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[Continued on next page]

- (54) Title: KALMAN ALGORITHM ELECTRICAL IMPEDANCE DEVICE, AND METHODS OF MAKING AND USING SAME

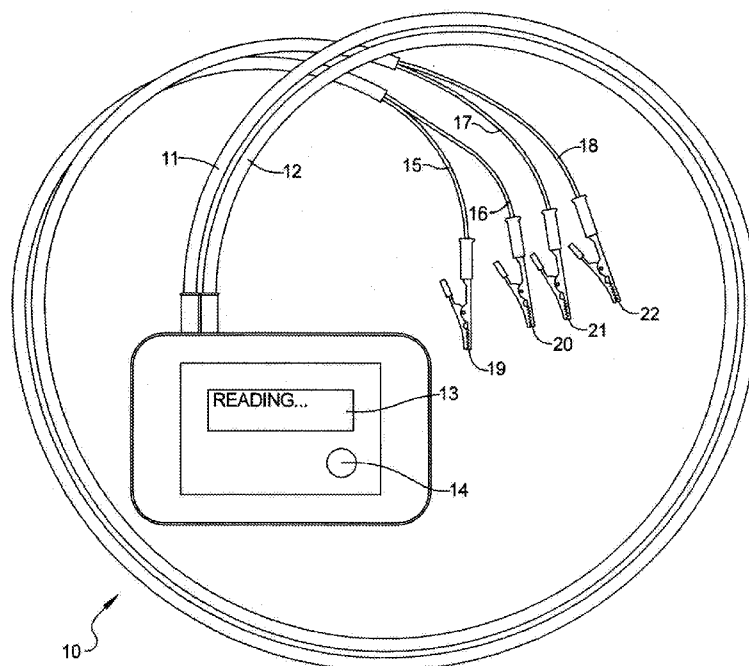


FIG 1

(57) Abstract: An electrical impedance measurement device having modern electronic and software components which include an internal digital signal processing system capable of incorporating a Kalman filter algorithm, advanced design which enables function at lower signal voltage output, hand-held portability and measurement results stability, and which is capable of immediate display of measured values on a display through a graphical user interface, and is powered by disposable batteries with built in tetra-polar shielded subject cables capable of multiple subject interface electrode arrays.

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**KALMAN ALGORITHM ELECTRICAL IMPEDANCE DEVICE, AND
METHODS OF MAKING AND USING SAME**

BACKGROUND OF THE INVENTION

The present invention relates generally to a multi-purpose generic electrical impedance device using one or more Kalman algorithms, and methods of making and using same.

More particularly the invention relates to a portable “multi-purpose” hand-held electrical impedance measuring device as described above with a tetrapolar electrode configuration which can be applied to biological and metallurgical materials for the measurement of electrical impedance values.

The terms “Kalman algorithm” and “Kalman filter” are used herein interchangeably, and mean an algorithm or filter that uses a series of measurements observed over time, containing noise (random variations) and other inaccuracies, and produces estimates of unknown variables that tend to be more precise than those based on a single measurement alone. More formally, the Kalman filter operates recursively on streams of noisy input data to produce a statistically optimal estimate of the underlying system state. Because of the algorithm’s recursive nature, it can be run in real time using only the present input measurements and the previously calculated state; no additional past information is required.

Electrical impedance analysis instruments have been devised and developed over the past one-hundred years. Various configurations of these instruments have evolved for specific purpose applications in the field of biology and metallurgy. Biological applications abound utilizing the measured values as the basis for mathematical manipulation for the estimation of various macro physiologic values to include body composition, body fluid volumes and distributions inclusive of water and blood. Metallurgic industrial applications include the assessment of fatigue, stress and

strength and resiliency.

Perhaps due to their historical longevity, instruments have not evolved to include more modern electrical engineering practices as well as component development, cost and sizes evolving to proffer newer applications and functions.

A common and recurring factor is signal-to-noise interference which limits accuracy and results in poor and reduced sensitivity, specificity and precision. In addition, high voltage in biological applications results in test subject alteration or trauma in micro- or mono-cellular utilizations.

Therefore, prior instrumentation is not suitable or practical for more sophisticated study purposes within the fields of endeavor and may be so specialized as to limit “multi-purpose” utilization.

The prior, but not necessarily relevant, art is exemplified by:

Ruchti et al. WO 03/063699 A1;
Chamney et al. EP 1 763 316 B1;
Farrington et al. EP 2 319 410 A1;
Moissl et al. EP 2 463 795 A1;
Pearlman US Patent 5,810,742;
Yang et al. US Patent 6,413,223;
Ruchti et al. US Patent 7,039,446;
Farrington et al. US Patent 7,502,643;
Cory et al. US Patent 7,865,236;
Podhajsky US Patent 8,262,652;
Cory et al. US Patent Application Publication US 2006/0085048;
Teixeira US Patent Application Publication US 2012/0277545;
Liedtke US Patent 6,631,292;

Singer et al. EP 2012665 A2;
Singer US Patent 6,587,715;
Singer US Patent 7,003,346;
Singer US Patent 7,136,697;
Singer US Patent Application Publication US 2005/0203433 A1;
Singer US Patent Application Publication US 2008/0306402 A1;
Singer US Patent Application Publication US 2010/0182021 A1;
Singer US Patent Application Publication US 2008/0224716;
Gallup et al. US Patent 5,372,141.

It is a desideratum of the present invention is to avoid the animadversion, disadvantages and deficiencies of conventional and prior devices and techniques, and to provide a more sensitive, specific and precise electrical impedance device that is less likely to have signal interference and have broad use in biological and metallurgical applications essentially as an all-purpose, generic electrical impedance device.

SUMMARY OF THE INVENTION

The present invention provides a multi-purpose electrical impedance device using one or more Kalman algorithms for determining and displaying resistance, reactance, impedance, and phase angle of a segment of a material or subject under test, comprising: current loop measurement leads and voltage sense measurement leads for selective and releasable connection to the subject under test; a constant current generator to which said current loop measurement leads are connected; a high impedance voltmeter to which said voltage sense measurement leads are connected; said constant current generator includes a digital to analog converter, a sense resistor, a balance resistor, two voltage followers, and an analog to digital converter shared by said constant current generator and said high impedance voltmeter;

said high impedance voltmeter includes two voltage followers, and a portion of said analog to digital converter; a digital signal processor for separating a voltage reading from any noise in a measurement; a program including one or more Kalman algorithms; said digital signal processor uses said program to synchronize all voltages and currents which are generated and read; as part of said program, said Kalman algorithms are used to separate noise from the voltages and currents; and a display connected to said digital signal processor for displaying resistance, reactance, impedance, and phase angle of a segment of material or subject under test.

An object of the invention is to provide a more sensitive, specific and precise electrical impedance instrument that is less likely to have signal interference and have broad use in biological and metallurgical applications essentially as an all-purpose, generic electrical impedance instrument.

Another object of the invention is to provide a device as described above, wherein said digital signal processor sends control and clock signals to said digital to analog converter.

A further object to the invention is to provide an instrument as described above that includes modern electronic and software components which include an internal digital signal processing system capable of incorporating a Kalman filter algorithm, advanced design which enables function at lower signal voltage output, hand-held portability and measurement results stability, and which is capable of immediate display of measured values on a display through a graphical user interface, and is powered by disposable batteries with built in tetra-polar shielded subject cables capable of multiple subject interface electrode arrays.

Another object of the invention is to provide a device as described above wherein said analog to digital converter measures voltage across said sense resistor; and said device is a single frequency, multi-frequency, or impedance spectroscopic device..

Another object of the invention is to provide a device as described above wherein the device is capable to provide function in biological entities as well as metallurgical, industrial functions configured as a mono-fixed frequency, multiple frequency or spectroscopic frequency scanning.

Another object of the invention is to provide a device as described above wherein a portion of said analog to digital converter measures voltage of said voltage sense measurement leads.

A further object of the invention is to provide a device as described above with potential utilization limits in any biological entity, multi-frequency and impedance spectroscopy applications, and whole-body, regional, local use as well as cells, portions (steaks-fillets) carcasses, primal cuts, etc.

Another object of the invention is to provide a device as described above wherein the device operates on a sampled single-frequency wave generated by said digital to analog converter and read back by said analog to digital converter and analyzed for phase and amplitude by sending sampled signal data through said Kalman algorithm using said digital signal processor.

Another object of the invention is to provide a device as described above wherein said digital to analog converter generates a single-frequency voltage which is set to the shorted impedance of the current loop.

Another object of the invention is to provide a device as described above wherein said Kalman algorithm reads the voltage across the sense resistor and determines the current in the loop.

Another object of the invention is to provide a device as described above wherein the voltage across the sense resistor and the voltage across the subject under test are read by said analog to digital converter and sent to said Kalman algorithm.

Another object of the invention is to provide a device as described above wherein said Kalman algorithm sends back four outputs, namely the amplitude and phase of each channel, and then the current is computed by the amplitude of the voltage across said sense resistor divided by the resistance of said sense resistor.

Another object of the invention is to provide a device as described above wherein: the impedance of the subject under test is determined by the differences of the phases in the two channels and the ratio of output voltage divided by the amplitude of the current; the resistance and reactance are determined

from the amplitude and phase; and all four values of resistance, reactance, impedance, and phase angle of the subject under test are displayed on said display.

A further object of the invention is to provide a device as described above wherein the measured electrical values correspond to cellular architecture of any biological entity, wherein R is inverse to ecw , X_c is proportional to cell mass, and phase angle to proportional to cell membrane function.

Other objects, advantages, and features of the present invention will become apparent to those persons skilled in this particular area of technology and to other persons after having been exposed to the present patent application.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG 1 shows the bioimpedance analysis device with its cables in accordance with a preferred embodiment of the present invention.

FIG 2 shows the rear side of the device..

FIG 3 shows the front side of the device.

FIG 4 is a block diagram of the device.

FIG 5 shows a human subject under test.

FIG 6 shows placement of the electrodes on the wrist and ankle.

DETAILED DESCRIPTION OF THE INVENTION

FIG 1 shows the device 10 and subject cables 11 and 12 extending from the device 10. The device 10 includes a display 13 and a power switch 14 which is the single measure and power switch.

Each cable 11 and 12 consists of two leads 15, 16 and 17, 18, respectively, with alligator clips 19, 20, 21 and 22 attached to associated ones of the lead ends.

One of the leads 15 and 17 in each cable 11 and 12 is colored black for a constant current generator 23, and the other leads 16 and 18 is colored red for the high impedance voltmeter 24.

The four leads 15, 16, 17 and 18 are used to measure internal impedance, meaning impedance where the contact resistance is not included in the reading. This is done by injecting a current at a different location from where the voltage measurement is taken. Because the current does not flow through the voltmeter leads, the current through the contact resistance is zero. Because there is no current flowing, the voltage drop is zero. The voltage read is the field where the current is flowing within the material or subject under test (SUT). Therefore, the reading measures the internal impedance of the material or SUT, and not the contact resistance.

FIG 2 shows a rear view of the device 10 with two AA batteries 25 and 26 and four surface pads 27, 28, 29 and 30.

FIG 3 shows measured values on the display 13.

FIG 4 shows a block diagram for the device 10 which includes the red leads 16 and 18, the black leads 15 and 17, the constant current generator 23, the high impedance voltmeter 24, a validation module 31, a program module 32, clock and control lines 33, a Digital Signal Processor (DSP) 34, and the display 13.

The black lead 15 is the positive terminal of the current loop of the measurement cable.

The black lead 17 is the negative terminal of the current loop of the measurement cable.

The red lead 16 is the positive terminal of the voltage sense of the measurement cable.

The red lead 18 is the negative terminal of the voltage sense of the measurement cable.

The validation module 31 switches loads in and out to validate that the device 10 is functional.

An analog to digital converter (A/D) 35 is shared by the constant current generator 23 and the high impedance voltmeter 24.

The constant current generator 23 includes an in-series sense resistor 43, a second balance resistor 36, a digital to analog converter (D/A) 37, voltage followers 38 and 39, and a first portion of the A/D 35.

The D/A 37 is constructed to have the two resistors 43 and 36 placed at the terminals, one at each of the two terminals. They are called balance resistors. They are both the same size, 470 ohms. One of the balance resistors serves double duty and is used as the sense resistor 43. The second one is the second balance resistor 36.

The output of the A/D 35 is the clock and control lines 33. Both the A/D 35 and the D/A 37 are connected to the DSP 34 through the clock and control lines 33.

The high impedance voltmeter 24 includes voltage followers 40 and 41 and a second portion of the A/D 35

The program 32 includes one or more Kalman filters or algorithms 42. The program 32 and Kalman algorithms 42 are actually in the memory portion of the DSP 34.

A two-state variable Kalman algorithm is used. The variables are the amplitude and phase. Two Kalman algorithms are used. One Kalman algorithm is used for the current, and one for the voltage.

The data for the current and voltage are sampled simultaneously by the A/D 35. This allows for the comparison of the voltage and current data with separate Kalman algorithms. The Kalman algorithm separates out the noise in both the current and voltage.

The device 10 may work based on a sampled single-frequency wave, such as, for example, a 50 KHz wave, generated by the D/A 37 and read back by the A/D 35, and analyzed for phase and amplitude by sending the sampled signal data through a Kalman algorithm 42 using the DSP 34.

The D/A 37 generates the sampled single-frequency wave, such as, for example, a 50KHz wave, voltage that is initially set to the shorted impedance of the current loop. In other words, the voltage is set to 425 microamps times the short circuit impedance.

The short circuit impedance is 940 ohms. Half of this is used at the current sensing resistor or 470 ohms.

The Kalman filter (algorithm) 42 then reads the voltage across the current sense resistor 43 and determines the actual current in the loop with the load included. It continues to raise the

voltage until 425 microamps is read across the sense resistor 43. The accuracy of the device 10 is between the 1 ohm and 1000 ohm level. Above the 1000 ohm level, the output voltage is limited and the current does not reach 425 microamps. A value is taken, but it is not specified as to accuracy above the device's 1000 ohm specified accuracy limit.

Both the output voltages are read by the A/D 35 and sent to the Kalman algorithm 42. The two voltages are the voltage across the sense resistor 43 and the voltage across the subject under test (SUT).

The Kalman algorithm 42 sends back four outputs, i.e., the amplitude and phase of each channel.

The current is computed by the amplitude of the sense resistor 43 divided by the sense resistance.

The SUT impedance is then determined by the difference of the phases in the two channels and the ratio of output voltage divided by the amplitude of the current.

The amplitude and phase are used to calculate resistance and reactance. All four values, impedance magnitude, phase, resistance and reactance are displayed (see FIG 3). After a set period of time the device 10 goes into hibernation. It is re-activated for the next test by using the power switch 14 which starts the sequence over again.

A low nominal current of 425 microamps at 50 kHz is used. At this current level, noise has to be taken into consideration as part of the measurement. This is accomplished by a setup using the DSP 34 to separate the voltage reading from the added noise of the measurement. The algorithm used to separate the signal from the noise is a Kalman algorithm.

The DSP 34 uses a program to synchronize all of the voltages and currents that are generated and read. As part of the program a Kalman algorithm is used to separate the noise from the signal.

More specifically, the DSP 34 sends control signals and clock signals to the D/A 37. This circuit generates a 50 KHz voltage signal.

Because the D/A 37 produces a voltage, the current going through the impedance to be measured (SUT) has to be read. This is done with the in-series sense resistor 43. The voltage across the sense resistor 43 is read with the A/D 35. The voltage across the sense resistor 43 is proportional to the current flowing through it. The is also in synch with the DSP 34 with clock signals and control lines 33.

The A/D 35 has a second section that measures the voltage of the voltage red leads 16 and 18 of the cables 11 and 12. These are read through voltage follower op amps to increase the input impedance of the A/D 35 which has the effect of not loading the circuit they are measuring. The A/D 35 and the D/A 37 have fully differential inputs and outputs.

In operation, the signals from the A/D 35 are sent to the DSP 34 where the noise is separated in the program using a Kalman algorithm. The amplitudes and phase difference between the two signals are then available for use.

In measuring an impedance, the current must first be established in the constant current current generator 23. This is done by first assuming the impedance is zero and setting voltage to a level such that the voltage divided by circuit impedance is 425 microamps. In the constant current generator 23 there is a the sense resistor 43 and the second balance resistor 36 whose values are both known. The actual impedance will be greater than or equal to zero impedance. The current source resistor is then read and voltage is brought up in steps until 425 microamps is reached. This ensures that 425 microamps is not exceeded. The voltage at the D/A 37 is also limited to a prescribed level. If as the voltage level is increased, 425 microamps is not reached, the process is stopped when the maximum voltage level of the D/A 37 is reached.

Once the current is established, the voltage at the cables is read by the second half or portion of the A/D 35. The current and voltage amplitudes and phase differences have now been determined.

From this the impedance is calculated. What is displayed is the magnitude and phase of the impedance are displayed, and then then the resistance and capacitive reactance are calculated. All four parameters are sent to the display 13 (see FIG3)..

In addition to this, resistive and reactive loads are switched into the measurement circuit before the measurements are made to validate that the circuit is operating correctly. This is performed by the validation module 31. When this is done, no current is sent down the cable.

Measurements are initiated by pressing the power switch 14.. The validation is done first, and then the impedance measurement. After the measurement is taken, the values of the impedance are displayed on the display 13 for a set period of time after which the device 10 automatically shuts down.

The present invention thus provides a multi-purpose electrical impedance device using one or more Kalman algorithms for determining and displaying resistance, reactance, impedance, and phase angle of a segment of a material or subject under test, comprising: current loop measurement leads and voltage sense measurement leads for selective and releasable connection to the subject under test; a constant current generator to which said current loop measurement leads are connected; a high impedance voltmeter to which said voltage sense measurement leads are connected; said constant current generator includes a digital to analog converter, a sense resistor, a balance resistor, two voltage followers, and an analog to digital converter shared by said constant current generator and said high impedance voltmeter; said high impedance voltmeter includes two voltage followers, and a portion of said analog to digital converter; a digital signal processor for separating a voltage reading from any noise in a measurement; a program including one or more Kalman algorithms; said digital signal processor uses said program to synchronize all voltages and currents which are generated and read; as part of said program, said Kalman algorithms are used to separate noise from the voltages and currents; and a display connected to said digital signal processor for displaying resistance, reactance, impedance, and phase angle of a segment of material or subject under test.

In a preferred embodiment, the device 10 comprises is a bioimpedance analysis device intended for the measurement of Impedance, Resistance, Reactance and Phase Angle in subjects aged six to ninety-two years of age in the home or clinical environment.

The device 10 is powered by the two disposable “AA” batteries 25 and 26 housed on the back accessed via a removable plastic cover.

The device 10 is self-validating and performs the validation routine internally each time it is energized.

Once the device 10 is connected to a subject 44 (see FIG 5) it will self-validate and begin the reading.

FIG 5 illustrates human whole-body only, but the device can also be used with regional and local use in humans as well as various configurations for any biological entity or metallurgical application.

The electrodes or leads 15, 16, 17 and 18 are placed on the subject 44 in relation to anatomical landmarks on the wrist and ankle; generally the right side of the body is used. However the left side may also be used. It is important to use the same side for each test for whole-body, but use of the device is not limited to whole-body study only. Red leads should be placed above black leads for a whole-body study only.

Then the examiner should make sure the test subject is positioned as illustrated, the electrodes are placed as illustrated and the clips of the subject cable are connected as illustrated in FIGS 5 and 6.

Next, the examiner should energize the device 10, and then turn towards the test subject 44 to ensure that the subject 44 is calm, flat and not moving. Then the examiner should record the measured values from the display 13 of the device 10. Once the results are written down, the examiner should disconnect the subject cable clips from the electrodes and set the device safely aside.

Many changes, modifications, variations, and other uses and applications will become apparent to those persons skilled in this particular area of technology and to others after having been exposed to the present patent application.

Any and all such changes, modifications, variations and other uses and applications which do not depart from the spirit and scope of the present invention are therefore covered by and embraced within the patent claims set forth hereinbelow.

CLAIMS

1. A multi-purpose electrical impedance device using one or more Kalman algorithms for determining and displaying resistance, reactance, impedance, and phase angle of a segment of a material or subject under test, comprising:

current loop measurement leads and voltage sense measurement leads for selective and releasable connection to the subject under test;

a constant current generator to which said current loop measurement leads are connected;

a high impedance voltmeter to which said voltage sense measurement leads are connected;

said constant current generator includes a digital to analog converter, a sense resistor, a balance resistor, two voltage followers, and an analog to digital converter shared by said constant current generator and said high impedance voltmeter;

said high impedance voltmeter includes two voltage followers, and a portion of said analog to digital converter;

a digital signal processor for separating a voltage reading from any noise in a measurement;

a program including one or more Kalman algorithms;

said digital signal processor uses said program to synchronize all voltages and currents which are generated and read;

as part of said program, said Kalman algorithms are used to separate noise from the voltages and currents; and

a display connected to said digital signal processor for displaying resistance, reactance, impedance, and phase angle of a segment of material or subject under test.

2. The device of claim 1, wherein:
said digital signal processor sends control and clock signals to said digital to analog converter.
3. The device of claim 2, wherein:
said analog to digital converter measures voltage across said sense resistor.
4. The device of claim 3, wherein:
a portion of said analog to digital converter measures voltage of said voltage sense measurement leads.
5. The device of claim 4, wherein:
the device operates on a sampled 50 Khz wave generated by said digital to analog converter and read back by said analog to digital converter and analyzed for phase and amplitude by sending sampled signal data through said Kalman algorithm using said digital signal processor.
6. The device of claim 5, wherein:
said digital to analog converter generates a single frequency voltage which is set to the shorted impedance of the current loop.
7. The device of claim 6, wherein:
said Kalman algorithm reads the voltage across the sense resistor and determines the current in the loop; and
said device is a single-frequency, multi-frequency, or impedance spectroscopic device.

8. The device of claim 7, wherein:

the voltage across the sense resistor and the voltage across the subject under test are read by said analog to digital converter and sent to said Kalman algorithm.

9. The device of claim 8, wherein:

said Kalman algorithm sends back four outputs, namely the amplitude and phase of each channel, and then the current is computed by the amplitude of the voltage across said sense resistor divided by the resistance of said sense resistor.

10. The device of claim 9, wherein:

the impedance of the subject under test is determined by the differences of the phases in the two channels and the ratio of output voltage divided by the amplitude of the current;

the resistance and reactance are determined from the amplitude and phase; and

all four values of resistance, reactance, impedance, and phase angle of the subject under test are displayed on said display.

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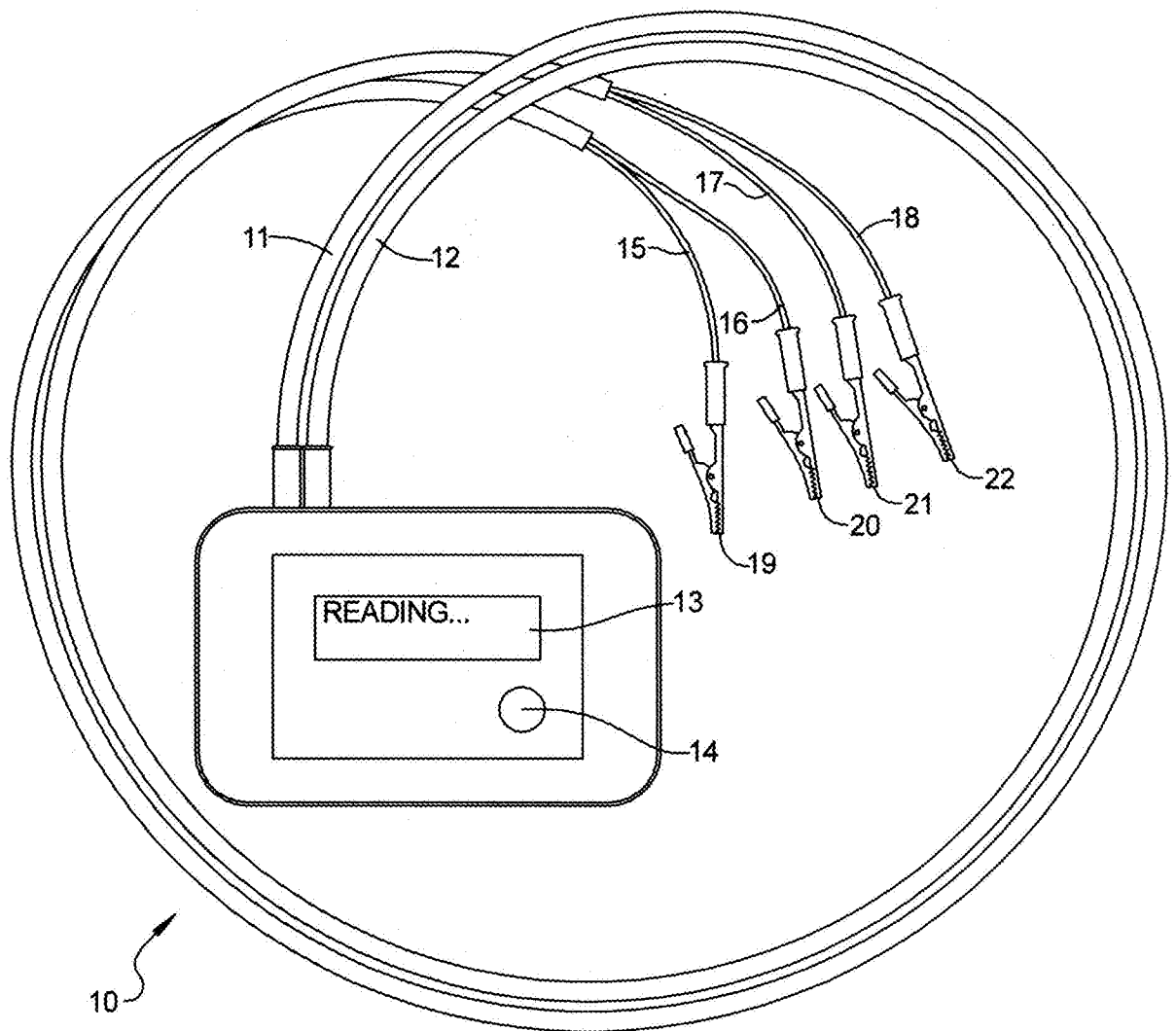


FIG 1

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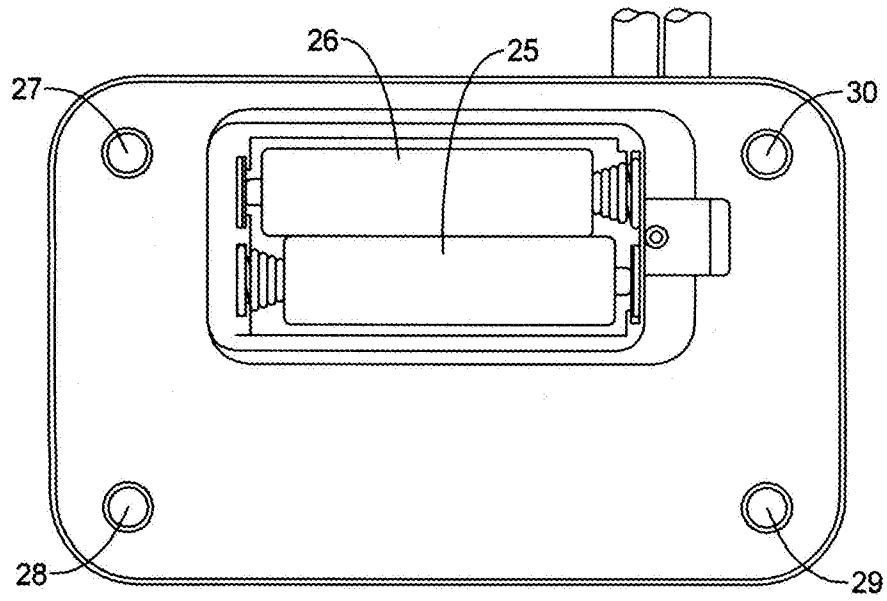


FIG 2

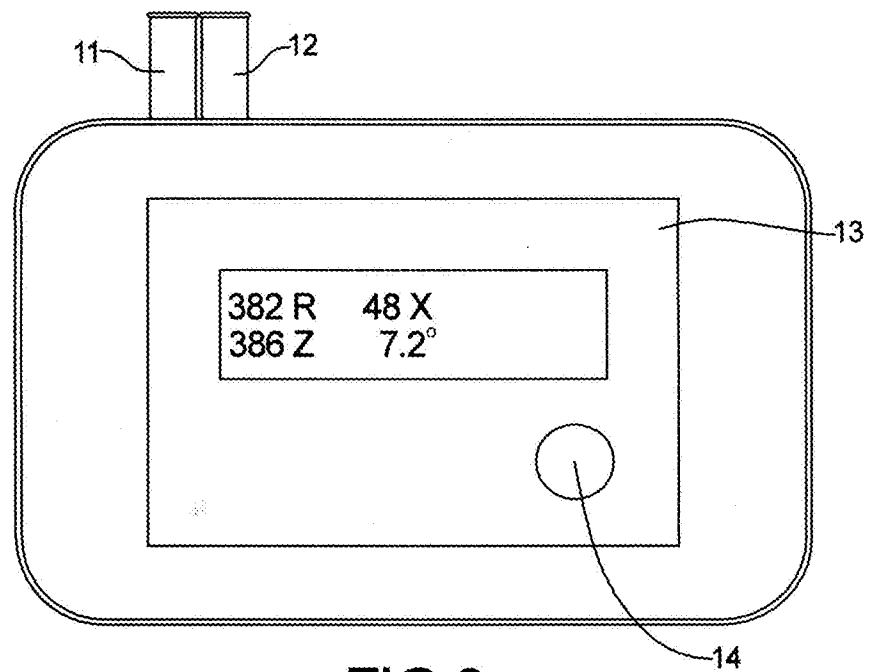


FIG 3

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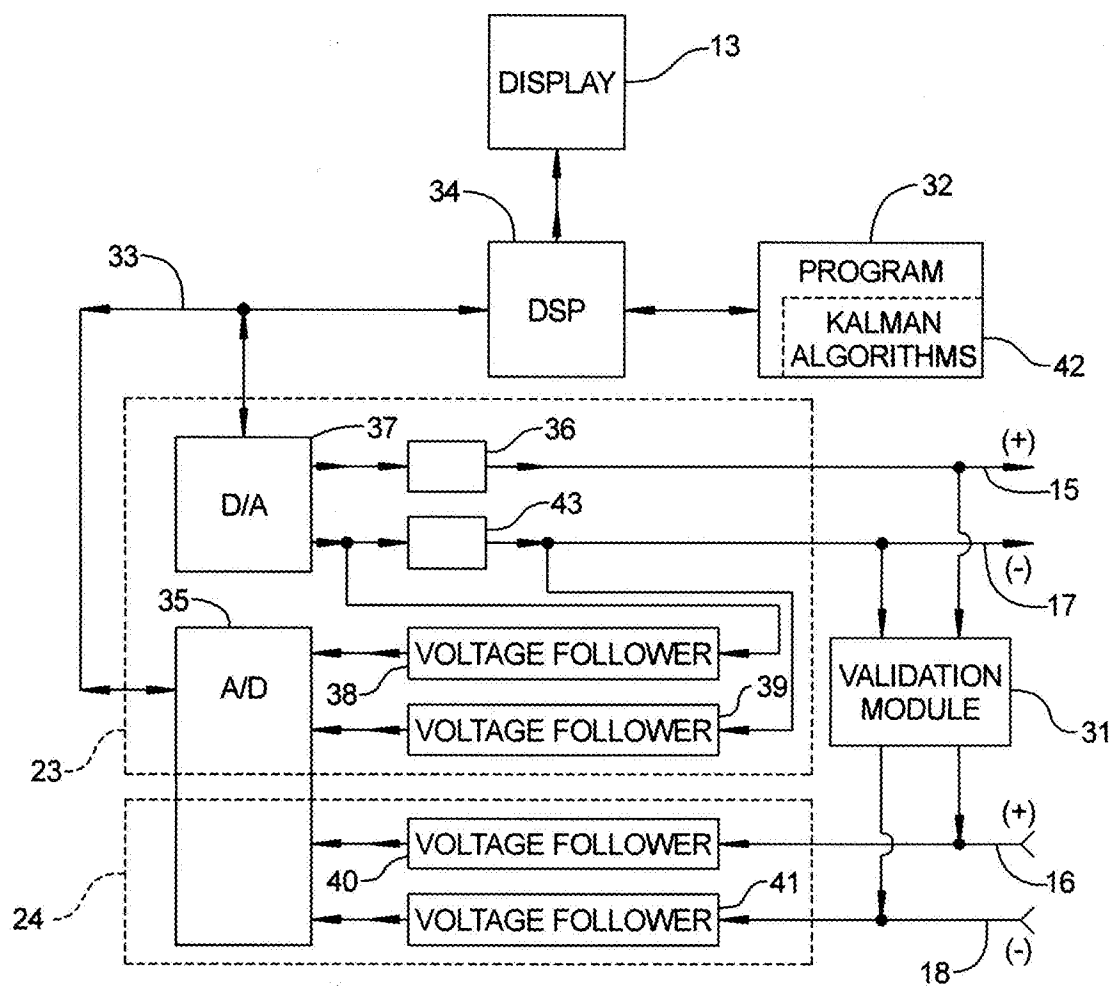


FIG 4

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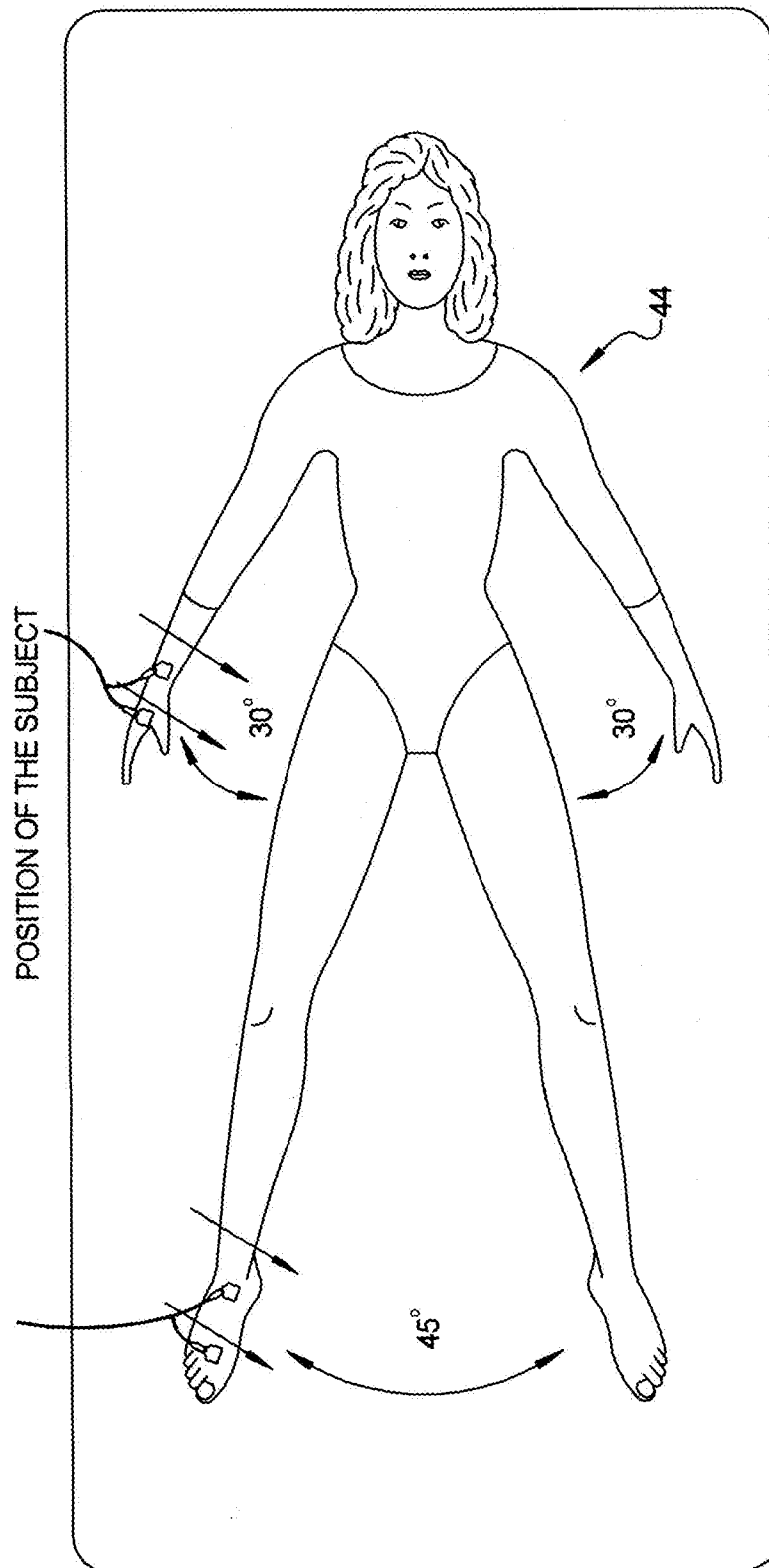


FIG 5

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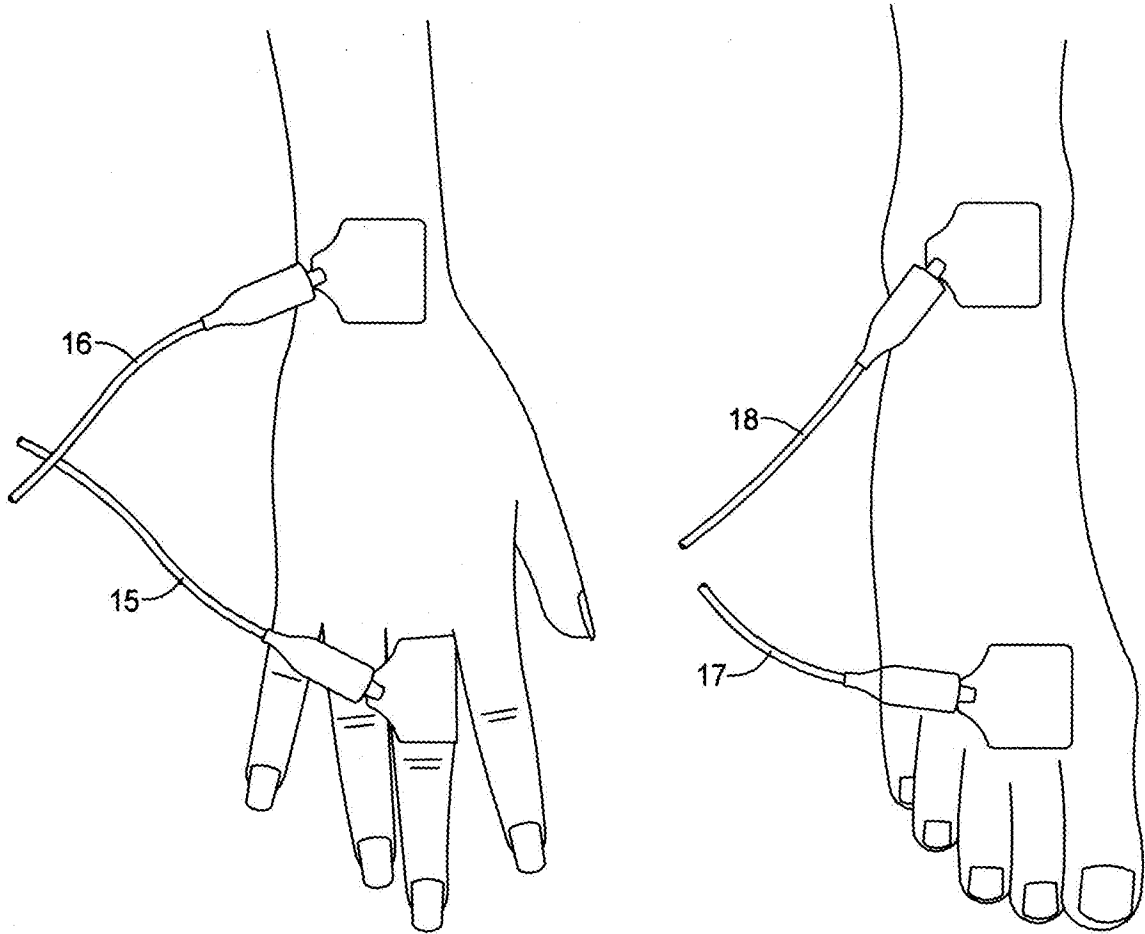


FIG 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2013/033576

A. CLASSIFICATION OF SUBJECT MATTER		A61B 5/053 (2006.01) G01R 27/02 (2006.01)	
According to International Patent Classification (IPC) or to both national classification and IPC			
B. FIELDS SEARCHED			
Minimum documentation searched (classification system followed by classification symbols)			
A61B 5/053, G01R 27/02			
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched			
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)			
PCT Online, USPTO, Esp@cenet, DWPI, CIPO (Canada PO), SIPO, AIPN, DEPATISnet, NCBI (PubMed), VINITI.RU, SCSML.FSSI.RU			
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category*	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
A	US 2006/0241514 A1 (RICHARD J. DAVIES) 26.10.2006, paragraphs [0116], [0151], [0152], [0158], [0162], [0163], [0164], [0166], fig. 1, 2		1-10
A	US 2005/0027205 A1 (LIONEL TARASSENKO et al.) 03.02.2005, paragraphs [0002], [0009], [0015], [0018], [0027], [0028], [0031], fig. 1		1-10
A	US 2004/0158167 A1 (KENNETH CARLESS SMITH et al.) 12.08.2004, paragraphs [0002], [0098], [0105], [0117], fig. 1-3A		1-10
A	WO 1992/019153 A1 (XITRON TECHNOLOGIES) 12.11.1992, abstract		1-10
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.			
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