically substituted. For the case of a fixed DC drive voltage of 5V, a circuit may be readily fashioned to interface the new (e.g. digital) signal source to the patient monitor, such as that shown in Fig. 6.

20 As illustrated in Fig. 6, resistor R1 **602** of the interface circuit **600** allows the patient monitor detect the 3Kohm impedance value ( $Z_{in}$ ) it normally sees when using the DPT. Additionally, resistors R2 **606** and R3 **608** set the differential output impedance ( $Z_{out}$ ) to 300 ohms. The output of node S+ **610** is biased to +2.5 V by reference amplifier U1 **616**, and amplifiers U2 **618** and U3 **620** (and their associated components) set the -S output according to Eqn. 11:

$$-S = 2.506 - .0025 \times E_{in} \quad (\text{Eqn. 11})$$

30 The differential output between +S and -S is given by Eqn. 12:

$$E_s = -0.006 + 0.0025 \times E_{in} \quad (\text{Eqn. 12})$$

The fixed offset of -6 mV (for the exemplary circuit of Fig. 6) can be “zeroed out” or cancelled by most patient monitors, leaving the output voltage  $E_s$  a function of the input voltage, and

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scaled such that a 1V input equals 100 mmHg. An alternative to nulling out the -6 mV with the monitor is to add a zero adjustment to amplifier U2 **618**.

While the circuit **600** of Fig. 6 (or any other similar circuit) works generally for any  
5 monitor that has a fixed +5V DC constant voltage excitation, it has significant shortcomings  
when one attempts to drive the many different types of patient monitors presently available.  
Many such patient monitors do not use constant +5V excitation, but rather use bipolar sine  
wave drive, or even pulse drive as a carrier between 2 KHz and 5 KHz, which is modulated by  
the pressure signal. These monitors use an AC drive to reduce bridge offset effects, and cancel  
10 noise. Furthermore, they require a synchronous demodulator as part of their signal conditioning  
circuitry, in order to recover the blood pressure modulation signal.

Therefore, in order to drive these monitors with a non-DPT device such as the  
aforementioned digital NIBPM, a circuit is needed that mimics the electrical profile and  
operation of a passive transducer bridge. The transfer function of such circuit must be  
15 effectively identical to that of the passive bridge, and the input and output impedances must  
match those of the passive bridge as well. The sensitivity factor of 5 uV /V/ mmHg previously  
described (or any corresponding value for the selected monitor) must also be maintained. The  
circuit must function with any type of excitation source including constant voltage drive of  
either polarity, constant current drive of either direction, and any AC voltage or current drive  
20 of any waveshape, duty cycle, and DC offset with a frequency of 1KHz to 10 KHz.

U. S. Patent No. 4,705,047 to Bailey issued November 10, 1987 and entitled "Output  
circuit for physiological measuring instruments" discloses an output circuit for a digital  
physiological measuring instrument. The output circuit provides means for a digital signal  
indicative of a physiological parameter to operate on an excitation signal from a monitor to  
25 provide a response signal for driving the monitor to generate a visual display of that parameter.  
The excitation signal is scaled in a digital-to-analog converter, corrected for a zero offset of the  
digital signal, and then applied to the monitor. A dummy excitation signal is provided to enable  
the output circuit to drive a readout device having an analog input but not providing an  
excitation signal. However, the invention of Bailey is not well adapted to all polarities and  
30 ranges of excitation signal, and utilizes a cumbersome offset correction technique which is not  
optimal for many applications.



U.S. Patent 6,471,646 issued October 29, 2002 to Thede and entitled "Arterial Line Emulator" discloses an arterial line emulator which interfaces a non-invasive blood pressure monitor with an invasive blood pressure monitor. The emulator receives pressure waveform signals from the non-invasive blood pressure monitor, and receives a transducer excitation voltage from the invasive blood pressure monitor. The emulator converts the pressure waveform signal from the non-invasive blood pressure monitor into an analog signal which is scaled as a function of the excitation voltage. The scaled analog pressure signal is supplied as an input to the invasive blood pressure monitor, and is intended to emulate the signal which would be received from a catheter-based blood pressure transducer. This system, however, uses digital processing (i.e., a microcontroller) and associated algorithms to perform the signal analysis and scaling, which can significantly slow or impede the signal processing, and increases the cost and complexity of the solution. Furthermore, the disclosed emulator of Thede is limited in the types of input excitation it can operate with, with apparently no ability to utilize alternating current (ac) excitation (see, e.g., polarity sensing circuit).

Based on the foregoing, what is needed is an improved apparatus and method for interfacing sensing devices producing time variant waveforms (such as for example the systolic, diastolic, and/or average blood pressure waveforms of a living subject) with monitoring devices. Such apparatus and method would ideally (i) be readily adapted to a variety of different configurations of monitoring or display devices, (ii) have a wide dynamic range; (iii) be able to operate on binary digital input (versus requiring conversion to analog first); (iv) maintain the desired sensitivity factor; (v) function with any type of excitation source including constant voltage drive of either polarity; (vi) function with a constant current drive of either direction, and (vii) function with any AC voltage or current drive of any waveshape, duty cycle, and DC offset. Furthermore, such circuit would optimally be electrically isolable from the monitor, be stable and have minimal error or drift through its simulation range, and include provision for the detecting when the monitoring device was electrically connected thereto.

#### Summary of the Invention

The present invention satisfies the aforementioned needs by providing improved apparatus and methods for interfacing time-variant signals between different hardware environments, including the blood pressure waveforms obtained from a living subject. In a

first aspect of the invention, an apparatus useful for interfacing a time-variant signal between two hardware environments is disclosed. In one exemplary embodiment, the apparatus is adapted to accurately simulate one or more types of passive bridge pressure transducer. The interface apparatus is configured to simulate any signal that the pressure transducer could produce, including waveforms having frequency ranging from direct current (i.e., 0 Hz) up through several hundred Hertz. In one variant of this apparatus, a circuit adapted to simulate the one or more blood pressure waveforms as would be produced by a disposable passive bridge pressure transducer (DPT) is provided. The circuit comprises a digital-to-analog converter (DAC) receiving digital inputs from the associated blood pressure sensing and processing apparatus (e.g., a pressure-based tonometric systems, or combined pressure/Doppler-based ultrasonic system, and its attendant signal processing), which are then conditioned using a linear transfer function which replicates that of a DPT bridge device. The circuit uses the excitation signal from the patient monitor as the reference, and advantageously requires no analog signal synthesis; accordingly, no dependency upon voltage references or errors inherent therein is present. The circuit is further "universal" in nature, being adapted to interface with essentially any different configuration of monitoring device, regardless of the type of excitation used by that monitoring device for the DPT, or type of output signal conditioning applied. The circuit also comprises an adjustable scale factor, such factor being based on the adjustment of the ratio of two resistance values, and inherently has very low drift, thereby further enhancing accuracy.

In a second aspect of the invention, a method for simulating a time-variant output signal from a first device using a second device is disclosed. The method generally comprises providing the second device; providing an excitation voltage to the second device; generating a digital representation of a time-variant waveform using the second device; applying a transfer function to the digital representation, the transfer function being substantially similar to that for the first device; and generating an output signal based at least in part on the digital representation and the transfer function, the output signal being substantially similar to that produced by the first device. In one exemplary embodiment, the first device comprises a passive bridge element, the time-variant waveform comprises a blood pressure waveform obtained from a living subject, and the second device comprises a non-invasive blood pressure monitor (NIBPM). The NIBPM is connected to a conventional monitoring device typically

used with prior art passive bridge DPT devices, the presence of the NIBPM being detected through the presence of a specified impedance (or alternatively, a voltage at a predetermined terminal of the monitor). The method further comprises buffering the excitation signal provided to the NIBPM, and disposing the DAC in feedback loop arrangement whereby the  
5 internal current thereof flows is a function of a predetermined parameter (e.g., the DAC count, N).

In a third aspect of the invention, an improved disconnect circuit for detecting when a monitoring device (such as a patient monitor) is disconnected from its sensing apparatus (e.g., Doppler blood pressure sensor) is disclosed. The disconnect circuit detects the presence of a  
10 monitor by detecting a signal associated with the monitor; e.g., the drive signal the monitor uses to excite the passive bridge normally used with the monitor. Rather than evaluating this signal directly, the disconnect circuit of the present invention evaluates a buffered version of the signal. In one exemplary embodiment, the disconnect circuit is physically disposed in the sensing apparatus. A window comparator transfer function is used for detection; thus, as long  
15 as some part of the drive signal waveform exceeds a predetermined signal magnitude, the output of the window comparator will be held in a predetermined state. This approach ensures that any signal of any shape or duty cycle will be detected by the circuit. A comparatively long time constant is also used to avoid zero-crossing waveforms or other momentary voltage dips from inducing unwanted or spurious artifacts.

In a fourth aspect of the invention, an improved apparatus for non-invasively measuring  
20 the blood pressure of a living subject is disclosed. In one exemplary embodiment, the apparatus comprises (i) an ultrasonic Doppler-based system adapted to measure the hemodynamic properties associated with the subject, such as blood kinetic energy or velocity, and determine arterial blood pressure there from, and develop at least one binary digital signal  
25 related thereto; and (ii) the interface circuit previously described. The hemodynamic parameter measurement system comprises a signal processor operatively coupled to an ultrasonic transducer and a pressure transducer, and an applanation device adapted to control applanation pressure applied to the transducer(s). The signal processor (and associated algorithms) generate  
30 a calibration function and determine blood pressure based on the measured data and the derived calibration function. The blood pressure measurement data is fed to the interface circuit, which conditions the signal so as to allow data communication with a monitor. The

interface circuit is adapted to communicate data with literally any type of monitor device (regardless of manufacturer), and hence the apparatus may advantageously be used to non-invasively measure blood pressure from a subject irrespective of the in situ monitoring equipment available. In a second embodiment, the ultrasonic system measures various parameters associated with the blood vessel of the subject, and determines blood pressure based at least in part by calculating time frequency distributions for the collected data. In yet another embodiment, the apparatus is configured with a wireless (e.g., radio frequency) data link such that digital data representative of the subject's blood pressure is transmitted to the interface circuit disposed proximate to the patient monitor, thereby obviating the need for electrical cords.

In a fifth aspect of the invention, an improved apparatus for monitoring the blood pressure of a living subject is disclosed. The apparatus generally comprises a non-invasive blood pressure monitoring (NIBPM) device coupled via the aforementioned simulation circuit to a monitor system, the latter adapted to monitor and optionally analyze, display, and record blood pressure waveform data (and other relevant data) relating to a given subject. In one exemplary embodiment, the NIBPM apparatus comprises an ultrasonic Doppler-based system adapted to measure the hemodynamic properties associated with the subject, such as blood kinetic energy or velocity, and determine arterial blood pressure there from, and develop at least one binary digital signal related thereto. The interface circuit previously described herein is used to provide hardware interface between the NIBPM and the monitor. The monitor comprises a device adapted to receive the analog signal from the NIBPM via the interface circuit, and analyze the data within the processing of the monitor in order to derive (and display) the resultant measured value of blood pressure.

In a sixth aspect of the invention, an improved method of providing treatment to a subject using the aforementioned apparatus and method is disclosed. The method generally comprises: obtaining data from the subject using a sensing device; generating a first signal based at least in part on the obtained data; conditioning the first signal using a conditioning circuit to produce a second signal; providing the second signal to a monitoring device, the latter producing a representation of a desired parameter, and providing treatment to the subject based on the parametric representation. In one exemplary embodiment, the data obtained from the subject comprises arterial hemodynamic data (e.g., pressure, velocity, kinetic energy)

obtained from the radial artery of the human being, and the sensing device comprises the aforementioned ultrasonic NIBPM system with associated interface circuit. The digital representation of arterial blood pressure generated by the NIBPM system is input to the interface circuit, which conditions the signal for "universal" use by any monitoring system.

5 The selected monitoring system takes the conditioned blood pressure signal and displays the waveform or other representation (such as digital values of mean, systolic, and diastolic pressures) for use by the care-giver. The caregiver then prescribes a course of treatment (such as the administration pharmaceuticals, or additional monitoring) based on the displayed information.

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#### Brief Description of the Drawings

Fig. 1 is a schematic diagram of an exemplary prior art circuit used to energize and recover the output signal from a passive resistance bridge used in a disposable pressure transducer (DPT).

15 Fig. 2 is a schematic diagram of a balanced bridge circuit which is electrically equivalent to that of Fig. 1.

Fig. 3 is a schematic diagram of the equivalent circuit of Fig. 2, except in an unbalanced condition.

20 Fig. 4 is a schematic diagram of an unbalanced bridge circuit which is electrically equivalent to that of Fig. 3.

Fig. 5 is a schematic diagram of the unbalanced bridge circuit of Fig. 4, excerpt wherein the circuit is simplified to reflect the bridge resistance  $R_b$  alone.

Fig. 6 is a schematic diagram of an exemplary prior art circuit adapted to interface a non-DPT signal source to a fixed DC drive voltage patient monitor.

25 Fig. 7 is a schematic diagram of an exemplary prior art passive bridge device illustrating the response thereof to a sine wave excitation signal applied at the drive input of the bridge.

Fig. 8 is a schematic diagram of one exemplary embodiment of the interface circuit of the invention.

30 Fig. 9 is partial schematic of a second embodiment of the interface circuit of the invention, wherein optical isolators are disposed in the data path to the DAC, thereby providing

electrical isolation.

Fig. 10 is a schematic diagram of one exemplary embodiment of the disconnect circuit optionally used in conjunction with the interface circuit of Figs. 8 or 9.

5 Fig. 10a is a graph illustrating the operation of the windowing function associated with the comparator of the disconnect circuit of Fig. 10.

Fig. 11 is a schematic diagram of a third embodiment of the interface circuit of the invention, also comprising self-test functionality.

10 Fig. 12 is a logical flow diagram illustrating one exemplary embodiment of the method of simulating the time-variant output of a first device using a second device adapted according to the present invention.

Fig. 13 is a functional block diagram of one exemplary embodiment of the apparatus for non-invasively measuring the blood pressure of a living subject according to the invention.

15 Fig. 13a is a functional block diagram of a second embodiment of the apparatus for non-invasively measuring the blood pressure of a living subject, wherein the interface circuitry is disposed proximate to the patient monitor.

Fig. 14 is a functional block diagram of a third embodiment of the apparatus for non-invasively measuring the blood pressure of a living subject, incorporating a wireless (e.g., radio frequency ISM band) data link.

20 Fig. 14a is a perspective view of one embodiment of the monitor receiver unit of the apparatus of Fig. 14, illustrating the form factor thereof.

Fig. 15 is a logical flow diagram illustrating one exemplary embodiment of the method of providing treatment to a subject using the aforementioned apparatus and methods.

### Detailed Description of the Invention

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Reference is now made to the drawings wherein like numerals refer to like parts throughout.

30 It is noted that while the invention is described herein primarily in terms of a method and apparatus for assessing the hemodynamic parameters of the circulatory system via the radial artery (i.e., wrist) of a human subject, the invention may also be embodied or adapted to monitor such parameters at other locations on the human body, as well as monitoring these

parameters on other warm-blooded species. Furthermore, in the broader sense, the invention may be readily applied outside the medical field, such as for example to pressure monitoring devices in fluidic systems, where it is desirable to have universal functionality or interconnection between the sensing device and an associated monitoring device. It can be used to drive the signal processing circuits for any bridge-type transducer monitor that processes time-variant signals (e.g., 200 Hz or less). All such applications, adaptations and alternate embodiments are considered to fall within the scope of the claims appended hereto.

As used herein, the term “non-invasive blood pressure monitor” or “NIBPM” refers to any apparatus adapted to measure or estimate the blood pressure within a blood vessel of a living subject in either partially or completely non-invasive manner, regardless of method used.

Referring now to Fig. 7, the response of an exemplary prior art passive bridge device to a sine wave excitation applied at the drive input of the bridge is analyzed. Assuming perfect matching in the bridge 700, the outputs +S 702 and -S 704 are also sine waves in phase with the excitation voltage, but at one-half the amplitude of the drive voltage. If the bridge 700 senses an applied pressure (for example, of 100 mmHg), its resistance is altered by an amount equal to  $\Delta R$ , and the output sine wave amplitudes at +S 702 and -S 704 change by 1.25 mV each, but in different directions. The differential output of the exemplary bridge 700 of Fig. 7 will be a sine wave in phase with the drive, with an amplitude of 2.5 mV. The amplitude of this differential signal will follow the blood pressure waveform applied to the device, which varies at a much lower frequency. Specifically, the period of the blood pressure signal can range between about 1.7 sec (35 beats / minute) to 0.25 sec (240 beats / minute). The blood pressure waveform can be obtained by synchronously demodulating the output signal with the drive excitation sine wave.

Recalling the transfer function of the passive bridge,  $E_s = E_d \times K_s \times P$  (Eqn. 10 above), it can be seen that the output of any interface circuit used to universally mimic or “simulate” the passive bridge must be a function of both the pressure signal  $P$ , and also a function of the drive excitation source  $E_d$ . Further, the transfer function shows that a multiplication must take place between the variables for the interface circuit to function the same as the passive bridge. Since  $E_d$  can be bipolar, at least 2 quadrant multiplication is implied.

Since the interface circuit is required to work for both DC drive, and AC drive, good

DC stability is required. Since the interface circuit is scaled to look like a transducer, its output is 25 uV / mmHg with a 5 VDC drive. If the drift error must be less than 1 mmHg over the operational temperature range of 10 °C to 40 °C, the drift must be less than 0.833 uV / °C. Furthermore, DPT's are only allowed a DC offset of 1.875 mV (75 mmHg) by specification, so  
5 the interface circuit must meet that requirement as well.

Referring now to Fig. 8, a first embodiment of the improved interface circuit **800** of the invention meeting the foregoing requirements is described. As shown in Fig. 8, the circuit **800** generally acts as an interface between the non-invasive blood pressure measurement system (such as that manufactured by the Assignee hereof) and prior art monitoring devices  
10 manufactured by any number of different entities which are adapted for passive bridge transducer or similar sensing devices (not shown). Specifically, jack or connector **J1 802** connects to the monitor **806** which supplies drive excitation voltage  $E_d$  at pin 1 (+E) **808**. Resistors **R1 810** and **R4 812** provide the input impedance, nominally selected in the present embodiment to be 3K ohms. During operation with the aforementioned passive bridge device,  
15 the monitor **806** looks for such an impedance in order to determine if the passive bridge transducer is electrically connected. Alternatively, the monitor may detect the presence of a passive bridge transducer by looking for the signal at +S **814** or -S **816**.

In the embodiment of Fig. 8, resistors **R1** and **R4** form a 2:1 divider and apply a signal of  $E_d/2$  to the inputs of two operational amplifiers **U1B 817** and **U2A 818**. The operational  
20 amplifiers **817**, **818** each comprise Model No. OPA2277 integrated circuit (IC) amplifiers manufactured by Texas Instruments Corporation, although other types, integrated or otherwise, may be used. The construction and operation of such operational amplifiers are well known in the electronic arts, and accordingly are not described further herein. Both operational amplifiers are configured as voltage followers (assume no current flow in resistor **R5 820** for  
25 purposes of the instant discussion), so that the voltage of their output signals are also represented by the relationship  $E_d/2$ . Resistors **R2 822** and **R3 824** couple the output signals of the amplifiers to the +S **814** and -S **816** terminals of the transducer output connector **J1 802**, and provide a differential output impedance of 300 ohms to the monitor, although it will be appreciated that other resistance values may be substituted. The aforementioned OPA2277  
30 amplifier is an extremely low offset (e.g., 25 uV) and low drift (e.g., 0.1 uV /°C) device, so the output offset is only on the order of 50 uV worst case (which corresponds to approximately 2



mmHg pressure). Total drift of this stage is only on the order of 3 uV over a 10 °C to 40 °C temperature range.

As shown in the exemplary embodiment of Fig. 8, the excitation voltage  $E_d$  is buffered by unity gain amplifier U1A **826** of the type well known in the art, and applied to the reference input of a 12-bit, bipolar, multiplying digital-to-analog converter (DAC) U3 **830**. While the present embodiment uses a 12-bit DAC, it will be recognized that DACs having other bit resolutions (such as 8-bit, 10-bit, 14-bit, or 16-bit) and operating characteristics (e.g., “flash” DACs) may also be utilized. Note also that in the present embodiment, the DAC supports the bipolar multiplication function. The digital inputs **832**, **834**, **836** of the DAC **830** carry the blood pressure waveform signal of the present embodiment. Among other functions, the DAC **830** performs the required multiplication function described by the bridge transfer function, namely that of Eqn. 13

$$Ed \times P \quad (\text{Eqn. 13})$$

15

The DAC **830** is connected in a feedback loop **840** with operational amplifiers U2B **842** and U4 **844** to form a bipolar, programmable, floating current source. In operation, the voltage at the reference input **848** of the DAC **830** causes an internal current to flow, the magnitude of which that is a function of the DAC count, N. This current flows through an internal feedback resistor (10K ohms in the present embodiment) connected to pin “2” **850** of the DAC **830**. The DAC summing junction (not shown) is held at 0 volts by the feedback action of amplifier U2B **842**. The output voltage at pin “2” of the DAC **830** is given by Equation 14:

20

$$PDAC = -Ed \times \frac{N}{4096} \quad (\text{Eqn. 14})$$

25

This signal is supplied by instrumentation amplifier U4 **844**, which is configured for a gain of 1 (unity) in the present embodiment. By virtue of its connection, the voltage across resistor R6 **854** becomes:

30

$$ER6 = Ed \times \frac{N}{4096} \quad (\text{Eqn. 15})$$

Amplifier U2B **842** will adjust its output voltage to satisfy Eqn. 15 above. The voltage at the other end of resistor R6 **854** is equal to  $E_d/2$ . Thus, the voltage at the output of amplifier U2B **842** becomes:

5

$$E(U2B7) = \frac{E_d}{2} - \left[ E_d \times \frac{N}{4096} \right] \quad (\text{Eqn. 16})$$

The output current which flows through R6 **854**, also flows through R5 **820**, which adds to the signal at the output of U2A **818**. It can be shown through analysis that the current flowing through R6 **854** is given by the following relationship:

10

$$I = \frac{E_d}{R6} \times \frac{N}{4096} \quad (\text{Eqn. 17})$$

Where N is the count programmed into the DAC **830** via the serial-to-parallel interface (SPI) (pins "5", "6", and "7") **832**, **834**, **836**. In the illustrated embodiment, N can be set for any value from 0 to 4095. Hence, if  $E_d$  is 5.0 V and  $N = 3000$  counts, the current I will be 44.388 uA per Eqn. 17. Note that as the drive voltage  $E_d$  reverses polarity, then the current I reverses direction, and the output signal at +S **814** reverses phase.

15

The current I develops a voltage across R5 **820** given by the following equation:

20

$$ER5 = R5 \times \frac{E_d}{R6} \times \frac{N}{4096} \quad (\text{Eqn. 18})$$

This makes the output at U2A **818** equal to:

25

$$E(+S) = \frac{E_d}{2} + \left[ R5 \times \frac{E_d}{R6} \times \frac{N}{4096} \right] \quad (\text{Eqn. 19})$$

Since the voltage at  $-S$  **816** is also  $E_d/2$ , then the differential output is:

$$E_s = \frac{K_s \times E_d \times N}{4096} \quad (\text{Eqn. 20})$$

where:

5 
$$K_s = \frac{R_5}{R_6}, \text{ and } 0 \leq N \leq 4095 .$$

Note that if the pressure  $P$  is substituted for the quantity  $N/4096$ , Eqn. 20 has the same form as the transfer function for the passive bridge previously described herein.

The ratio of  $R_5$  **820** to  $R_6$  **854** sets the sensitivity value for the circuit, and the scaling for the pressure transfer function. For example, for  $5 \text{ uV} / \text{V} / \text{mmHg}$ ,  $K_s = 0.002048$ . Note  
10 also that in the present embodiment, the constants are arranged so that the value of  $N$  scales as  $0.1 \text{ mmHg} / \text{count}$ . Thus  $N = 3000$  yields  $3000 \times 0.1 = 300 \text{ mmHg}$ .

Additionally, in the present implementation, resistors  $R_1$  **810** and  $R_4$  **812** are selected to be low tempco (  $25 \text{ ppm/oC}$ ) and matched to  $0.1\%$ . Resistors  $R_5$  **820** and  $R_6$  **854** are also low tempco types ( $10 \text{ ppm} / \text{oC}$ ), and have accuracy better than or equal to  $0.05\%$ . Ideally, the  
15 resistors ( $R_5$  AND  $R_6$ ) should be a custom network in a common thermal environment so that differential thermal gradients are minimized. For the values of  $R_5$  **820** and  $R_6$  **854** shown, the nominal accuracy of the output signal is advantageously within  $0.02\%$  at  $300 \text{ mmHg}$ .

One of the advantages of the circuit **800** of the embodiment of Fig. 8 is that the circuit is capable of utilizing a digital representation of the blood pressure (BP) input signal, as  
20 opposed to requiring an analog representation of the BP signal. This capability is significant from the perspective that any deleterious effects on accuracy, drift, and non-linearity associated with the analog synthesis are avoided, since no conversion between the digital and analog domains is performed prior to input.

The circuit **800** is also advantageously ratio-metric with respect to the drive signal  $E_d$   
25 supplied by the monitor to which the circuit is connected. Specifically, any change in  $E_d$  is also reflected in the proper ratio at the outputs  $+S$  and  $-S$ . Also, the output scaling of the circuit **800** is adjustable, and the transfer function is inherently linear as described by equation 20, where  $K_s$  is the ratio of  $R_5$  to  $R_6$ . As yet another advantage, digital processing of the (digital) BP signal is readily accomplished prior to inputting the signal to the DAC **830**, so any BP

signal anomalies and/or artifacts can be conveniently eliminated through signal processing techniques of the type well known in the art.

Since blood pressure is a dynamic (i.e., time variant) signal, it is necessary to send out a new digital representation of the BP value to the DAC **830** whenever the BP value changes. 5 The Assignee hereof has noted that in an exemplary application, 1000 values per cardiac cycle provide sufficient resolution, although other values (higher or lower) may be used consistent with the invention. In such application, each value of N takes approximately 3 usec to load, so updating of the DAC **830** can be performed completely within 3 msec (i.e., 1000 values x 3E-06 sec/value). In comparison, the fastest cardiac cycle occurs in roughly 250 msec. In 10 practice, it can be shown that as few as 40 points per cardiac cycle is sufficient to define typical blood pressure waveform signatures. This allows a sample rate as low as 160 Hz for the DAC in order to accommodate cardiac cycles up to 240 beats per minute.

For the purposes of calibration, the DAC **830** can be set to N=0, and the attached monitoring device can be zeroed (via, for example, its front-panel transducer zero control). In 15 the context of the previous example, the DAC **830** can then be set to N=1000, which correlates to 100 mmHg. This approach provides a constant output which is easily displayed on the monitor, and further provides a span calibration check. If for any reason the monitor displays a reading offset from the 100 mmHg calibration value, then that value can be readily compensated for, such as for example through insertion of an error term via the non-invasive 20 blood pressure monitor (NIBPM) with which the circuit is associated. In one exemplary embodiment, the error term is entered through a keypad input device associated with the NIBPM device manufactured by the Assignee hereof, although other methods (software or otherwise) may be used with equal success.

In another embodiment of the interface circuit **900** of the invention (Fig. 9), the digital 25 programming lines **932**, **934**, **936** to the DAC **930** are optically isolated via an optical isolator module **955**, and an isolated power supply **957** of the type well known in the electronic arts used to power the circuit **900**. This approach advantageously provides complete floating isolation of the interface circuit, and eliminates any potential for ground loops, compromise of patient and/or operator safety, and the like.

30 It will be recognized that while the foregoing embodiments of the interface circuit of the invention (i.e., Figs. 8 and 9) are cast in terms of discrete electrical components (i.e.,

operational amplifiers, resistors, capacitors, etc.) arranged on an exemplary printed circuit board, the circuit, and even ancillary components associated therewith, may be embodied in one or more integrated circuit (IC) devices using any of the well understood semiconductor design synthesis and fabrication techniques known to those of ordinary skill. Such integrated circuit may even include the electronic components of the sensing device (e.g., NIBPM) if desired. For example, the signal processor, ADC, and interface circuit 800 may all be embodied as an application specific integrated circuit (ASIC) on a single silicon die. Other arrangements (including the use of multiple integrated circuit devices) are also contemplated, all such variants and alternate embodiments falling within the scope of the claims appended hereto.

### *Disconnect Circuit*

Referring now to Fig. 10, one exemplary embodiment of the monitor disconnect circuit **1000** of the invention is described. This circuit **1000** detects the presence of an electrically connected patient monitoring device by detecting the drive signal the monitor uses to excite the normally connected passive bridge. Rather than detecting this signal directly, the circuit **1000** looks at a buffered version of the signal (Pin 1 of U1A **826** in Fig. 8), labeled  $E_{d\text{buf}}$  **1010** in Fig. 10.

The construction and operation of the disconnect circuit **1000** is now described. As illustrated in Fig. 10, the drive signal  $E_d$  is applied to comparators U8A **1012** and U8B **1014**. The comparator threshold values are set by resistors R21 **1016**, R25 **1018**, and R27 **1020** to a predetermined value, +/- 1V in the illustrated embodiment. The wired "or" connection **1022** at the output of U8A **1012** and U8B **1014** forms a window comparator arrangement **1024** and transfer function, as illustrated in Fig. 10a. Thus, as long as some part of the drive signal waveform exceeds the magnitude of the predetermined value (e.g., |1V|), the output of the window comparator **1024** will be low. This configuration ensures that any signal, whether DC or AC, and of any shape or duty cycle, will be detected by the window comparator formed by the comparators **1012**, **1014** and output connection **1022**. The low output impedance of the window comparator arrangement discharges capacitor C11 **1026** through resistor R24 **1028**. As long as the voltage across C11 **1026** is less than the threshold of comparator U9A **1030** (e.g., +1V), the output of comparator U9A **1030** will be low. If the drive signal  $E_d$  is lost due

to an electrically disconnected monitor, then the output of the window comparator arrangement **1024** goes to a high impedance state, and C11 **1026** starts to charge to a selected voltage (e.g., +5V) through resistor R22 **1034**. When the voltage across C11 **1026** exceeds the predetermined value (e.g., +1V), comparator U9 **1030** output goes high indicating that the monitor is electrically disconnected. The time constant ( $\tau$ ) for this detection is set by R22 **1034** and C11 **1026**, and is approximately 100 mS for the values shown in the illustrated embodiment. The use of a comparatively long time constant in the illustrated embodiment ensures that momentary loss of signal, such as periodic zero-crossings of a sine wave drive signal, are not detected by the circuit **1000**. For the aforementioned 100 mS time constant, the drive signal frequency can advantageously drop as low as about 100 Hz. In actual practice however, the drive signal frequency received by the circuit will characteristically remain much higher, typically on the order of 2 to 5 KHz.

It is noted that the output from comparator U9A **1030** comprises a logic level-compatible signal that can be read by an input/output (I/O) port of any processor running from a 5V **1042** supply. Note that since U9A **1030** is an open collector comparator, R23 **1038** can be returned to any supply voltage such as 1.5V, 1.8V, or 3.3V for compatibility with a wide range of modern microprocessors or other parts.

#### 20 *Alternate Embodiment of Interface (and Disconnect) Circuit with Self-Test*

Referring now to Fig. 11, yet another embodiment of the interface circuit (with disconnect circuit) of the present invention is described. It will be noted that in the embodiment of Fig. 11, the circuit **1100** is adapted to provide enhanced functionality in various aspects as compared to the embodiment of Figs. 8 and 10, and Fig. 9, including self-test functionality, as described in greater detail below. The circuit **1100** of Fig. 11 also has greater complexity, however, and accordingly may be optimal for applications where its enhanced functionality is required and/or where the increased cost is not a significant issue.

As shown in Fig. 11, the supply voltages for the various analog circuitry of the interface circuit **1100** are set to +/- 7.5 in order to reduce the power requirements and heat generation rate of the circuit **1100**, and to increase its reliability. Additionally, the amplifier U11B **1126** buffers the drive voltage Ed **1108** (+E) after the voltage divider formed by R19

1110 and R17 1112, as compared to the arrangement of Figs. 8 and 10. The output of U11B 1126 is also configured to drive the reference input 1148 of the DAC U6 1130, and the comparators U1A 1170, and U1B 1172, via switch S1B 1174. The voltage  $E_d/2$  1162 is also made available to the A/D converter (not shown) for measurement. Furthermore, in order to  
5 compensate for the scale factor error that occurs due to this configuration, the resistance values of resistors R7 1120, and R8 1154 have been changed, with the ratio of 244.1:1. These modifications keep the circuit scale factor at 10 counts / mmHg.

Additionally, the reference voltages for the window comparator U1A 1170, and U1B 1172 of the circuit 1100 have been changed from +/- 1V to +/- 0.5V. This is accomplished by  
10 changing the values of the resistors in the divider; R3 1176, R4 1178, and R5 1180.

As shown in Fig. 11, the output comparator for the monitor detector circuit utilizes a Schmidt trigger logic gate, NC7WZ14 1181. Its output can drive either 3.3V or 5 V logic devices, although it will be recognized that other devices adapted to provide similar functionality yet different drive voltages, may be substituted. The output of the comparator  
15 1181 is read directly by the microprocessor (or other comparable processing device).

The circuit 1100 of Fig. 11 also includes radio frequency interference (RFI) protection via choke T1 1165, and capacitors C17 1166, C22 1167, C24 1168, and C28 1169. Electrostatic discharge (ESD) protection of the patient monitor connector output 1102 is also provided via over-voltage clamp U9 1184. As a result of this protection, the range of the  
20 patient monitor drive voltage (+E) 1108 is limited to +/- 7.5V, or 15 V p-p.

As previously referenced, the circuit 1100 of Fig. 11 also includes a self-test sub-circuit 1177, which provides an independent means of insuring that the output signal to the patient monitor 806 is correct. This circuitry 1177 is now described in greater detail.

In order to have an independent means of insuring that the patient monitor circuit is  
25 functioning correctly, the unknown external drive voltage from the patient monitor (PM) 806 is disconnected, and a known reference signal 1185 used instead. In the illustrated embodiment, the known reference is generated by a precise voltage reference device (not shown), which provides +2.500 volts to S1A 1186. S1A 1186 and S1B 1174 effectively form an electronic single pole double throw switch which is controlled by the state of control line TMAI 1187. In  
30 normal operation S1A is off, and S1B is on. When it is desired to check the function of the PM circuit, TMAI 1187 is asserted true, and S1A 1186 turns on and S1B 1174 turns off. This

disconnects the external PM drive signal and connects the known +2.5 V reference to the DAC U6, **1148** U7A **1117**, U7B **1118**, U1A **1170**, and U1B **1172**. The MONITOR output **1182** should go high for this condition, and can be verified by the microprocessor. This checks the ability of the circuit to detect connection to the PM. To the circuit, the +2.5 V reference behaves the same as a +5.000 V drive signal from the external PM. The 2.5V reference **1185** can be read by a second A/D converter (not shown) via the output of buffer U11A **1188** at REFMON **1189**. This advantageously provides an independent check of the reference.

To verify the zero offset condition of the circuit **1100**, the DAC **1130** is now set to a count of 0000. Under this condition, which simulates a 0 mmHg signal, the outputs of U7A **1117**, and U7B **1118** are nominally +2.500 volts. Ideally their difference would be zero, but both amplifiers have a finite offset of up to 25 uV in the illustrated embodiment. The differential output can therefore be as much as 50 uV, which is equivalent to 2 mmHg for a 5 V drive. In order to measure this output signal U10 **1190** is connected across the outputs of U7A **1117** and U7B **1118** through resistors R13 **1122** and R6 **1124**. U10's gain is set to 400 via R16 **1191** and R15 **1192**. The output signal TLFDBK **1193** thus has a scale factor of 10 mV/mmHg. For the zero condition, TLFDBK **1193** will be in the range of +/- 20 mV. The network of R14 **1194**, C23 **1195**, R12 **1196**, and C18 **1197** at the input of U10 **1190**, form a single pole low pass filter with a nominal cutoff frequency of 1.6 KHz when configured as illustrated. This filter prevents high frequency signals from entering U10 **1190**, and affecting its output. U10 **1190** itself has an offset which can be as much as 50 uV. This offset must also be compensated since it represents +/- 2 mmHg as well. Switch S1C **1198** is used for this purpose. Switch S1C **1198** is placed across the outputs U7A **1117**, and U7B **1118** through resistors R13 **1122** and R6 **1124**. Switch S1C **1198** is turned on ZMAI **1199** is asserted true (logic 0). This shorts out the differential offset error of U7A **1117**, and U7B **1118** and allows the A/D converter (not shown) to measure the offset error of U10 **1190** at TLFDBK **1193**. Switch S1C **1198** is then opened, and the A/D (not shown) again measures the output of U10 **1190** at TLFDBK **1193**. This value represents the true "zero" signal being presented to the PM, and can become the baseline against which all non-zero outputs are referenced.

It should be noted that by making differential measurements as in the present embodiment, all of the offset errors in the A/D measurement channel advantageously cancel



out. If either measurement falls outside a predetermined range, then a fault condition exists, and an alarm is generated (e.g., visual, audible, etc.), or other condition enabled (such the writing of data to a trace file). Note that the external PM must be zeroed to compensate for the small differential output of +/- 2 mmHg. This is done when TMAI **1187** is 0, ZMAI **1199** = 1, and DAC **1130** count = 0000.

To verify the gain accuracy of the circuit **1100**, the DAC **1130** is set to a count of 1000. This should result in an output signal to the PM representing a predetermined value (e.g., 100 mmHg). Since U10 **1190** is scaled at 10 mV/mmHg, its output signal TLFDBK **1193** should be 1.000 V above the zero reference value established earlier. If the measurement falls outside a predetermined range, then a fault condition exists, and an alarm (or other condition) is generated. If both the zero offset and gain of the PM circuit are verified as OK, then the circuit is reset to its normal condition: TMAI **1187** = 0, and ZMAI **1199** = 1.

Another advantageous aspect of the self test sub-circuit **1177** is that it can assess the proper operation of the monitor adapter interface circuit **1100** during normal operation if the external PM uses a constant DC drive signal. This is true for most modern monitors, although some still use either a sine wave AC drive, or a pulsed DC drive. When a fixed DC drive is used, the A/D converter can measure the value of the drive signal at ED/2 **1162**. By knowing this, the output for any pressure signal value can be computed, and compared against the actual measured output at TLFDBK **1193**. If these values don't agree within a predetermined range, a fault condition exists, and appropriate alarms would be generated (or other action taken). As an example of the foregoing, assume the external patient monitor drive is +6.000 Volts. The A/D would measure +3.000 volts at ED/2 **1162**. Knowing that the actual drive voltage is 2 X +3.000 = +6.000 volts, the output signal can be computed as in Eqn. 21 below:

25

$$E_s = (5 \text{ uV} / \text{V} / \text{mmHg}) \times (+6.000 \text{ V}) \times 400 \times P_{\text{out}}, \quad (\text{Eqn. 21})$$

where  $P_{\text{out}}$  is expressed in mmHg. For a  $P_{\text{out}}$  value of 100 mmHg, (DAC **1130** count = 1000)  $E_s$  will be equal to +1.200 V.  $E_s$  would be measured at TLFDBK **1193**. Note that in the illustrated embodiment, the output signal must be referenced to a zero value DAC **1130** = 0000, in order to cancel out the offset errors.

30

If the external PM **806** uses either a sine wave AC drive, or a pulsed DC drive, then operation can only be verified by switching to the +2.500 V reference. This can be done when the system first powers up, or when monitoring is suspended for some reason.

#### 5 *Method of Simulating Time Variant Output*

Referring now to Fig. 12, the method for simulating a time-variant output signal from a first device using a second device according to the invention is described. It will be recognized that while the following discussion is cast in terms of a passive bridge transducer device such as those previously described (“first device”) and its associated monitor, and a non-invasive  
10 blood pressure monitor (“second device”), the methodology of the invention may be readily applied to other applications and combinations of devices both within and outside the medical field, such as for example pressure measuring devices in industrial fluidic systems.

As shown in Fig. 12, the first step **1202** of the method **1200** comprises providing the non-invasive blood pressure monitor (NIBPM); a tonometric pressure-based system such as  
15 that manufactured by the Assignee hereof is used in one embodiment, although myriad other types and configurations may be substituted. The NIBPM is then electrically connected to one of the aforementioned prior art patient monitoring systems (e.g., those manufactured by General Electric, et al), per step **1204**. The connection of the NIBPM is optionally detected in step **1208** through the presence of a specified impedance across two or more terminals in the  
20 patient monitor (or alternatively, a voltage at a predetermined terminal of the patient monitor), based on an applied excitation voltage provided to the NIBPM by the patient monitor (step **1206**). In step **1210**, the excitation signal is buffered within the interface circuit **800, 900, 1100** as previously described. Note that any of the foregoing interface circuits **800, 900, 1100** (or combinations of the desirable features thereof) may be used consistent with the method **1200**.

25 In step **1212**, the NIBPM generates a digital representation of the time-variant blood pressure waveform(s) through the data generated by pressure transducer elements (and optionally, acoustic transducer elements if so equipped) associated therewith. Generation of this signal is completely independent of the excitation signal applied by the monitor. The transfer function is next applied to the digital representation (step **1214**) using the interface  
30 circuit **800, 900, 1100**, the transfer function being substantially similar to that for the passive bridge device as previously discussed.

Lastly, the output signal from the interface circuit **800, 900, 1100** is produced which is

compatible with the patient monitoring system (as well as being “universally” compatible with the patient monitoring systems of other vendors) per step **1216**. The output signal of step **1216** is based at least in part on the digital representation of the waveform (e.g., blood pressure) provided to the DAC **830, 1130** of the circuit **800, 900, 1100**, respectively, the applied drive signal **802, 1102** from the patient monitor **806**, and the applied transfer function, the output signal being substantially similar to that produced by the passive bridge device under comparable excitation signal and measured pressure waveform.

#### *Apparatus for Hemodynamic Assessment*

10 Referring now to Fig. 13, an improved apparatus for non-invasively assessing hemodynamic parameters (e.g., arterial blood pressure) associated with a living subject is described. In the exemplary embodiment of Fig. 13, the apparatus **1300** comprises, *inter alia*, (i) a blood pressure measurement system **1302** adapted to measure the blood pressure and/or other hemodynamic properties (such as for example blood kinetic energy or velocity) associated with  
15 the subject, and develop at least one binary digital signal related thereto; and (ii) the interface circuit **800, 900, 1100** previously described. The blood pressure/hemodynamic parameter measurement system **1302** comprises generally a signal processor **1304** operatively coupled to one or more pressure transducers **1308**, as well as an applanation device **1310** adapted to control applanation pressure applied to the transducer(s) **1308**. The signal processor **1304** (and  
20 associated algorithms running thereon) determine arterial blood pressure based on the measured data. One key advantage of the present invention, in addition to its effectively universal adaptability to various types of monitors as previously described, is its adaptability to any number of different parametric measurement devices, whether adapted for medical applications such as blood pressure measurement or otherwise. For example, the present  
25 invention may be readily used with the apparatus and techniques described in detail in co-pending U.S. Patent Application Serial No. 09/534,900, entitled “Method And Apparatus For Assessing Hemodynamic Parameters Within The Circulatory System of A Living Subject” filed March 23, 2000, assigned to the Assignee hereof, and incorporated herein by reference in its entirety, may be utilized. In one aspect, the aforementioned application describes a method  
30 generally comprising the steps of: measuring a first parameter from the blood vessel of a subject; measuring a second parameter from the blood vessel; deriving a calibration function

based on the second parameter; and correcting the first parameter using the derived calibration function. Once calibrated, the second parameter is monitored continuously or periodically; changes in that parameter are used to indicate changes in the hemodynamic property of interest. In an exemplary embodiment, the first parameter comprises a pressure waveform, and  
5 the second parameter comprises the total flow kinetic energy of blood within the blood vessel. During measurement of the pressure waveform, the blood vessel is applanated (compressed) so as to induce changes in the hemodynamic properties within the blood vessel and circulatory system; the kinetic energy and/or velocity during such applanation is then measured and used to identify one or more artifacts (such as for example a “hump” in the kinetic energy or  
10 velocity profile). A correction function is then generated based on these artifacts, and applied to the measured pressure waveform to generate a corrected or calibrated waveform representative of the actual pressure within the blood vessel. In one exemplary embodiment, the calibration method comprises measuring the pressure waveform from a blood vessel of the subject; measuring a second parameter from the same blood vessel at least once; identifying at  
15 least one artifact within the pressure waveform based on the second parameter; deriving a calibration function based on the measured second parameter and at least one property associated with the at least one artifact; applying the calibration function at least once to the pressure waveform to generate a calibrated representation of pressure within the blood vessel; and continuously monitoring the second parameter to identify variations in blood pressure with  
20 time.

As yet another alternative, the methods and apparatus of co-pending U.S. Patent Application Serial No. 09/815,080 filed March 22, 2001 and entitled “Method And Apparatus For Assessing Hemodynamic Parameters Within The Circulatory System Of A Living Subject”, also assigned to the Assignee hereof and incorporated herein by reference in its  
25 entirety, may be used with the present invention. In one aspect, this methodology utilizes detection of the lumen disposed within a blood vessel. The method comprises transmitting acoustic energy into the blood vessel; evaluating the signal level of reflections of the acoustic energy as a function of propagation of the energy within the blood vessel, and identifying at least one region of reduced signal level within the reflections. In one exemplary embodiment,  
30 a power metric is derived from the A-mode envelope. The integral of the backscattered power as a function of depth is utilized to identify artifacts (e.g., “plateaus”) which are used, with

appropriate constraints, to detect the depth of the lumen. In a second embodiment, backscattered energy (e.g., A-mode signals) are analyzed using a power calculation performed over pre-selected depth intervals to identify regions of reduced signal level therein. In another aspect, a method of detecting at least one wall of a blood vessel comprises transmitting  
5 acoustic energy into the blood vessel; detecting at least one region associated with the lumen in the blood vessel; and detecting the location of at least one wall of the blood vessel relative to the lumen; wherein detecting the location comprises analyzing A-mode data derived from the transmitted acoustic energy. In one embodiment, the wall is detected by comparing the integrated power at a given depth with the average lumen power. In another embodiment, the  
10 level (amplitude) of the envelope-squared signal is compared to that of the lumen. In yet another aspect, an improved method of determining the diameter of a blood vessel comprises transmitting acoustic energy into the blood vessel; detecting the region associated with the lumen in the blood vessel; detecting the location of a first wall of the blood vessel relative to the lumen; detecting the location of a second wall of the blood vessel relative to the lumen; and  
15 determining the diameter of at least a portion of the blood vessel based at least in part on the locations of the first and second walls.

It will be recognized, however, that yet even other techniques for measuring blood pressure may be employed by the blood pressure/hemodynamic assessment apparatus **1300** of the invention, including for example the time-frequency distribution based system disclosed in  
20 co-pending U.S. Patent Application Serial No. 09/342,549, entitled "Method and Apparatus for the Noninvasive Determination of Arterial Blood Pressure" filed June 29, 1999, now U.S. Patent 6,471,655 issued October 29, 2002, or co-pending U.S. Patent Application Serial No. 09/489,160, entitled "Method and Apparatus for the Noninvasive Determination of Arterial Blood Pressure" filed January 21, 2000, both assigned to the Assignee hereof, and both  
25 incorporated herein by reference in their entirety. More broadly, literally any type of sensing apparatus which produces an electrical output (whether for measuring physiologic parameters or otherwise) may be utilized consistent with the invention.

The digital domain blood pressure data generated by the exemplary measurement system **1302** is fed to the interface circuit **1300**, which conditions the signal as previously  
30 described so as to allow seamless data communication with the selected patient monitor. As previously discussed, the interface circuit **1300** is adapted to communicate data with literally

any type of patient monitor device (regardless of manufacturer), and hence the apparatus **1300** of Fig. 13 may advantageously be used to non-invasively measure blood pressure from a subject irrespective of the in situ patient monitoring equipment available.

The apparatus of Fig. 13 is further adapted to be physically contained within a unitary or discrete device **1320** with associated electrical connector **1322** such that the connector **1322** may be plugged directly into the corresponding electrical receptacle within the in situ patient monitoring device. Since the receptacle configuration generally varies from monitor to monitor, the connector **1322** may be configured to mate with an adapter **1324** which receives the connector **1322** of the device **1320** in a first portion **1326**, and mates with the associated receptacle **1340** of the patient monitoring device **1342** via a second portion **1328**. In the illustrated embodiment, the adapter **1324** comprises a female-male plug (i.e., the connector **1322** of the NIBPM device **1320** is received in a female connector **1330** in the first portion **1326**, and the male connector **1332** disposed on the second portion **1328** is received in the corresponding patient monitor female receptacle **1340**). Such patient monitor female receptacle configuration is widely used for purposes of reducing electrical shock hazard, since the electrical terminals carrying excitation voltage to the sensing apparatus **1300** are shielded from casual contact. It will be recognized, however, that other arrangements may be employed in the adapter **1324** consistent with the invention, including for example female/female, male/male, and male/female (as differentiated from female/male in the embodiment of Fig. 13). Furthermore, ganged or multiple adapter configurations may be employed, such as in the case where it is desirable to have (i) two or more NIBPM devices **1320** (or devices of mixed configuration) electrically communicating with a sole patient monitor **1342**. Other configurations and variations on the foregoing themes are possible, all such configurations and variations falling within the scope of the claims appended hereto.

Furthermore, it will be readily apparent that the connector **1322** of the apparatus **1300** may be adapted to be received directly by or within the receptacle **1340** of the selected monitor **1342**. For example, if certain medical/treatment facilities uniformly utilize only one type of patient monitor, they may wish to procure NIBPM devices with connectors **1322** which are adapted for direct receipt by the receptacle **1340** of that type of patient monitor, thereby obviating the need for separate adapters (and any cost, safety, or electrical performance issues potentially relating thereto.)

Referring now to Fig. 13a, a second embodiment of the apparatus for non-invasively assessing hemodynamic parameters associated with a living subject is described. In the embodiment of Fig. 12a, the apparatus **1380** is configured such that the interface circuit **800, 900, 1100** is disposed proximate to the patient monitor **1342**, specifically as part of the adapter **1384** used to couple the connector **1322** to the patient monitor receptacle **1340**. The interface circuit components (including DAC, comparators, amplifiers, resistors, capacitors, etc.) are disposed on a small form factor substrate **1386** such as a printed circuit board. Miniature circuit boards are well known in the microelectronic/surface mount electronics arts, and accordingly are not described further herein. The interface circuit **800, 900, 1100** is then electrically disposed in the circuit path between the NIBPM digital data output and patient monitor receptacle **1340**, such that (i) the digital data produced by the NIPBM is provided to the input terminals of, e.g., the DAC **830** (see Fig. 8), and the ground, excitation ( $E_d$ ), and reference potentials necessary to operate the interface circuit are provided to the appropriate points in the circuit **800, 900, 1100**. The substrate **1386** with components is physically contained in an over-molding **1390** which encapsulates the assembly in a polymer/elastomeric material, thereby increasing its durability and resistance to external effects such as temperature variation, moisture, dust, electromagnetic noise, and physical trauma. The assembly is also optionally electromagnetically shielded using, for example, a grounded tin-copper alloy metallic shield element of the type well known in the art, such shield being disposed within the over-molding **1390**.

In yet another embodiment, shown as Fig. 14 herein, the apparatus of Fig. 13 (and patient monitor) may be configured to include a wireless link **1402** between the apparatus **1400** and the patient monitor **1342**, such that the interface circuitry **800, 900, 1100** is disposed proximate to the patient monitor **1342**. As illustrated in Fig. 14, the link **1402** comprises a radio frequency (RF) communications system of the type well known in the electrical arts. For example, in one exemplary variant, an RF transceiver **1410** and modulator device **1412** are provided and adapted to generally comply with the well known "Bluetooth™" wireless interface standard. The Bluetooth "3G" wireless technology allows users to make wireless and instant connections between various communication devices, such as mobile devices (e.g., cellular telephones, PDAs, notebook computers, local or remote patient monitoring stations, and the like) and desktop computers or other fixed devices. Since Bluetooth uses radio

frequency transmission, transfer of data is in real-time. The Bluetooth topology supports both point-to-point and point-to-multipoint connections. Multiple 'slave' devices can be set to communicate with a 'master' device. In this fashion, the NIBPM device **1406** of the present invention, when outfitted with a Bluetooth wireless suite, may communicate directly with other Bluetooth compliant mobile or fixed devices including the patient monitor receiver **1427** disposed at the monitor **1342**, or alternatively other Bluetooth-capable devices such as a cellular telephone, PDA, notebook computer, or desktop computer.

The monitor receiver **1427** comprises a Bluetooth compatible transceiver **1429** adapted to receive binary digital data in the form of radiated RF energy from the corresponding transceiver **1410** on the NIBPM device, and decode the binary data for input to the DAC **830** of the interface circuitry **800, 900, 1100**. Hence, the operation of the wireless link **1402** is effectively transparent to the interface circuit and patient monitor **1342**.

The monitor receiver unit **1427** is configured physically to mate with the patient monitor receptacle **1340** (either directly or via an interposed adapter **1324**, as previously described), such that the unit **1427** may be simply "plugged in" to the receptacle **1440** and remain free-standing. The Bluetooth transceiver **1429** of the unit **1427** and components of the interface circuit **800, 900, 1100** (as well as other attendant electronic components) are readily contained within the rectangular form factor (Fig. 14a) of the receiver **1427**, although it will be appreciated that other forms may be utilized (such as a cylinder, sphere, square, etc.). Additionally, it will be recognized that for purposes of saving space within the apparatus **1400**, the signal processing and transceiver/modulator components of the NIBPM device **1400** may be embodied in a fully integrated "system on a chip" (SoC) application specific integrated circuit (ASIC) of the type generally known in the semiconductor fabrication arts (not shown). The SoC ASIC incorporates, *inter alia*, a digital signal processor (DSP) core, embedded program and data random access memories, RF transceiver circuitry, modulator, analog-to-digital converter (ADC), and analog interface circuitry necessary to support sampling, conversion, processing, and transmission of the blood pressure (or other) data to the receiver **1427**. The SoC device design is generated using VHSIC Hardware Description language (VHDL) in conjunction with design and synthesis tools of the type well known in the art. A 0.18 micron MOS-based process is used to fabricate the device of the illustrated embodiment, although other semiconductor fabrications processes including for example 0.35 micron or 0.1



micron may be substituted, depending on the degree of integration required.

Alternatively, a number of different subjects undergoing blood pressure monitoring/analysis using the NIBPM of the present invention (or other comparable devices) may be monitored in real time at a centralized location using a single monitor receiver **1427**.  
5 Specifically, the monitor receiver **1427** and transceiver **1429** are adapted to receive a plurality (currently seven, under prevailing Bluetooth architecture, although such number may be increased or decreased) of signals from remote devices (e.g., NIBPMs), whereby the individual signals may be multiplexed or alternatively processed in parallel by the interface circuit **800**,  
**900**, **1100** (with the addition of appropriate multiplexing or parallel processing hardware of the  
10 type well known in the electronic arts). Hence, a patient monitor **1342** configured to receive such multiplexed or parallel channel data may be used to monitor multiple subjects at once.

Bluetooth-compliant devices, *inter alia*, operate in the 2.4 GHz ISM band. The ISM band is dedicated to unlicensed users, including medical facilities, thereby advantageously allowing for unrestricted spectral access. Maximum radiated power levels from the transceiver  
15 **1410** of Fig. 14 are in the mW range, thereby having no deleterious effect on the physiology of the subject due to radiated electromagnetic energy. As is well known in the wireless telecommunications art, radiated power from the antenna assembly (not shown) of the transceiver **1410** may also be controlled and adjusted based on relative proximity of the transceiver **1410**, thereby further reducing electromagnetic whole body dose to the subject.

20 The modulator **1412** of the illustrated embodiment uses one or more variants of frequency shift keying, such as Gaussian Frequency Shift Keying (GFSK) or Gaussian Minimum Shift keying (GMSK) of the type well known in the art to modulate data onto the carrier(s), although other types of modulation (such as phase modulation or amplitude modulation) may be used.

25 Spectral access of the device may be accomplished via frequency divided multiple access (FDMA), frequency hopping spread spectrum (FHSS), direct sequence spread spectrum (DSSS, including code division multiple access) using a pseudo-noise spreading code, or even time division multiple access, depending on the needs of the user. For example, devices complying with IEEE Std. 802.11 may be substituted in the probe for the Bluetooth  
30 transceiver/modulator arrangement previously described if desired. Literally any wireless interface capable of accommodating the bandwidth requirements of the system may be used.

As yet another embodiment, an infrared device (e.g., Infrared Data Association "IrDA") may be substituted or even used in conjunction with the aforementioned RF link **1402**.

#### *Method of Providing Treatment*

5 Referring now to Fig. 15, a method of providing treatment to a subject using the aforementioned hemodynamic assessment and interface circuit apparatus is described in detail. It will be recognized that while the following method of treatment is cast in terms of arterial blood pressure monitoring for a living subject, parameters other than blood pressure may be monitored using the methods of the invention, and other courses of therapy or treatment  
10 provided.

As illustrated in Fig. 15, the first step **1502** of the method **1500** comprises obtaining data from the subject using a sensing device such as the NIPBM described previously herein. The data obtained from the subject comprises hemodynamic data (e.g., pressure, velocity, kinetic energy) obtained from the subject, such as from the radial artery. A digital domain  
15 signal is next generated in step **1504** based at least in part on the data obtained in step **1502**; blood pressure signal generation is described explicitly in the aforementioned co-pending U.S. Patent Applications previously incorporated herein. Next, in step **1506**, the digital domain signal is conditioned using the interface circuit **800, 900, 1100** to produce an analog signal. As previously described herein, the interface circuitry, *inter alia*, applies a transfer function to the  
20 data after conversion from the digital domain to the analog domain, so as to substantially replicate the output which would be provided by a desired "target" device, in this case a passive resistor bridge circuit of the type well known in the art.

The conditioned analog signal is then provided to the patient monitoring device in step **1508**, the latter producing a representation of the desired parameter in real time. Such  
25 representation may comprise, for example, calibrated displays the systolic, diastolic, and mean pressure waveforms obtained from the subject, or alternatively other representations such as digital values of the systolic, diastolic, and mean pressures. Lastly, in step **1510**, treatment is provided to the living subject based on the parametric representation of step **1508**. The caregiver may prescribe a course of treatment based on the displayed representation, such as  
30 the administration pharmaceuticals, or additional monitoring. Alternatively, such calibrated measurements may be collected over an extended period of time and analyzed for long term

trends in the condition or response of the circulatory system of the subject. As yet another alternative, the treatment may be automatically provided based on the signals output to the patient monitor (or derivations thereof), for example such as sounding an alarm to draw attention to the rapidly falling mean blood pressure level of the patient, or adjusting parameters associated with the NIBPM or other monitoring devices being used on the subject.

5 It will be appreciated that while certain aspects of the invention have been described in terms of a specific sequence of steps of a method, these descriptions are only illustrative of the broader methods of the invention, and may be modified as required by the particular application. Certain steps may be rendered unnecessary or optional under certain  
10 circumstances. Additionally, certain steps or functionality may be added to the disclosed embodiments, or the order of performance of two or more steps permuted. All such variations are considered to be encompassed within the invention disclosed and claimed herein.

While the above detailed description has shown, described, and pointed out novel features of the invention as applied to various embodiments, it will be understood that various  
15 omissions, substitutions, and changes in the form and details of the device or process illustrated may be made by those skilled in the art without departing from the invention. The foregoing description is of the best mode presently contemplated of carrying out the invention. This description is in no way meant to be limiting, but rather should be taken as illustrative of the general principles of the invention. The scope of the invention should be determined with  
20 reference to the claims.

WHAT IS CLAIMED IS:

1. A circuit adapted to simulate one or more waveforms, comprising:  
5 a digital-to-analog converter (DAC) receiving digital inputs from at least one sensing apparatus adapted to generate at least one time variant waveform, and producing an analog output signal related at least in part to said digital inputs; and  
at least one amplifier operatively coupled to the output of said DAC,  
wherein said at least one amplifier operates so as to satisfy a predetermined  
10 relationship between its output voltage and an applied excitation voltage.
2. The circuit of Claim 1, wherein said DAC comprises a multiplying DAC, and said floating current source is bipolar.
3. The circuit of Claim 1, wherein said circuit is operatively coupled to a monitoring device, and said analog output signal is further related at least in part to said  
15 excitation voltage generated by said monitor device.
4. The circuit of Claim 1, wherein said circuit is adapted to interface with one or more of a plurality of different monitoring devices irrespective of the excitation generated by such monitoring device(s).
5. The circuit of Claim 4, wherein said circuit is adapted to simulate waveforms  
20 having a frequency ranging from 0 Hz (DC) to 200 Hz.
6. The circuit of Claim 4, wherein said at least one sensing apparatus comprises an NIBPM, and said circuit is adapted to simulate the output waveform produced by a passive bridge transducer when said passive bridge transducer is applied to measure the blood pressure of a living subject.
- 25 7. The circuit of Claim 1, further comprising first and second resistors disposed relative to the output of said DAC and said at least one amplifier, the ratio of the resistance values of said first and second resistors determining the scale factor for said circuit.
8. The circuit of Claim 3, further comprising at least one filter element disposed in said circuit and adapted to filter signals transferred between said monitoring device and said  
30 circuit.
9. The circuit of Claim 8, wherein said at least one filter element comprises a choke coil.

10. The circuit of Claim 3, further comprising an over-voltage protection element disposed in said circuit and adapted to mitigate voltage transients generated by said monitoring device.

5 11. The circuit of Claim 1, further comprising a test circuit operatively coupled to said circuit adapted to simulate, said test circuit being configured to test the functionality of at least a portion of said circuit adapted to simulate.

12. The circuit of Claim 11, wherein said test circuit is adapted to test the functionality during normal operation of said circuit adapted to simulate.

10 13. The circuit of Claim 7, wherein at least one of said first and second resistors is adjustable, thereby rendering said scale factor adjustable.

14. The circuit of Claim 1, wherein said at least one amplifier is connected in a feedback loop with said DAC to form a floating current source.

15 15. A method for simulating a time-variant output signal from a first device using a second device, comprising:

15 providing a first device having at least one transfer function associated therewith;

providing said second device, said second device being adapted to sense at least one time-variant parameter and provide a representation based at least in part thereon;

providing an excitation voltage to said second device;

20 generating a representation of said time-variant parameter using said second device;

applying a transfer function to said representation, said transfer function being substantially similar to that for said first device; and

25 generating at least one output signal based at least in part on said representation and said transfer function, said at least one output signal being substantially similar to that produced by said first device.

16. The method of Claim 15, wherein the act of sensing at least one time-variant parameter comprises sensing a pressure waveform from the blood vessel of a living subject.

30 17. The method of Claim 16, wherein the act of sensing is performed non-invasively.

18. The method of Claim 16, wherein said first device comprises a passive bridge

element, and the act of generating a representation comprises generating a binary digital representation.

19. The method of Claim 18, wherein the act of applying a transfer function comprises:

5 receiving said binary digital representation at a digital-to-analog converter (DAC);

converting said binary digital representation to an analog representation;

10 amplifying said analog representation to produce an amplified signal, said amplified signal being provided to said DAC in a feedback loop and forming a floating current source; and

producing a predetermined relationship between said amplified signal and an excitation signal applied to said second device.

20. The method of Claim 15, further comprising detecting the electrical connection between said second device and an externally applied excitation signal by detecting the presence of a specified impedance value.

21. The method of Claim 15, further comprising detecting the electrical connection between said second device and an externally applied excitation signal by detecting the presence of a voltage at a predetermined terminal of the device supplying said excitation signal.

20 22. A method of determining the status of electrical connection between a monitoring device and a sensing device, wherein said monitoring device provides an excitation signal to said sensing device during operation, comprising:

detecting the presence of the excitation signal provided by said monitoring device;

25 buffering said excitation signal to produce a buffered excitation signal; and analyzing said buffered excitation signal to identify variations therein indicative of said status of electrical connection.

23. The method of Claim 22, wherein the act of analyzing comprises applying at least one transfer function to said buffered excitation signal.

30 24. The method of Claim 23, wherein the act of applying comprises applying a window comparator transfer function.

25. The method of Claim 22, wherein the act of analyzing comprises specifying a time constant adapted to compensate for zero-crossing waveforms or other short-duration voltage transients.

26. Apparatus, comprising:

5 sensing apparatus adapted to sense at least one waveform, and generate a binary digital representation related thereto; and

an interface circuit operatively coupled to said sensing apparatus, said interface circuit being adapted to applying a transfer function to said digital representation, and generate at least one output signal, said at least one output signal based at least in part on said binary digital representation and said transfer function, said at least one output  
10 signal being substantially similar to that produced by a passive bridge device.

27. The apparatus of Claim 26, wherein said sensing device comprises a non-invasive blood pressure monitor.

28. The apparatus of Claim 27, wherein said binary digital representation comprises  
15 data representative of blood pressure obtained from the blood vessel of a living subject.

29. The apparatus of Claim 28, wherein said binary digital representation is derived at least in part by calculating time frequency distributions for said at least one waveform.

30. The apparatus of Claim 28, wherein said binary digital representation is derived  
by:

- 20 (i) measuring a first parameter from said blood vessel;
- (ii) compressing said blood vessel;
- (iii) measuring a second parameter from said blood vessel during said act of compressing;
- (iv) deriving a calibration function based at least in part on said second  
25 parameter; and
- (v) calibrating the first parameter using said calibration function.

31. The apparatus of Claim 30, wherein said first parameter comprises pressure within said blood vessel, and said second parameter comprises blood flow kinetic energy.

32. The apparatus of Claim 26, further comprising a wireless communications  
30 interface, said wireless interface being adapted for the communication of data between said sensing apparatus and said interface circuit.

33. The apparatus of Claim 26, further comprising a wireless communications interface, said wireless interface being adapted for the communication of data between said apparatus and a monitoring device.

34. The apparatus of Claim 32, wherein said wireless interface utilizes radio  
5 frequency energy to communicate said data.

35. The apparatus of Claim 34, wherein said radio frequency energy is disposed substantially within the ISM band.

36. The apparatus of Claim 34, wherein said wireless interface comprises a spread spectrum device.

10 37. Apparatus for monitoring a time-variant waveform, comprising:  
a non-invasive blood pressure sensing device, said device being configured to produce at least a binary digital representation related to said time variant waveform;  
interface circuitry in data communication with said sensing device, said  
interface circuitry being adapted to condition said at least binary digital representation  
15 according to at least one transfer function, and produce an analog representation thereof;

a monitoring device, in communication with at least said interface circuitry, adapted to utilize said analog signal for the monitoring of said waveform.

20 38. The apparatus of Claim 37, wherein said sensing device is adapted to sense at least one blood pressure waveform, and said monitor is adapted to either analyze or display information representative of said blood pressure waveform.

39. The apparatus of Claim 37, wherein said at least one transfer function substantially replicates that of a passive bridge transducer.

25 40. The apparatus of Claim 38, wherein said at least one transfer function substantially replicates that of a passive bridge transducer.



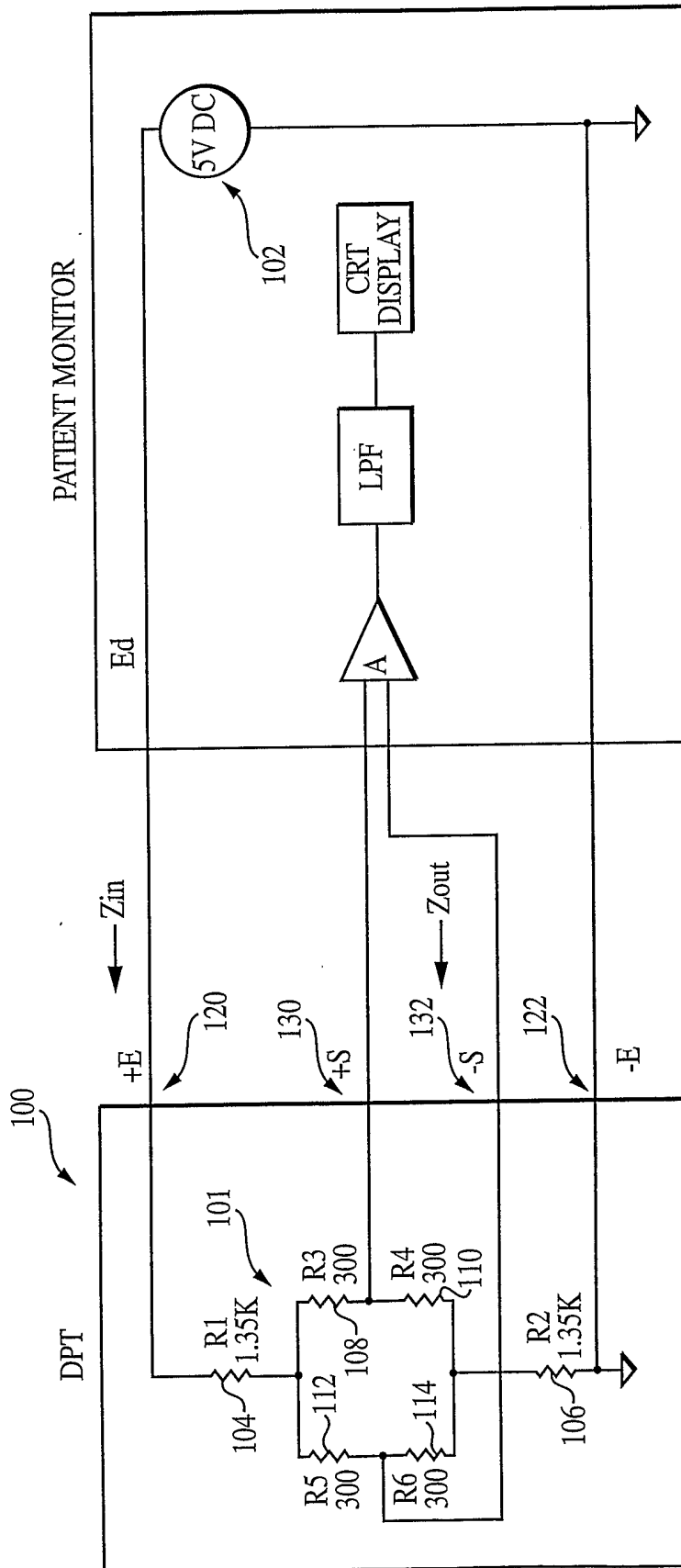


FIG. 1

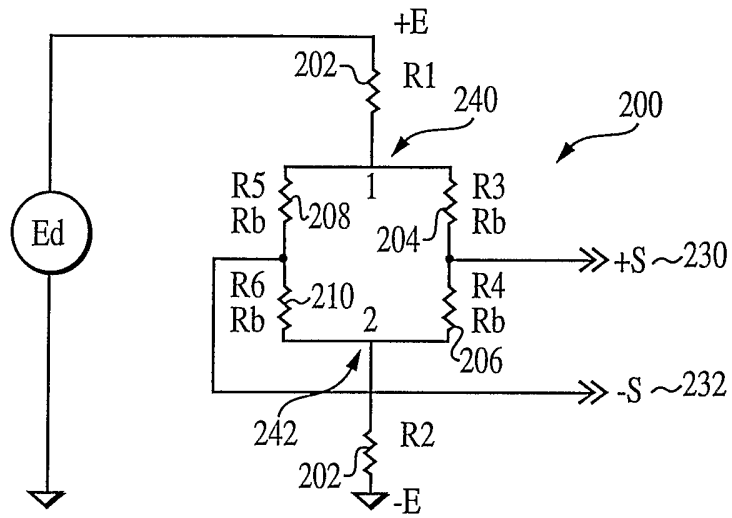


FIG. 2

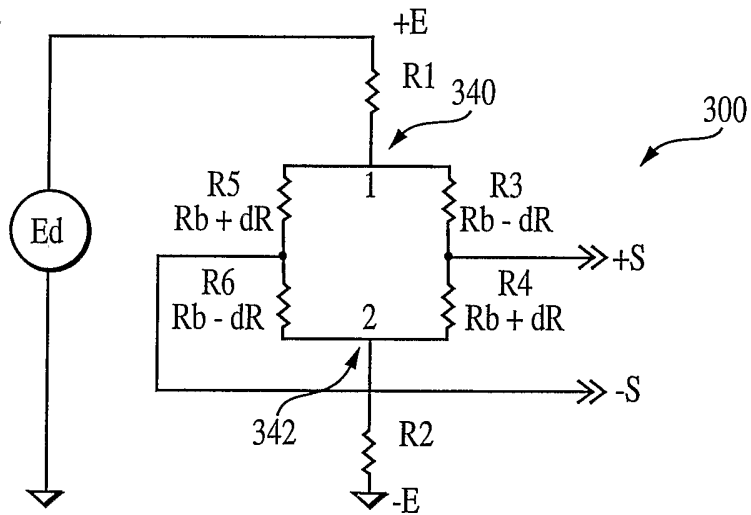


FIG. 3

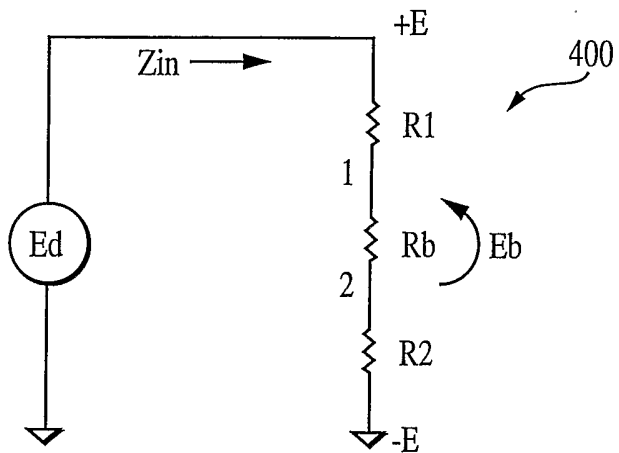


FIG. 4

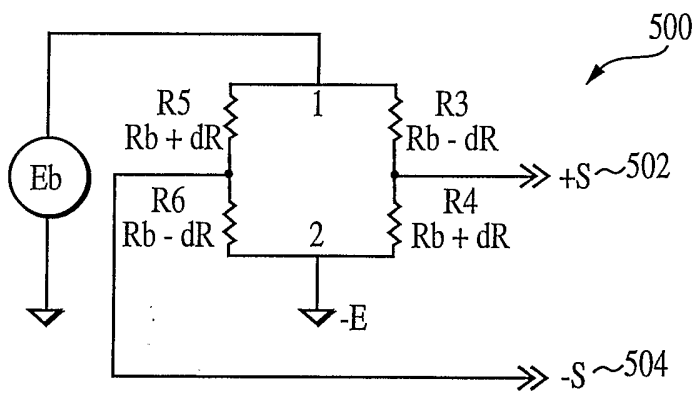


FIG. 5

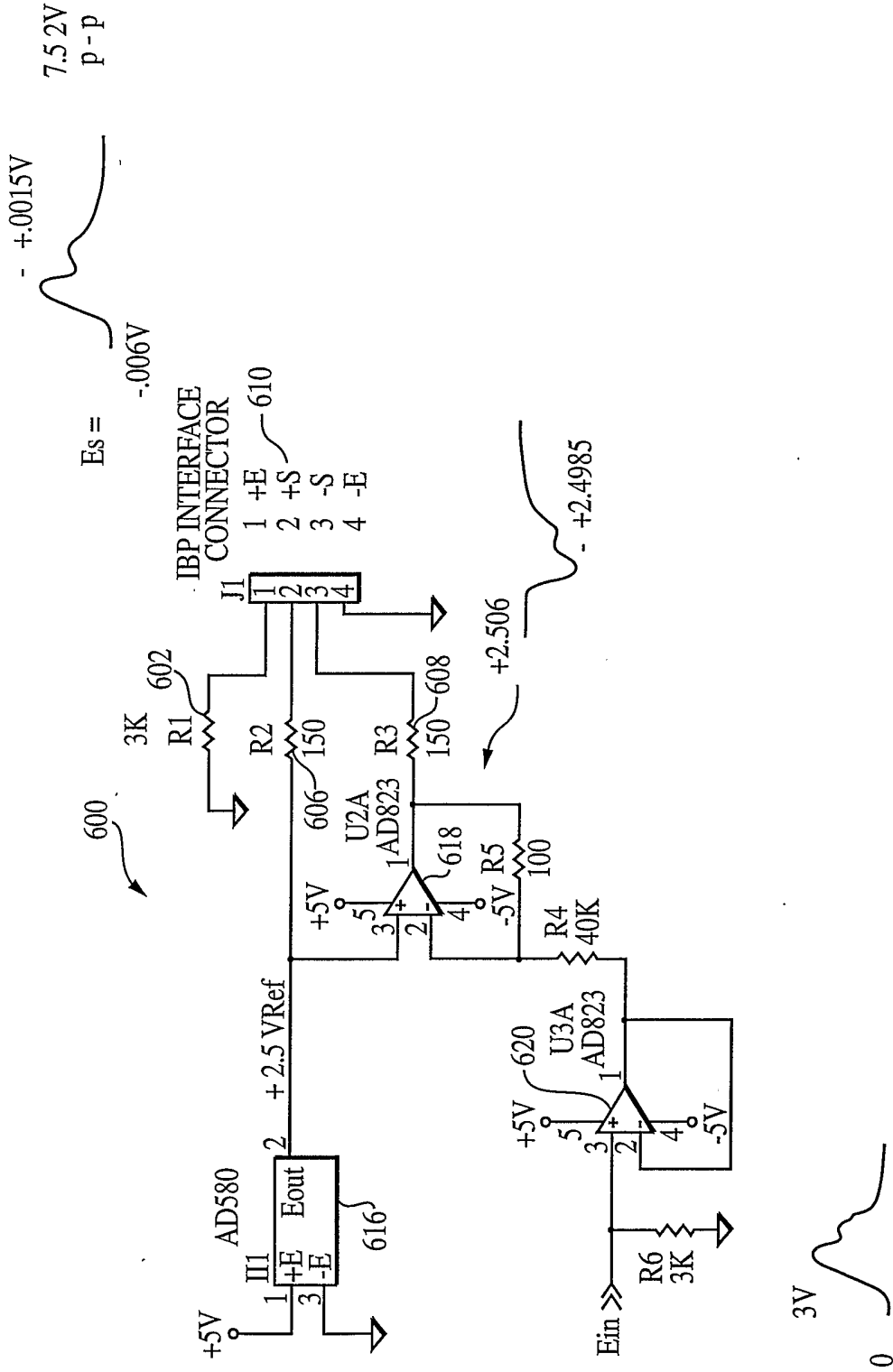
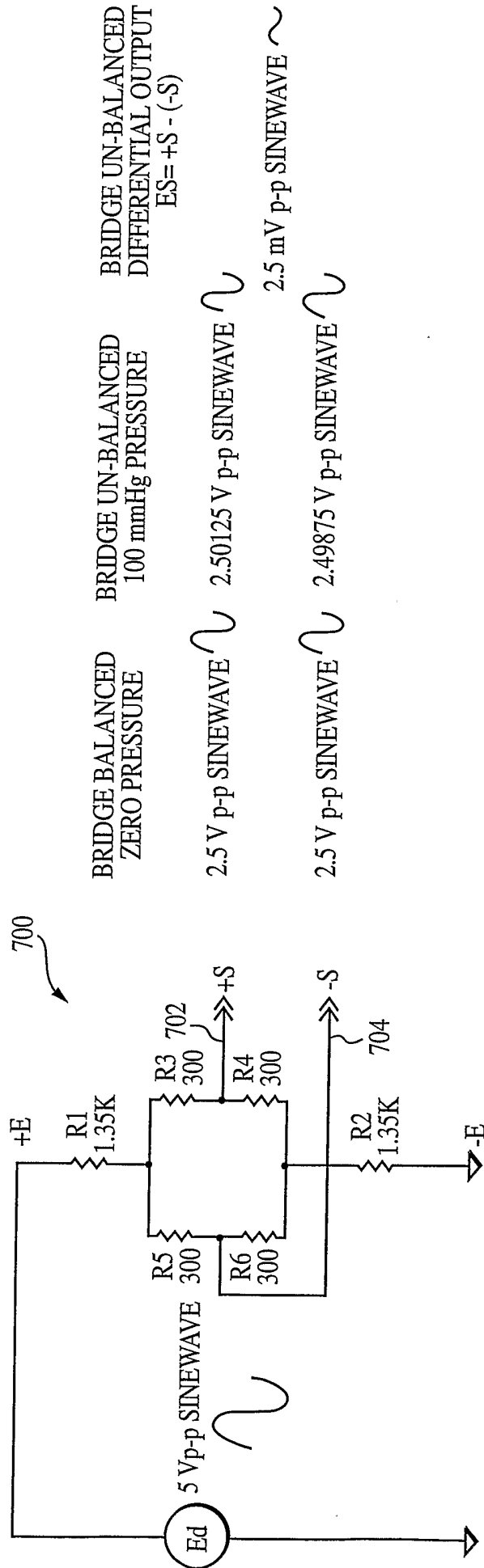


FIG. 6

0 → 300 mmHg  
Bp SIGNAL



BRIDGE BALANCED  
ZERO PRESSURE

BRIDGE UN-BALANCED  
100 mmHg PRESSURE

BRIDGE UN-BALANCED  
DIFFERENTIAL OUTPUT  
ES= +S - (-S)

2.5 V p-p SINEWAVE

2.50125 V p-p SINEWAVE

2.5 mV p-p SINEWAVE

2.5 V p-p SINEWAVE

2.49875 V p-p SINEWAVE

FIG. 7

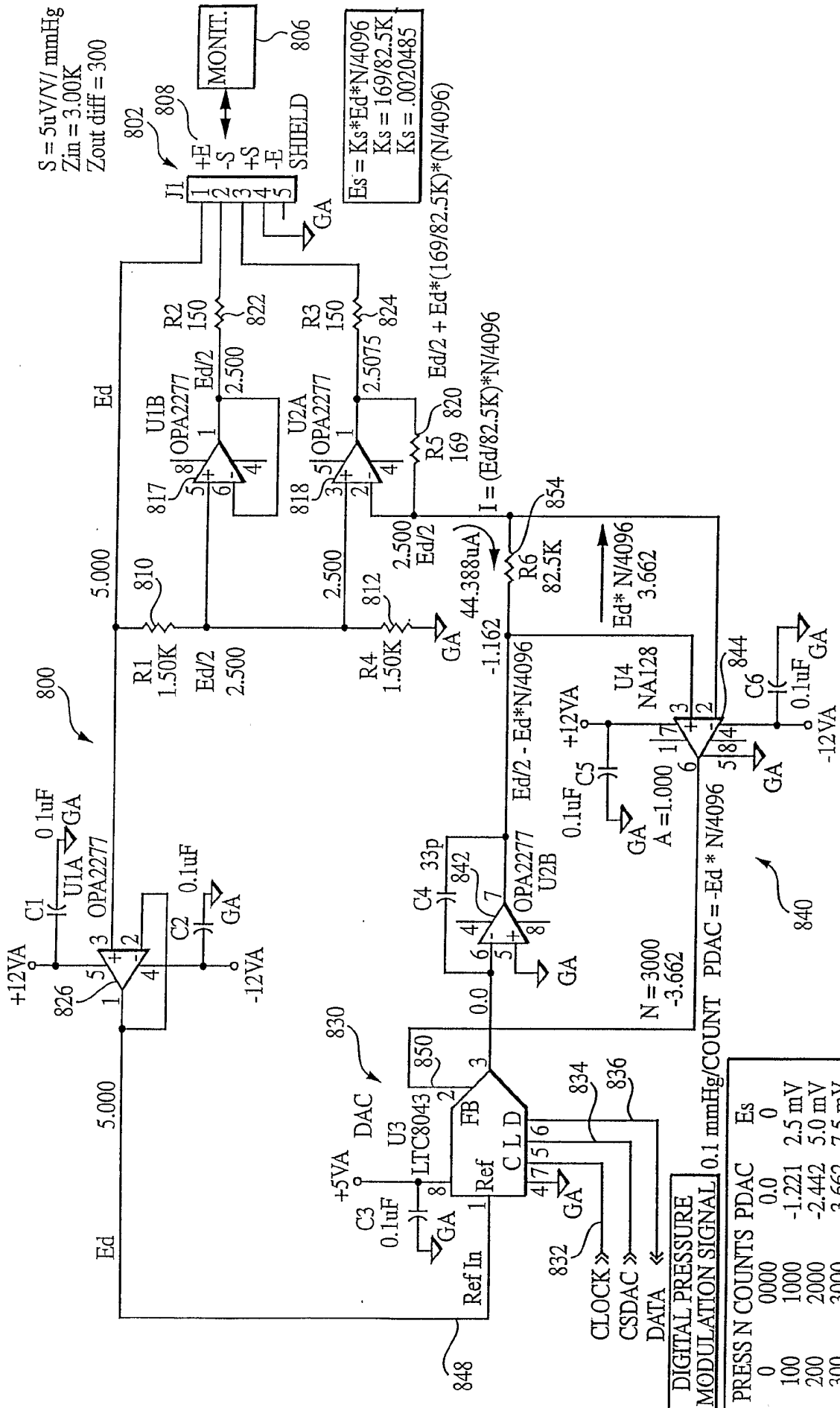


FIG. 8

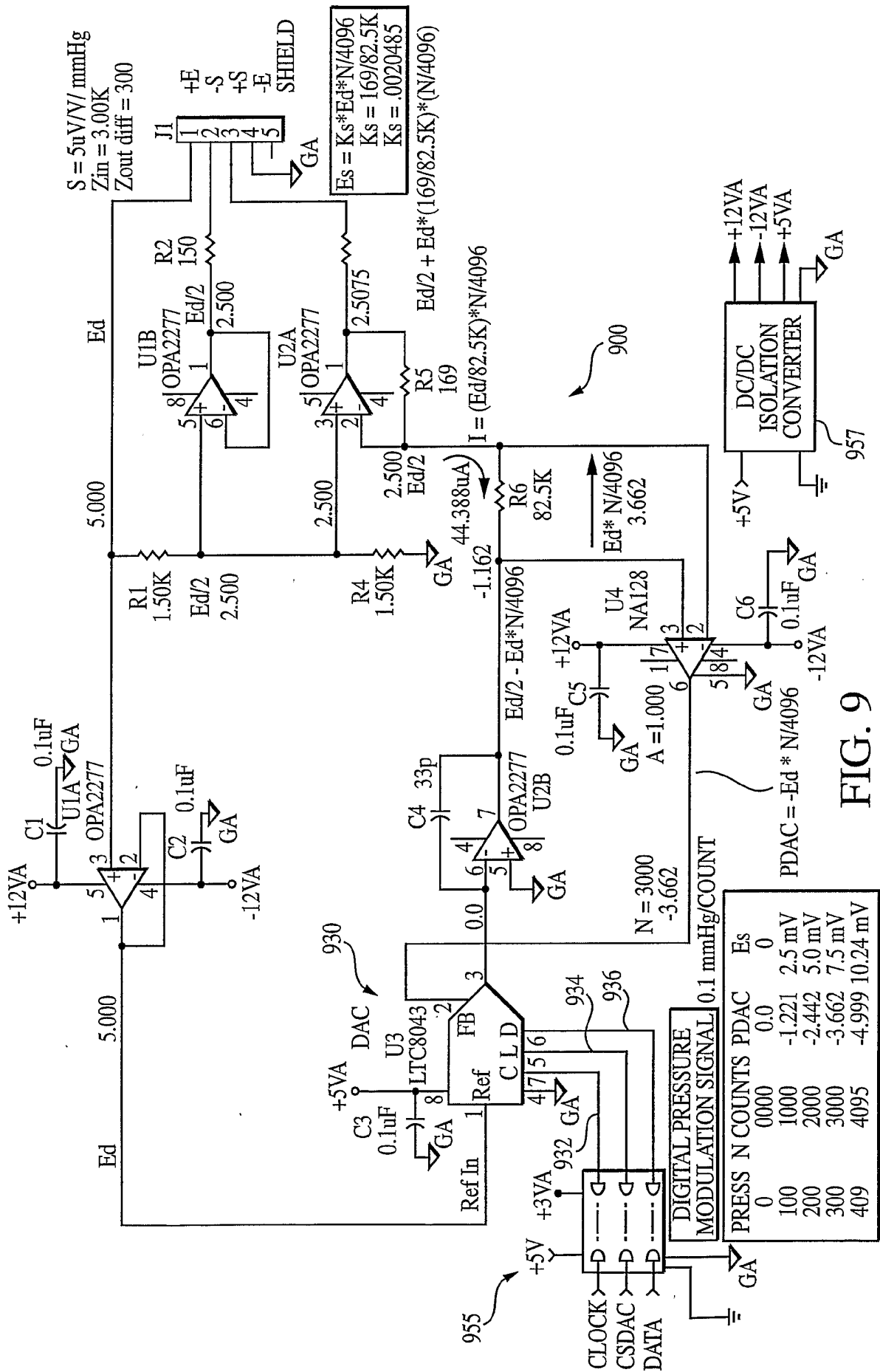


FIG. 9

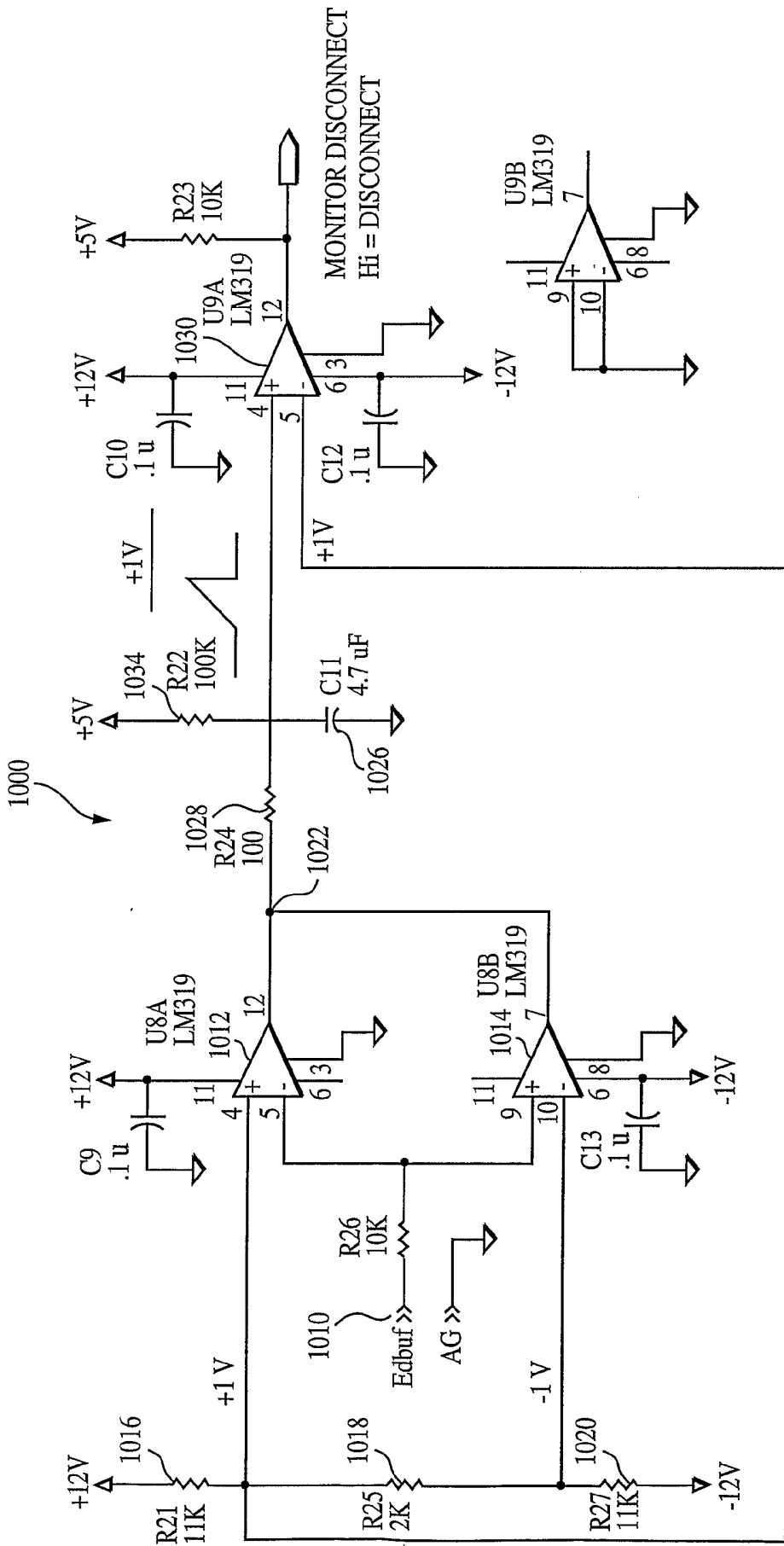


FIG. 10

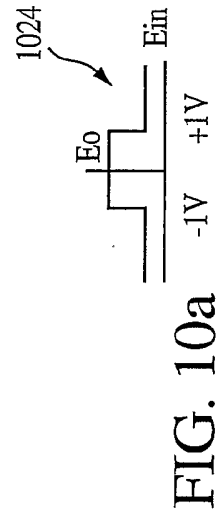


FIG. 10a



FIG. 11  
(PART 1 OF 4)

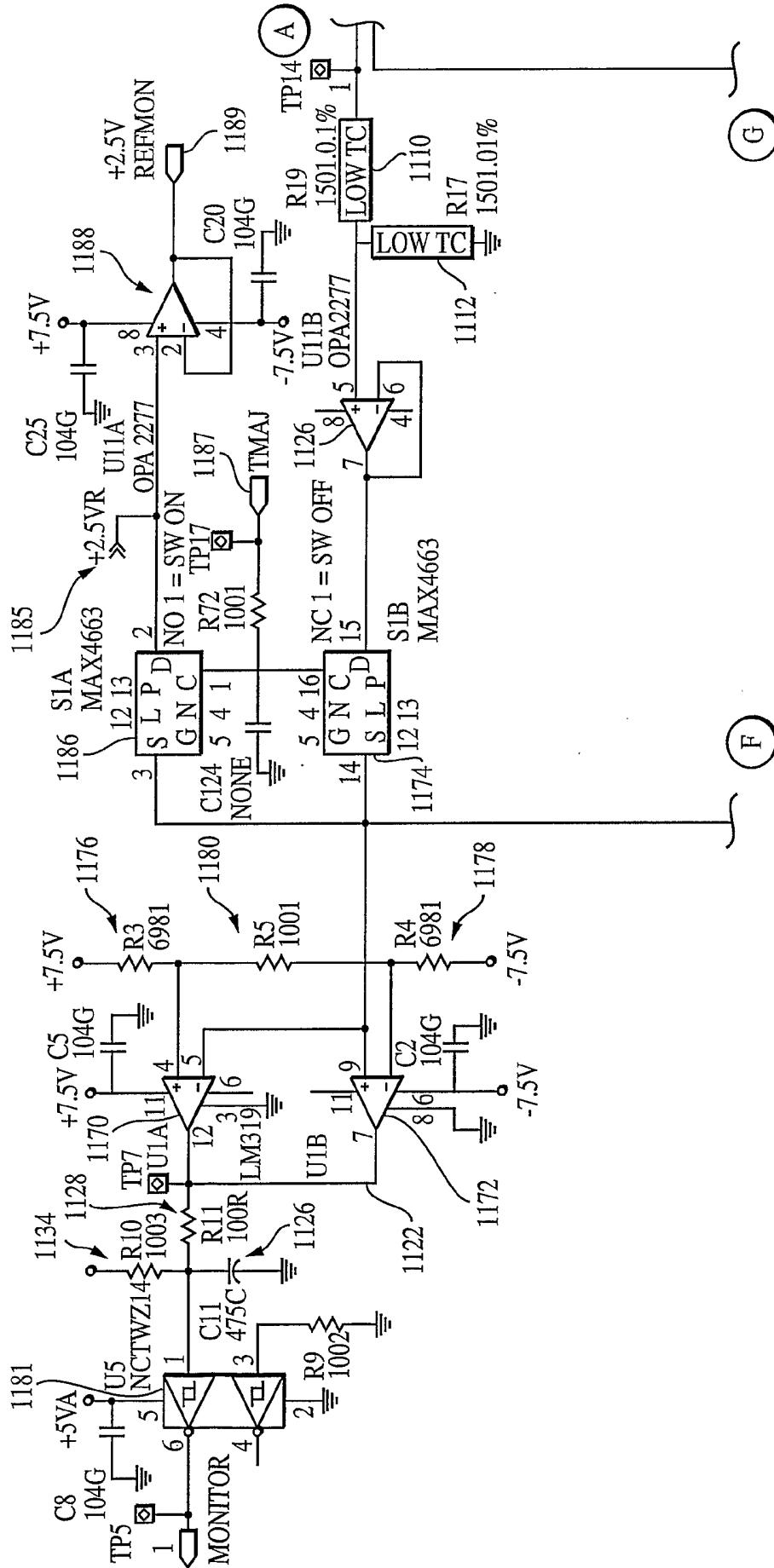
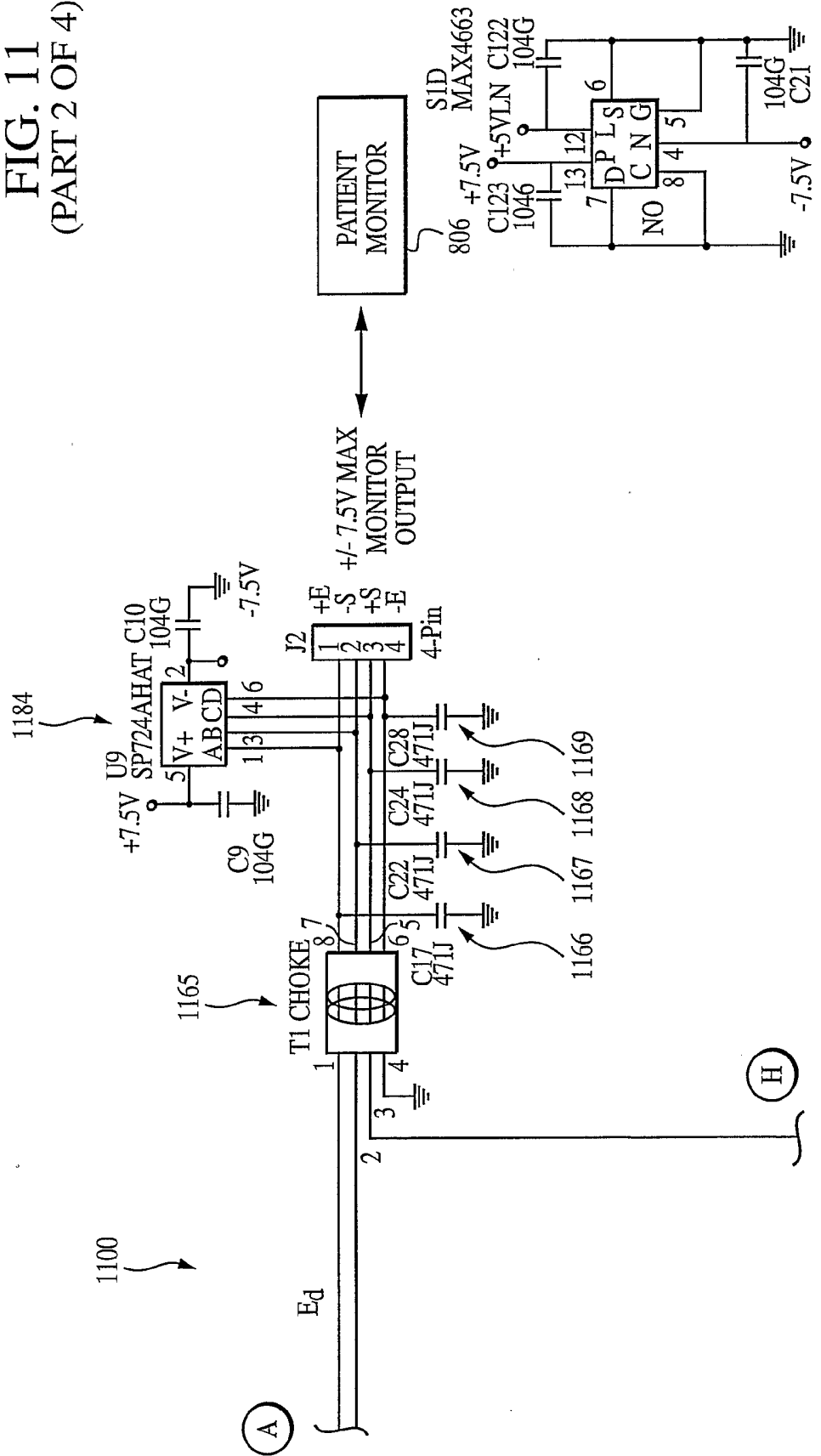


FIG. 11  
(PART 2 OF 4)



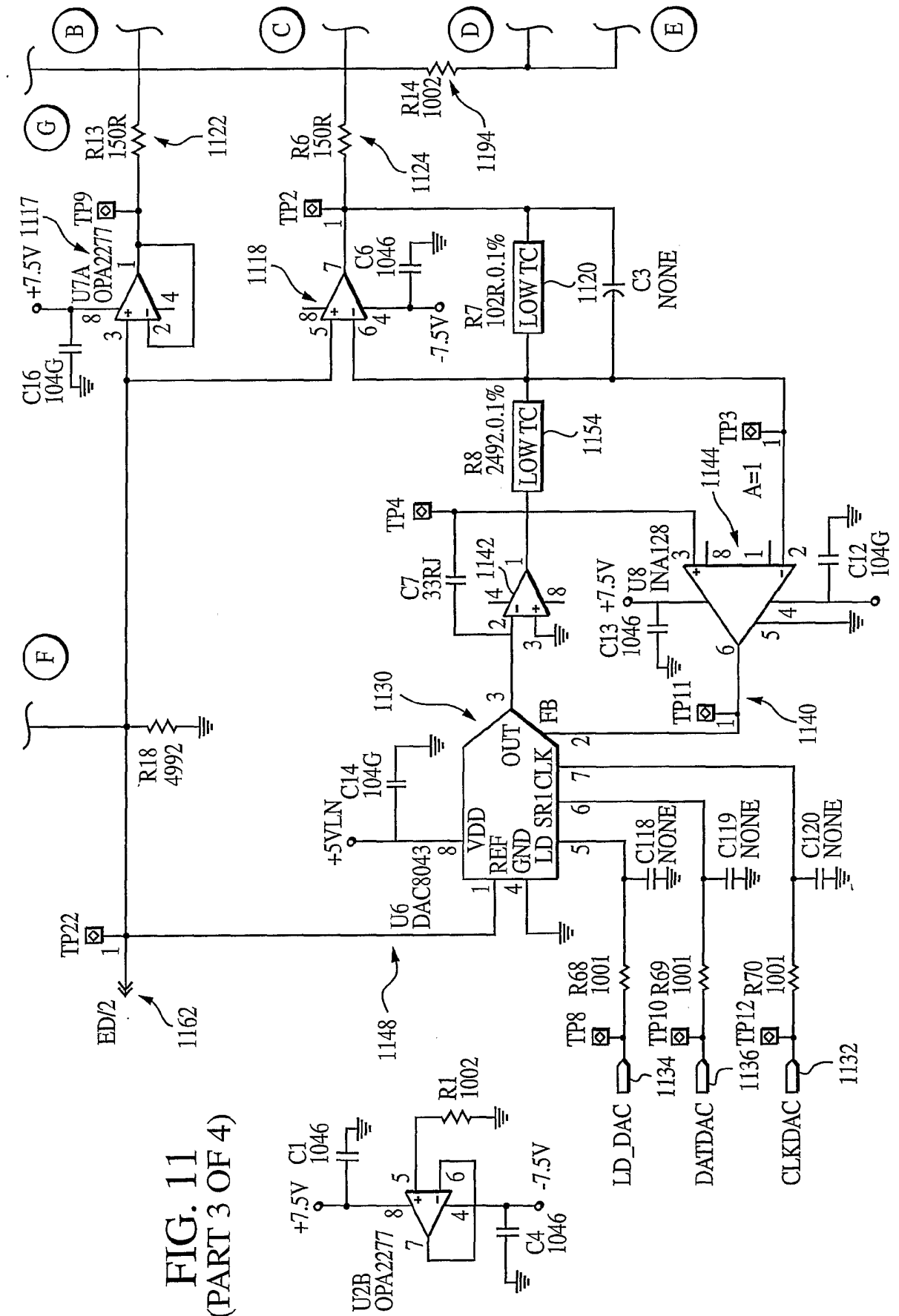


FIG. 11  
(PART 3 OF 4)

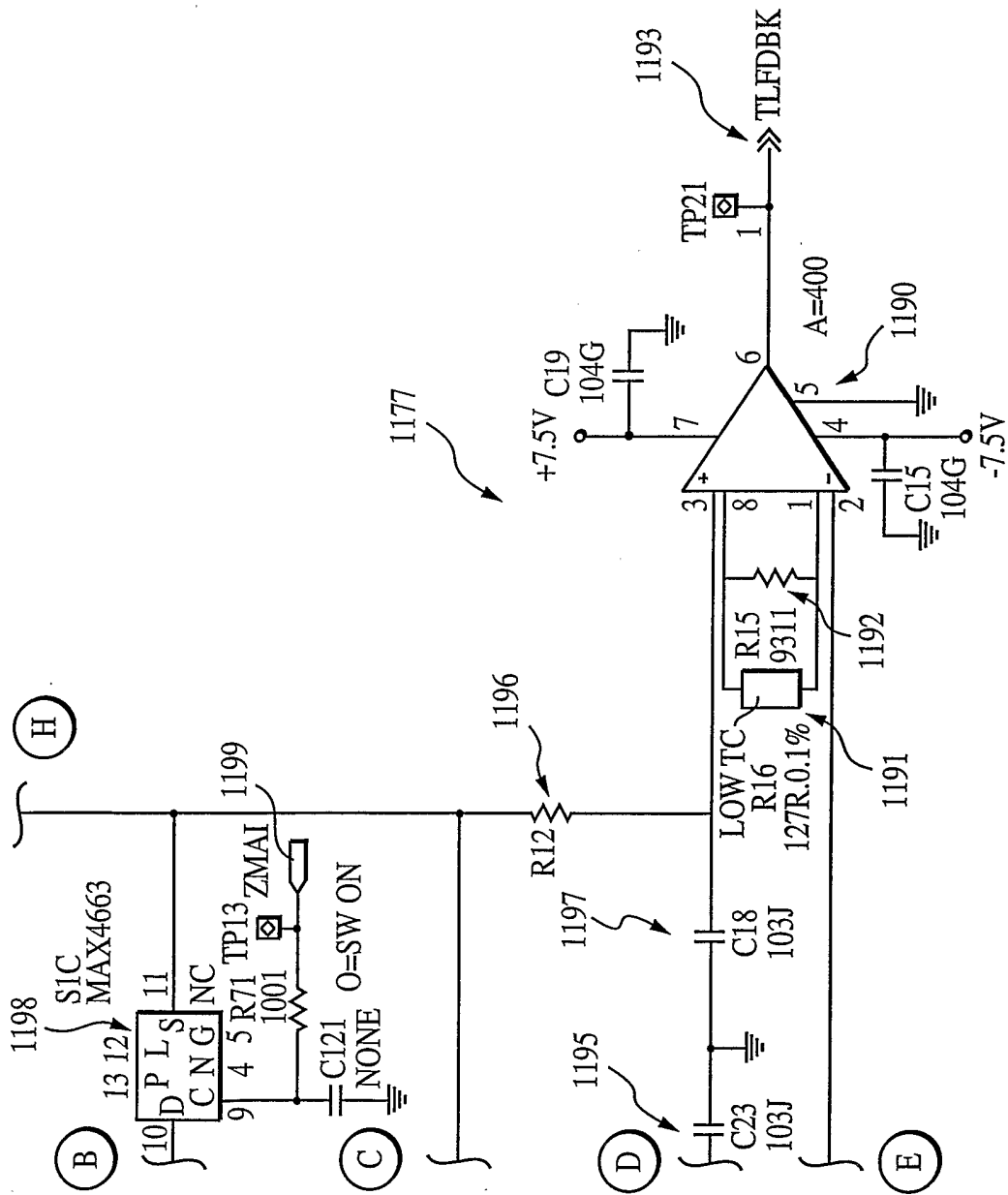


FIG. 11  
(PART 4 OF 4)

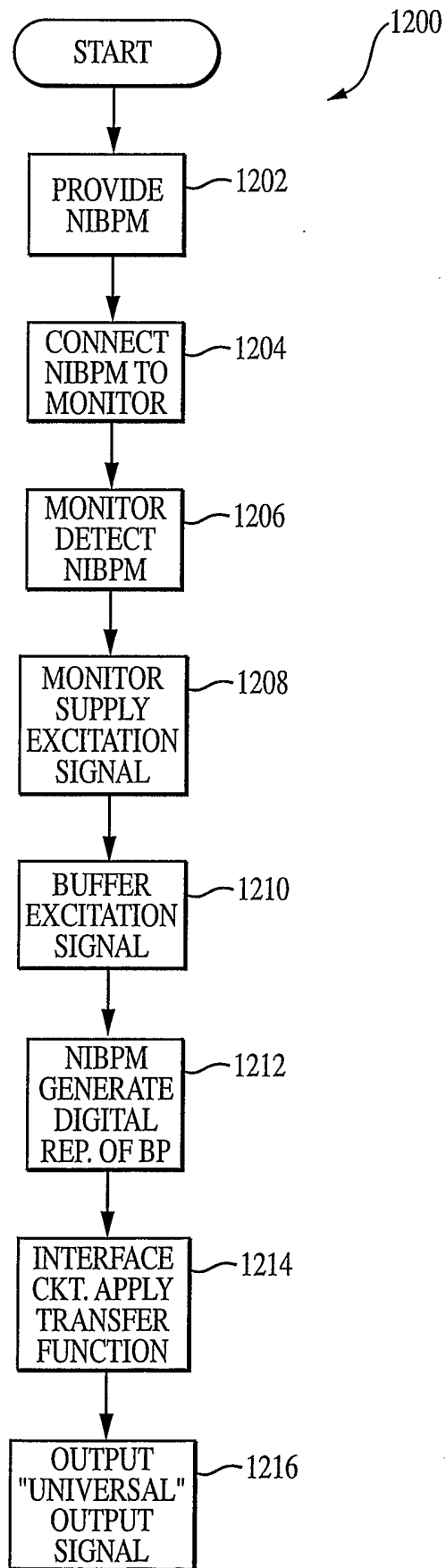


FIG. 12

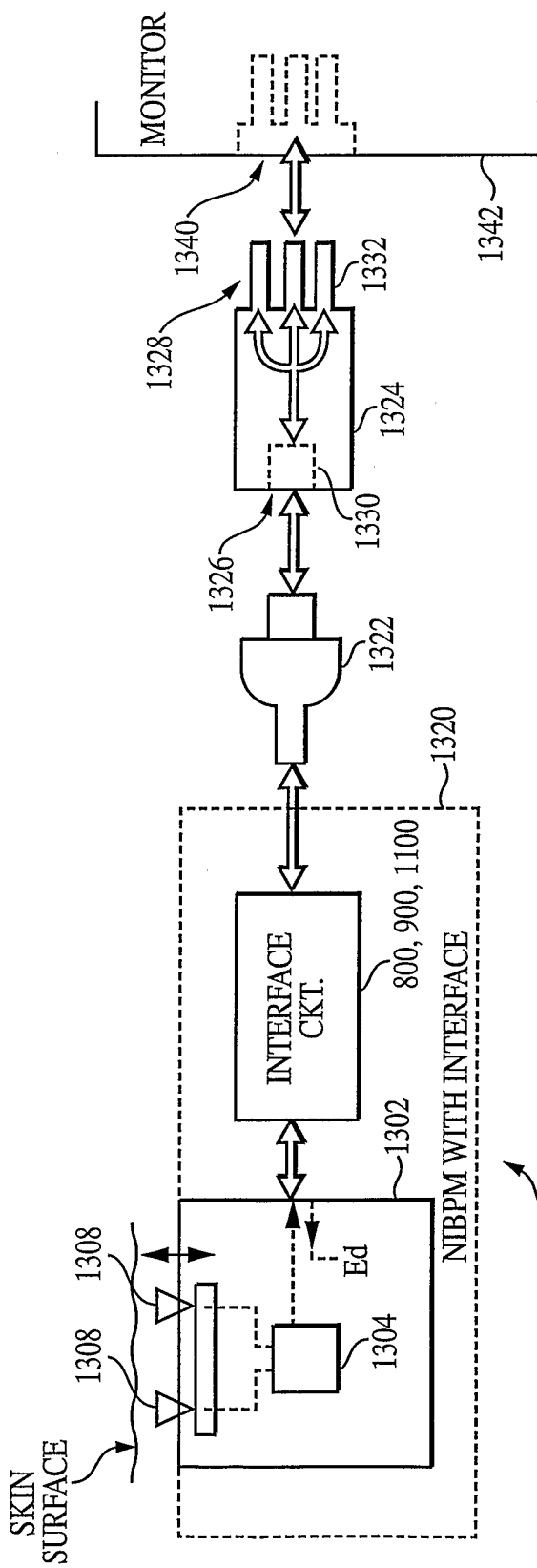


FIG. 13

1300

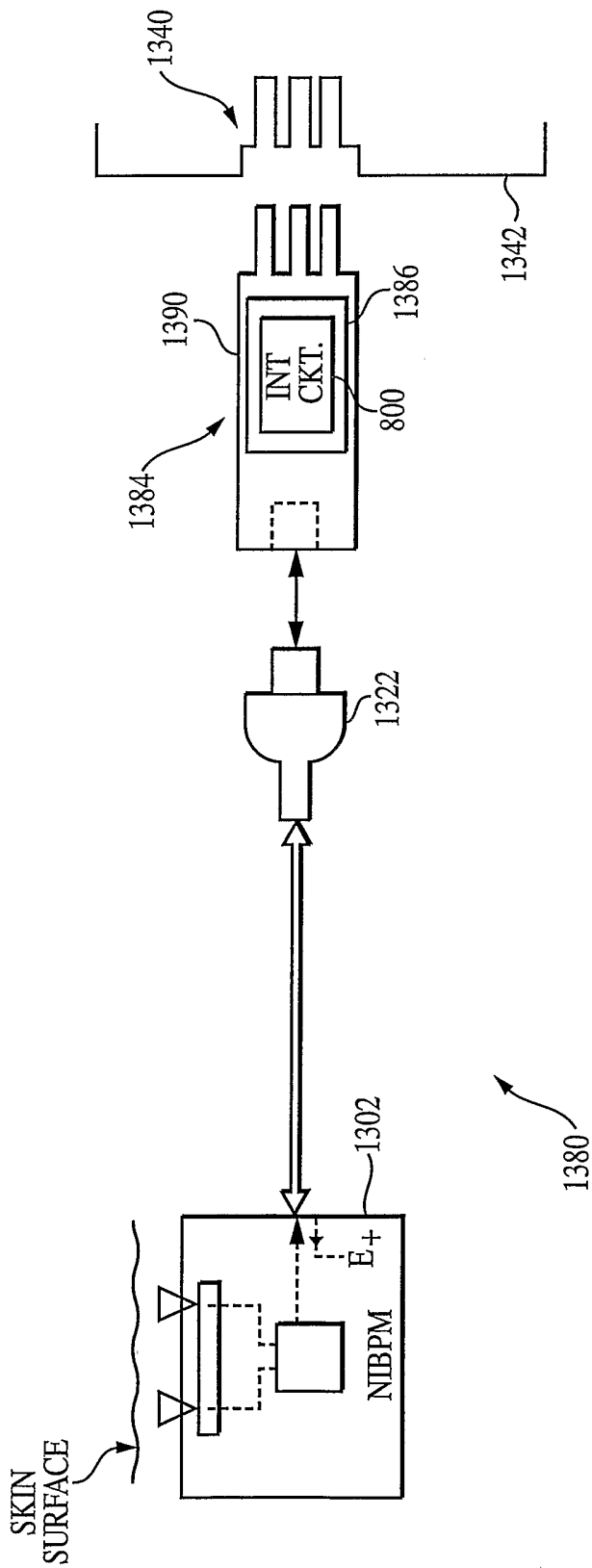


FIG. 13a

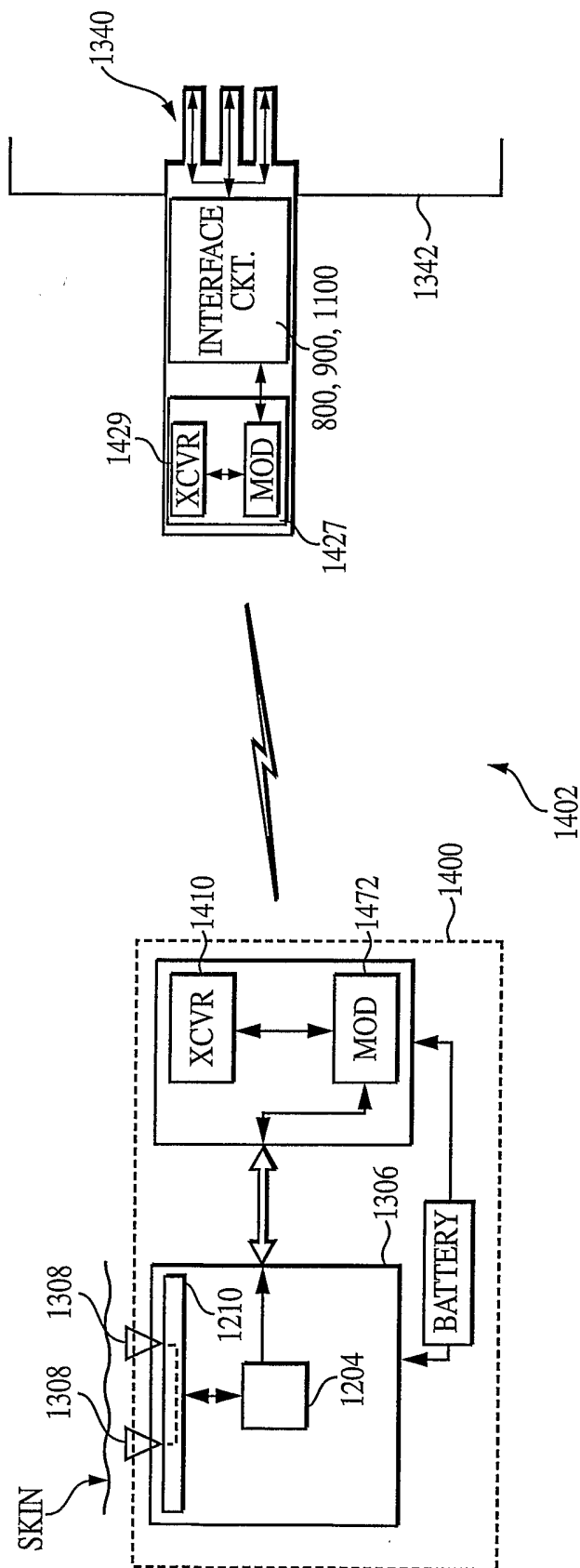


FIG. 14



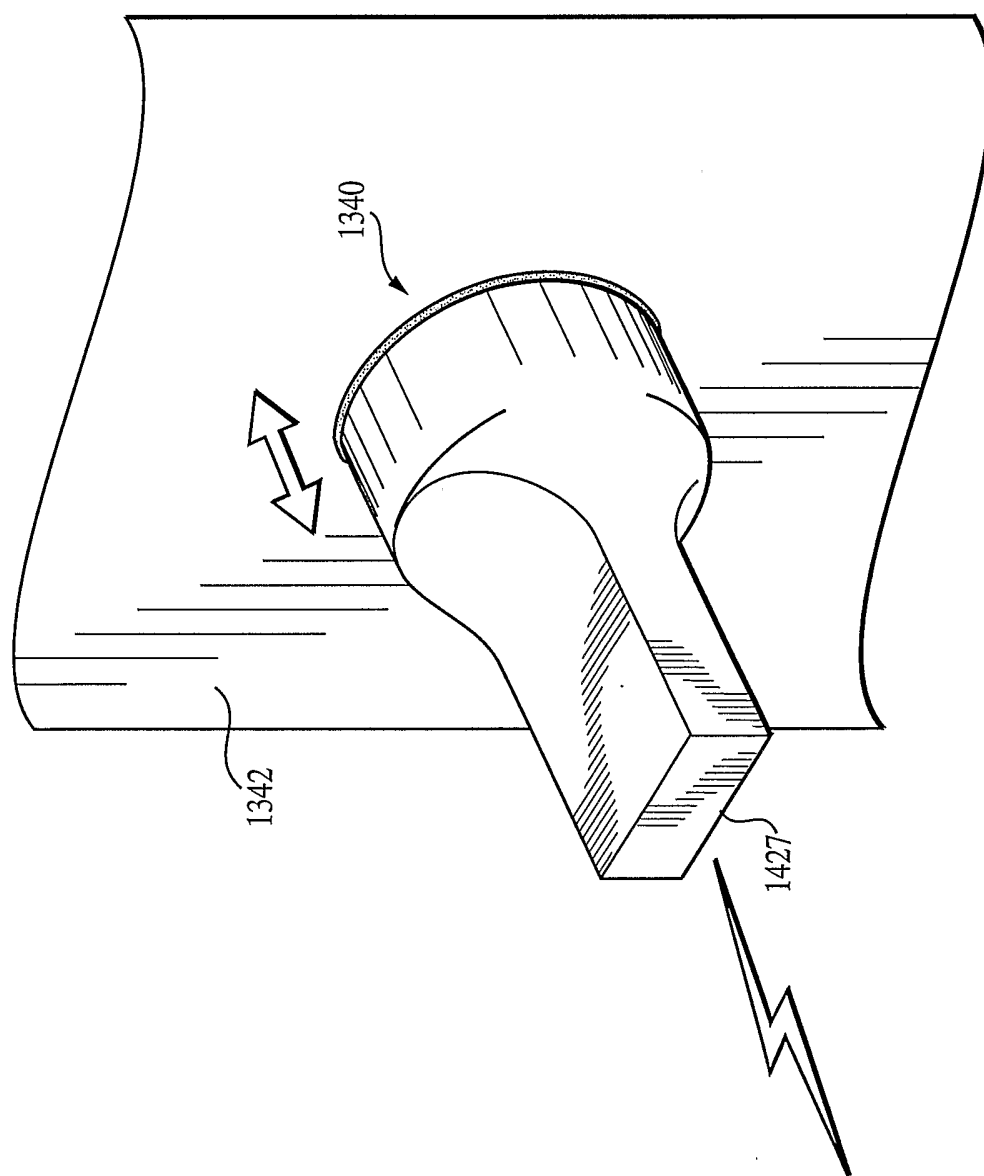


FIG. 14a

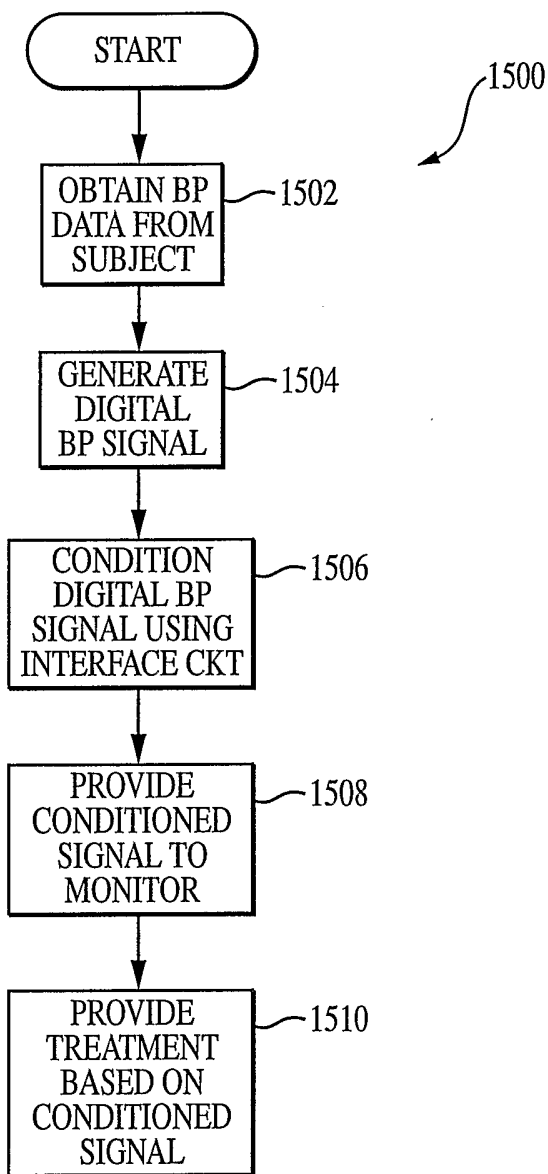


FIG. 15