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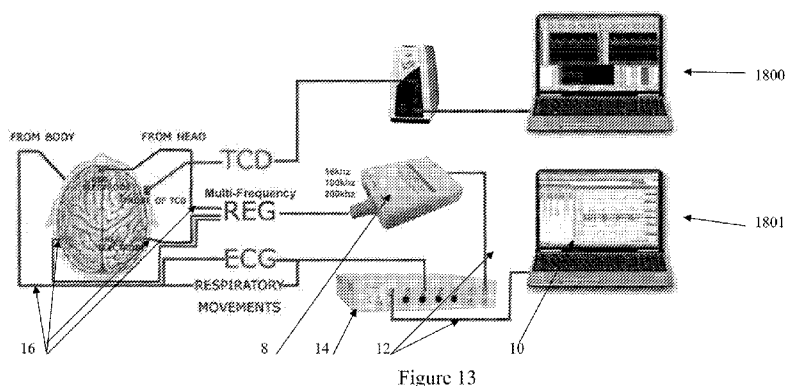
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(54) Title: THE MEASUREMENT OF PHYSIOLOGICAL CHARACTERISTICS



(57) Abstract: A system for measuring physiological aspects has a non-invasive monitor configured to generate monitor signals relating to fluid characteristics in the head and body. A computational device is operatively connected to the monitor and is configured to process the monitor signals to generate characterizing data relating to at least one of regional fluid volumes, intra/extracellular fluid volume ratios and blood flow. A data output device is connected to the computational device and is configured to output the characterizing data. A method and a computer program product for recording, measuring, and displaying physiological characteristics are also provided.

THE MEASUREMENT OF PHYSIOLOGICAL CHARACTERISTICS

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FIELD OF THE INVENTION

The present invention generally relates to the measurement of physiological characteristics. In particular, **the** present invention generally **relates** to **a** method, **a** system and **a software** product to measure and display the dielectric properties of the fluid **mediums** within the head and body of humans and animals.

15

BACKGROUND ART

[Mere reference to background art herein should not be construed **as** an admission that such art constitutes common general knowledge in relation to the invention.]

Redistributions of fluids between segments of the head and body are often of central clinical importance, particularly **in** humans. This includes redistributions of fluids **between** the **infra-cellular** and extra-cellular **compartments** within the segments. Measurement of these redistributions can be useful, particularly for monitoring and assessing the response and adaptation of the body to various orthostatic and anti-orthostatic dysfunctions.

However, currently employed methods of measuring redistributions of fluids between segments of a body are either invasive **or** bulky and expensive. For example, tracer dilution techniques involve invasively administering a dose of an appropriate tracer to the body, collecting blood samples, and measuring the tracer. The tracer fluid does not always safely disperse after the test. Alternatively, MRi technologies can be used but **MRI** equipment is both costly and bulky, making it impractical readily to measure redistributions of fluids between segments of a body. A further disadvantage of these techniques is that **they do** not yield **easily used** real-time data during **physiological** stress or **clinical** diagnosis. Nor are there auto-regulation or homoeostatic balance **ranges** that can be applied generally **to** both adults and infants. An elderly adult, mature adult, young adult, child, infant (male or female) may have different ranges of auto-regulation.

The amount of "water" that a cell takes on in the brain is of critical importance in brain injury management as is the cardiovascular competence level of the **heart/lung/body**.

The individual should be able to maintain body "homeostasis" - when the person cannot "Auto-regulate" then he/she has exceeded reasonable physiologic capacity.

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SUMMARY OF THE INVENTION

According to a first aspect of the invention, there is provided a system for measuring physiological characteristics, the system comprising:

a non-invasive monitor configured to generate monitor signals relating to fluid characteristics of the body;

a computational device operatively connected to the monitor and configured to process the monitor signals to generate characterising data relating to at least one of the regional fluid volumes, intra/extracellular fluid volume ratios and blood flow; and

a software program installed on the computational device and configured to record, calculate, and display the characterising data.

The generated characterising data may be in the form of any one or more of the following which are also capable of being displayed in various formats:

1. CCe (Cranial Compliance)
2. CSFm (Cerebrospinal fluid movement)
- 10 3. CBF (Cerebral blood flow)
4. CVR (Cardio Vascular Reactivity)
5. R1 (extracellular resistance)
6. R2 (intracellular resistance)
7. C (brain tissue capacitance)
- 15 8. ReZ (full brain tissue resistance)
9. The ratio of reactance and resistance $\text{tg}\phi = \text{Im}Z/\text{Re}Z$ - the phase angle of brain bio-impedance.
10. Spectral Analysis

The non-invasive monitor is preferably a multi-frequency multi-channel impedance rheoencephalograph (REG) in conjunction with a Transcranial Doppler (TCD).

Specifically, the rheoencephalograph waveform combined with the Transcranial Doppler waveform produces a unique new waveform that allows for the generation of the characterising data. In particular, the rheoencephalograph can determine capacitance and resistance for different tissue structures and distinguish between connective tissue and blood.

In other words, the rheoencephalograph can distinguish between intracellular fluid volume of one or more cells and extracellular fluid.

The system has the capacity to separately monitor the left hemisphere and the right hemisphere of the head as a portion of the body.

5 The software program installed on the computational device will preferably have capacity to record steady state resistance on each frequency as well as the pulsing wave on 3 frequencies. Additional frequencies may be necessary to provide even more specific monitoring capacity.

The steady state resistance values are preferably received at a frequency of 100 times
10 per cardiac cycle.

The software program is preferably automated to perform the necessary calculations on this monitor signals and compute values for R₁, R₂ and C from the data contained in the monitor signal and plot the changes during any single selected cardiac cycle.

Measurements of basic resistance between electrodes of a preferred
15 rheoencephalograph device are possible to calculate parameters associated with head tissue. From an electrical point of view, brain tissue may be represented as a set of resistances and capacities intricately connected to each other. Formulae can then be used to calculate the required parameters. Views of persons in the art differ as to the best equivalent circuit of the brain and the formula chosen typically depends upon which equivalent circuit of the brain is
20 selected. Two different equivalent circuits of the brain are illustrated in Figures 26 and 27.

The equivalent electrical circuit of the brain represented in Figure 26 provides Formula (1):

$$Z = \frac{R_1 \left(R_2 + \frac{1}{i\omega C} \right)}{R_1 + R_2 + \frac{1}{i\omega C}}, \quad (1)$$

Where:

- 25 Z is the brain tissue impedance;
R₁ is the extracellular resistance;
R₂ is the intracellular resistance;
C is the cellular electric capacitance;

ω is the angular frequency; and

i is the imaginary unit $i = \sqrt{-1}$.

The equivalent electrical circuit of the brain represented in Figure 22 provides Formula (2):

$$Z = \frac{(R_e + R_i) + i\omega C R_e R_i}{1 + i\omega C R_i} \quad (2)$$

Where:

Z is the brain tissue impedance;

R_e is the extracranial resistance,

R_i is the intracranial resistance;

C is the cellular electric capacitance; and

ω is the angular frequency.

Future progress in this mode of calculation, which could permit additional data to be received, could be based on including one more frequencies, for example, any one or more of 16 kHz, 32 kHz, 50 kHz, 100 kHz, 150 kHz, 200 kHz or 250 kHz, in addition to or instead of the frequencies suggested in the preferred embodiment.

Estimation may be performed by interpolation methods. By having three measurements at three various frequencies the impedance function can be approximated with a simpler function $Z(f)$. Thereafter, estimation of the impedance value at a fourth frequency with function $Z(f)$ can be achieved by interpolation. The calculations as presented substantiate the conclusion that the transcephalic measurement of electrical impedance that has been used is a measurement of the electrical impedance of the whole head as the volume conductor from the head surface by a non-invasive method.

The program preferably allows computation automatically of values of impedance parameters (R_i , R_e , C in circuit—Fig.32 and R_e , R_i , C in circuit Fig.27).

Input data for the preferred software are values of impedance measured at three preferred distinct frequencies (16 kHz, 100 kHz, 200 kHz). The least squares method can be used to estimate the parameters of impedance magnitude. The impedance parameters are reduced to finding the minimum regression sum using the following formula:

$$S = \sum_{i=1}^3 (Z_i - I_i)^2$$

For solving the minimum of the regression sum, the quasi—Newton BGFS method is preferred and is typically included in the software.

These manipulations allow evaluation of different brain impedance parameters in
5 each of the circuits.

The method of calculation of CSF mobility and CCe indexes is typically presented by special automation on the base of selecting of systolic and diastolic fragments (pre and post maximal value of the TCD pulse) and exporting this data to the software for display or output.

10 The first step is preferably normalization of data, which is the transformation of the real ranges of TCD and REG pulse changes to a scale with limits of 0.0—1.0. It is then possible to create an initial "XY" plot (plot 1), where X is Doppler and Y is REG(100kHz). This plot may be approximated by a straight line (line 1). Coordinates of the first point in this line are (X1, Y1) and the last point are (X2; Y2). CCe value may be estimated as the
15 negative tangent of the slope angle of this line.

$$CCe = |k| = -\tan \alpha = \left| \frac{Y_2 - Y_1}{X_2 - X_1} \right| \quad (3)$$

where α is the slope angle of line 1.

20 Using this data, a new X',Y' plot (plot 2) is created from the second half of the pulse data, where X' is TCD and Y' is REG (100kHz). Next, the area parameter of the new plot is estimated.

For this estimation, the plot is approximated by a straight line (line 2). The coordinates of the first point in this line are (X3; Y3) and the last points are (X4; Y4).

25 CSFm may then be estimated as the residual between the total (line 2) area and integral of (plot 2).

$$CSFm = \left(\frac{Y_3 + Y_4}{2} \right) * (X_4 - X_3) - \int_{X_3}^{X_4} f(x) dx \quad (4)$$

where f(x) is the function of plot 2.

The software is preferably automated to perform the necessary calculations on the data and compute values for R_i , R_2 and C from this data and plot the changes during any single selected cardiac cycle.

According to a particularly preferred embodiment, there are two different ways of
5 analysing multi-frequency data:

1. Calculations of R_1 , R_2 , C based on resistance values between electrodes with three different frequencies gives information about steady state conditions for comparison of different individuals or for the same individual with different physiological conditions - For example before and after brain surgery as well as evaluation of changes in brain tissue
10 during the recovery period. For these purposes it is necessary to calculate these parameters every 5 seconds.

2. Calculations of changes of R_1 , R_2 , C during the cardiac cycle. R_i represents the resistance of the skull bones and its connective tissues. If a value of R_i is only occasionally sampled it will always be 'generally unchanging'. However if it is sampled 100 times per
15 cardiac cycle the values will demonstrate a pulsating wave and should correspond to CCe or the elasticity of the skull bone interfaces during the cardiac cycle.

The software of one preferred embodiment also allows the calculation of spectral analysis.

The accuracy of the method can be (and has been) confirmed by comparing the
20 resistance spectrum to the rheoencephalograph pulsing spectrum (i.e. slow fluctuations). R_2/C = changing of intracranial fluids divided by the unchanging value of the brain tissue which corresponds to $CSFm$.

The rheoencephalograph is combined with dopplergraphy to produce a unique new waveform for input to the software and thus provide a completely new way to evaluate
25 intracranial fluid dynamics. Additionally, it provides a basis for the meaning of CCe as essentially being a measurement of skull bone elasticity or movement between the skull bones at their connecting joint surfaces.

Based on the fact that the reactive component " C " (capacitance) depends on the frequency of the current - measurements of basic resistance between electrodes while using a
30 number of electrodes, typically at three different preferred frequencies (16, 100 and 200 kHz), are examples of frequencies used in the preferred embodiment - and allows the calculation, by three mathematical equations, of the values of:

Brain tissue impedance:

RI (extracellular resistance),

R2 (intracellular resistance)

C (brain tissue capacitance)

5

and also the full brain tissue resistance (the complex impedance ReZ) and the reactance (ImZ). In addition, the software can also preferably calculate the ratio of reactance and resistance $\text{tg}\phi = \text{ImZ}/\text{ReZ}$ - the phase angle of brain bio-impedance.

The software of the preferred embodiment preferably calculates and delivers these
10 mathematically calculated values automatically from the basic resistance. This approach allows the separation of extracranial components from the intracranial components as they are represented in the values of the basic resistance between electrodes. Failure to separate these components had previously been the main deterrent and limitation to widespread use of the rhocnccphalograph method as a "stand alone" method for cerebral investigations.

15 Underpinning the present analysis is the concept that the amount of "water" that a cell takes on in the brain is of critical importance in brain injury management. This is as important to the brain as is the cardiovascular competence level of the heart/lung/body to the human body maintaining homeostasis.

The individual should be able to maintain body "homeostasis" - when the person
20 cannot "auto-regulate" then he/she has exceeded reasonable physiologic capacity. This invention provides a means whereby the physiological aspects of the head and/or body related to the distribution of fluids can be monitored and displayed in near real time.

More particularly, the present invention relates to monitoring head and/or body
25 segment impedances for determining fluid volumes and fluid flows in a head and body in near real time.

Blood pressure, temperature, ECG, chest respiratory movements and tire oxygen and carbon dioxide saturation levels of the blood and blood flow characteristics may be incorporated and combined for analysing trends of the auto-regulation phase particular to an individual.

30 This invention provides an improved method of analysing physiological data using a rheoencephalograph combined with dopplerography and the specialized software platform (IAS).

In one embodiment, the computational device or computer and software are configured for determining fluid volumes and fluid flows in a head and/or body segment in at least near real time which overcomes or ameliorates one or more of the disadvantages or problems described above, or which at least provides a useful alternative. One embodiment
5 of the invention discloses a critical near real time analysis combining and displaying different types of data simultaneously. This results in more time efficiency and effective decision-making by the treating physician, and the best choice of the correct medical intervention to be applied to the patient.

For the sake of convenience, the term "monitor" should be understood to mean one or
10 more monitors.

The non-invasive monitor is preferably a rheoencephalograph and preferably a multi-frequency, multi channel rheoencephalograph combined with a doppler or ultrasound device.

Specifically the rheoencephalograph developed may operate on multiple frequencies simultaneously; or be electronically switched automatically by prc-sct command between frequencies (16, 100, 200 Kilohertz) at an adjustable rate to record and calculate simultaneously the desired physiological data including the capacitance and resistance for
15 different tissue structures - connective tissue vs. blood (intracellular fluid volume of one or more cells vs. extracellular fluid), and may be configured to display for head and/or body segments. In one embodiment, the monitor may be a single instrument with all fluids monitored down to intracellular and extracellular fluid levels. The doppler is configured in a manner allowing constant signal monitoring and data storage and retrieval by the software in
20 order to generate the combined waveform from the rheoencephalograph and doppler data inputs.

The system may include at least two excitation electrodes for providing an electrical stimulus across selected head and/or body regions. The system typically also includes at least one or more monitoring electrodes.

The monitor may have a number of electrodes that are configured for placement in a non-invasive manner for effective operative engagement with the head or body; such that at least one electrode engages each of a number of selected segments of the head and/or body.

The monitor may be configured to use any number of different frequencies but three frequencies have been found to provide the optimum number of frequencies. This spread of frequencies provides sufficient information to allow calculation of all desired characterizing parameters.

The software of the preferred embodiment may be configured to store the impedance parameters and doppler signals; extract data segments relating to test sequences, combine the waveforms and produce the desired calculated data graphs, spectral analysis graphs and resultant calculations for display or storage into a database for subsequent access and comparison of the subject's physiological conditions. Furthermore, the software preferably allows queries to be run on the database to provide comparative analysis based on a cumulative database structure enabling detection of anomalous subject conditions. An array of subject tests can be configured to allow different subject test results to be compared on a multiple display. Near real time monitoring of the subject's physiologic condition can be relayed to a larger screen via HDMI or VGA output.

The software of the preferred embodiment may be configured to output the characterizing data in any one or more of the following forms:

- a) near real-time;
- b) replay of previously recorded characterizing data; and/or
- c) together with mathematically reconstructed waveforms or graphs.

According to a second aspect of the invention, there is provided a method for measuring physiological characteristics, the method comprising the steps of:

engaging a non-invasive monitor(s) with a body, the non-invasive monitor being configured to generate data and monitor signals relating to fluid characteristics in the body;

processing the data to generate characterising analyses relating to at least one of regional fluid volumes, intra/extracellular fluid volume ratios and blood flow; and

outputting the characterizing data.

The step of engaging a non-invasive monitor(s) with the body may include the step of engaging an electrode montage with the body such that any one or more segments of the body are monitored, combining for example a head segment, a chest segment, a splanchnic segment, a pelvic segment and a leg segment.

The chest segment, the splanchnic segment, the pelvic segment and the leg/arm segments may be monitored using an initial instance of the rheoencephalograph, while the head segment may be monitored using a second instance of the rheoencephalograph and doppler.

The step of processing the monitor signals may include the step of processing the monitor(s) signals to generate resistance and reactive capacitance data and to process the

combined waveform data from the rheoencephalograph and doppler and to input that data to generate the characterizing data.

The step of outputting the characterizing data may include the step of normalizing the data and displaying the data visually and/or outputting in a computer readable form.

The characterizing data may be outputted in any one or more of the following forms:

- a) near real-time;
- b) replay of previously recorded characterizing data; and/or
- c) together with mathematically reconstructed waveforms.

It follows that the system and method of the invention output and monitor fluid data, including fluid movement data, between the brain/head, chest, abdomen, pelvis, thigh, lower legs, and arms regions of a body. The output fluid information of these body regions may provide descriptions of the hemodynamic and volume responses in a human body in conjunction with other physiological data.

The output may be used to characterize regional fluid volumes, intra/extracellular fluid volume ratios, hemodynamic status and blood flow in near real time during clinical and research protocols that allow the quantification of segmental blood flows, total segmental volumes, and segmental compartment volumes in near real time. In the event of trauma and in the absence of outward signs of injury, the detection of abnormal blood pooling or flow is critical in the diagnosis and application of specific treatment.

The computer may be programmed with a software product, in accordance with the invention, such that the computer uses a de-convolution algorithm on data obtained from the microprocessor system to obtain parameters for an R-C equivalent circuit used to model the intravascular, interstitial and intracellular fluid spaces.

In one embodiment, the rheoencephalograph will be portable. Furthermore, the rheoencephalograph may be configured to independently monitor the fluid data itself.

The electrode leads may require shielding to prevent interference such as from environmental interference. The electrodes may be disposable EKG electrodes.

The instruments of the system and method may be battery powered, power supply powered, USB powered or a combination. A voltage level indicator may be provided on all battery powered devices (if any) and the voltage level is read prior to conducting tests to ensure adequate battery power is available for the tests.

According to a third aspect of the invention, there is provided a computer program product comprising a computer usable medium including a computer readable program for

measuring physiological aspects, wherein the computer readable program, when executed on a computer, causes the computer to:

process data received from a non-invasive monitor(s) engaged with the body to generate characterizing data relating to at least one of regional fluid volumes, intra/extracellular fluid volume ratios and blood flow; and
5 output the characterizing data.

The computer readable program, when executed on a computer, may cause the computer to output the characterizing data in one of the following forms:

- a) near real-time
- 10 b) a replay of previously recorded characterizing data
- c) together with mathematically reconstructed waveforms.

The following description is not intended to limit the scope of the above paragraphs or the scope of the claims. As such, the purpose of the following description is to describe to a person of ordinary skill in the art how to put an embodiment of the invention into practice.

15

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be more readily understood and put into practice, one or more preferred embodiments thereof will now be described, by way of example only, with
20 reference to the accompanying drawings, in which:

Figure 1 shows a system, in accordance with the invention, for measuring physiological characteristics.

Figure 2 shows one possible example of an electrode montage of the system, in use.

Figure 3 shows an output of a unique new waveform generated by the coupling of the
25 rheoencephalograph and doppler waveform segments.

Figure 4 shows a flow chart indicating an initial stage of a method, in accordance with the invention, carried out by a system, also in accordance with the invention, when a software product, also in accordance with the invention, is executed by components of the system.

30 Figure 5 shows a flow chart indicating a log in stage of the method of Figure 4.

Figure 6 shows a flow chart indicating a digital control and 'alert settings' stage, a stage for adding nodes and setting dictation characteristics, and a stage for changing sensor settings.

Figure 7 shows a flow chart indicating a stage for capturing data.

Figure 8 shows a flow chart indicating a stage for analyzing data, a stage for carrying out a second phase analysis on the data, and a comparison phase.

Figure 9 shows a flow chart indicating a stage for either importing or exporting data.

5 Figure 10 shows a flow chart indicating a stage for either e-mailing or printing data.

Figure 11 shows a flow chart indicating a stage for setting up hardware that executes the software product.

Figure 12 shows a flow chart indicating a stage for exiting a software product and a stage for selecting help.

10 Figure 13 shows a system, in accordance with the invention, for measuring physiological characteristics configured for laboratory examination and using the combined waveform from a rheoencephalograph and a transcranial doppler system.

Figure 14 shows one possible example of a portable system for field/emergency examination according to a preferred embodiment.

15 Figure 15 shows the rheoencephalograph of a preferred embodiment connected to a laptop.

Figure 16 shows an output of calculated data generated by the system of figure 13.

Figure 17 shows an output of spectral data generated by the system of figure 13.

20 Figure 18 shows the software test selection and test filter screen graphical user interface according to a preferred embodiment.

Figure 19 shows the calculated CVR Physical (CVR Chemical is available also) in graphical form based on the information contained in the Table illustrated in Figure 20.

Figure 20 shows the extracted data in a table for the R1, R2, and C based on a test performed using the system illustrated in Figure 13.

25 Figure 21 is a schematic illustration of an equivalent electrical circuit of the human brain according to one author.

Figure 22 is a schematic illustration of an equivalent electrical circuit of the human brain according to a second author.

30 DESCRIPTION OF PREFERRED EMBODIMENT

Figure 1 shows broadly, a system, in accordance with the invention, for measuring physiological aspects of a body. The system includes a computer 10 that defines a computational device and a data output device of the invention. Output data 11 generated by

the computer 10 can be graphs displayed on a screen of the computer 10, but may take any suitable form, such as tables or metrics. The computer 10 is connected to Multi Frequency REG rheoencephalograph monitors represented with reference 13 in figure I, via a microprocessor system 14. A doppler system 17 with its own ultrasound sensors 18 is
5 connected via cable 19. The computer 10 can be a stationary desktop model or preferably a laptop computer for portability. For the sake of convenience, the monitors will be referred to as the rheoencephalograph monitor 13 and doppler monitor 17.

In the embodiment shown in figure 1, the cable 12 is connected to the computer 10 using a universal serial bus (USB) interface, but it is envisaged that other interfaces could be
10 used, such as wireless or Bluetooth.

Different frequencies can be selected for use by the Multi Frequency Multi Channel REG monitors 13; however 16Khz, 100Khz, and 200Khz have been found to be the most suitable for the R1, R2 and C calculations. Where the monitor is a multi-frequency bio-impedance monitor, it uses a constant current transformer coupled excitation stage in
15 conjunction with a digital demodulation stage to supply both resistive and reactive impedance components. Thus, the monitor 13 can be configured to generate monitor signals relating to fluid characteristics in the body; in this example, said fluid characteristics being resistive and reactive impedance components. The doppler system 17 stores blood flow data in the form of ultrasound waveform parameters and waveform segments prior to
20 communicating the data to the computer 10 for processing to generate a combined doppler and rheoencephalograph waveform used to then generate characterizing data for on-line near real time analysis and display.

A software product, in accordance with the invention, when executed by the computer 10, uses a de-convolution algorithm applied to the impedance parameters and
25 signal waveform segments to obtain parameters for an R-C equivalent circuit used to model the intravascular, interstitial, and intracellular fluid spaces as well as other required data.

The monitor 13 is connected to a montage 15 having ten electrodes 16. As depicted in figure 2, a suitable electrode montage is provided which divides the body into five segments for segmental blood flows and volume change analysis. These are a head segment
30 20, a chest segment 21, a splanchnic segment 22, a pelvic segment 23, and a leg segment 24. The chest segment 21, splanchnic segment 22, pelvic segment 23, and leg segment 24 of the body are monitored by the monitor 13 using a rheoencephalograph impedance system. The

head segment 20 is monitored by the rheoencephalograph monitor 13 and doppler monitor 17 configuration for monitoring cerebral (head) blood flow responses.

As depicted in figure 14, a suitable electrode montage is provided which attaches to the head and can also be configured to attach to the body segments for segmental blood flows and volume change analysis. Possible configurations are a head segment 20, a chest
5 segment 21, a splanchnic segment 22, a pelvic segment 23, and a leg segment 24. The chest segment 21, splanchnic segment 22, pelvic segment 23, and leg segment 24 of the body are monitored by the monitor 8. Multiple monitors 8 can be used if more channels are required.

Electrodes 25 and 26 are excitation electrodes for supplying a minute electrical
10 charge at different frequencies to the body to be read by the other electrodes.

The electrodes need shielding along the length of the electrode leads to prevent interference and artefacts such as from environmental interference. A suitable electrode is a general purpose disposable EKG electrode.

The unique waveform generated by the combination of the rheoencephalograph
15 monitor 13 and the doppler monitor 17 are represented in figure 3.

A process of Transforming the Wave and a brief Summary thereof is set forth below:

1. Import text data from file or clipboard into IAS - the data is in the form of data points. This includes the Lab Chart header which details channel names and dates.
2. Synchronize the TCD doppler and REG impedance channels by matching the
20 minimum points at the commencement of recorded segment.
3. The X or TCD doppler values are then scaled to cover the full width of the graphing area (preferably the arbitrary range 0 to 2 is used). The Y or REG impedance values are scaled proportionally to match these changes.
4. The Diastolic half of the wave has its REG (rheoencephalograph) values
25 inverted to flip the axis as desired.
5. The Systolic is then plotted on the left side and should fit perfectly if scaled correctly in Step 3.

6. The Diastolic is then plotted on the right; however the ending point may be higher or lower than the baseline of the graph. The final point is extended to match the baseline.

7. The CSFm, angles. Delta V and Delta T are then calculated and displayed.

5 8. Data is saved into a database under the relevant de-identified and encrypted 'Subject' listing for retrieval using a filter query.

Impedance data can be recorded from the body segments in near real time and within a clinical environment. A vector board version can also be used to generate resistance or reactance recordings at various impedance sampling frequencies.

10 An aspect of the invention relates to the manner in which the data is collated and organised for analysis. Accordingly, the software product of the invention is configured to facilitate such collection and organization. Figures 4 to 12 are flowcharts that represent a method of collecting and processing data generated by the invention system. In particular, the software product of the invention is configured so that when executed by at least the
15 computer 10, at least the computer 10 carries out the steps indicated in these flowcharts. For convenience, this example is described assuming that only the computer 10 carries out the steps of the method. Thus, in the following description, the phrase "the computer 10 carries out ..." should be understood to mean that, when the software product of the invention is executed by at least the computer 10, at least the computer 10 carries out the relevant step. In
20 light of that, it is to be appreciated that the steps as set out below can readily be carried out on one or more further dedicated computer components.

In figure 4, reference 30 generally indicates a flow chart representing a data collection method carried out when the software product is executed. At 32, the software product initiates a method by opening the program of the software product. At 34, the
25 computer 10 queries a user as to the time when the collected data was previously backed up. If the response is such that the data was backed up more than a predetermined period of time ago, the computer 10 requests that the user engage some form of removable storage device or media with the computer 10, at 36. If the response is such that the data was backed up less than said predetermined period of time ago, the computer queries as to whether or not the
30 user would like to create a backup, at 38. If the response is positive, the computer requests that some form of removable storage device or media be engaged with the computer 10, at

40. Otherwise, the computer 10 queries as to whether this particular opening is an initial opening at 42.

If the response is positive, the computer 10 requests the input of initial settings at 44. Otherwise, the computer 10 requests that the user log in using his or her log in details at 46
5 (Figure 5). The log in details are preferably any one of fingerprints, iris scans or other biometric identifiers.

The computer 10 then queries whether or not the user is logged in to an existing account at 48. If the answer is negative, the computer 10 creates a new account and/or options to create a new voice profile for dictation and configures the settings at 50.
10 Otherwise, the computer 10 queries whether or not the user wishes to use his or her existing settings, at 52. If the answer is positive, the computer 10 allows for settings to be selected and adjusted and also allows for workflow and set up to be carried out, at 54. Otherwise, the computer 10 makes a number of tabs available for the user at 56.

In figure 6, reference 58 generally indicates a flow chart for allowing a user to select
15 digital control and alert settings. At 60, the computer 10 allows the user to select a particular subject who is being tested. At 62, the computer 10 allows the user to select data for controlling a sequence of steps. At 64, the computer 10 allows the user to set the necessary parameters to trigger events and to set the type of events required. Alerts and a digital device channel are also set and tested. At 66, the computer 10 saves data input at 60, 62, 64 to a
20 database 68. At 70, the computer 10 allows the user to display the data selected with a handheld device. At 72, the results of the selection are displayed on a screen for analysis and results of a digital control sequence are also displayed.

Reference 73 generally indicates a flow chart for allowing a user to add notes and to select dictation settings. At 74, the computer 10 allows the user to select a particular subject
25 being tested. At 76, the computer 10 allows the user to select data for the addition of notes. At 78, the computer 10 allows the user to log into a particular profile of a doctor. At 80, the computer 10 allows the user to select a particular vocal profile. At 82, a computer 10 allows noted to be dictated into patient data. At 84, the computer 10 allows the user to save dictated data to the database 68. At 86, the computer 10 allows the user to display the data selected
30 with a handheld device. At 88, the computer displays the results of the dictation on the screen and the user is permitted to make corrections and to check notes.

Reference 90 generally indicates a flow chart for allowing a user to add notes and to change sensor settings. At 92, the computer 10 allows the user to select a particular subject

being tested. At 94, the computer 10 allows the user to select a particular sensor having settings to be changed. At 96, the computer 10 allows the user to adjust those settings. At 98, the computer 10 tests the settings. At 100, the computer 10 saves the settings. The settings are saved to the database 68 at 102. At 104, the computer 10 allows the user to display the data selected with a handheld device. At 106, the computer 10 displays the results of the sensor settings.

In figure 7, reference 110 generally indicates a flow chart for allowing a user to capture data with the computer 10 executing a software product of the invention.

At 112, the user is prompted to enter information regarding the subject. This can be done by way of drop-downs and checkboxes. At 114, the computer 10 creates a new patient database or adds the patient data to a data base at 116. The computer 10 then queries as to whether the relevant monitor is connected at 118. If the response is negative, the computer 10 generates a warning, at 120, for connection of the monitor to the patient. If the response is positive, the computer 10 generates a number of tabs, at 122 for capturing data. More specifically, the computer 10 generates a "start new session" tab at 124, a "start monitor" tab at 126 and an "analyse data" tab at 128.

If the tab 126 is selected, the computer 10 collects the data at 130. At 132, the user is able to select a command for the computer 10 to allow the user to select data to be displayed using a handheld device at 134. At 136, the results of the data collection are displayed on a screen. If the user selects the command at 132, the computer 10 queries a user as to whether or not he or she wishes to carry out an analysis, at 138. If the response is positive, the computer 10 displays the tab 128. Then, the computer 10 performs the analysis at 140. The user is then prompted to save the results of the analysis, at 142, to the database at 116. Otherwise, the computer 10 returns to the step at 112.

In figure 8, reference 150 generally indicates a flow chart representing the possible steps subsequent to the "analyse data" tab being selected. At 152, the user is prompted to select a subject. At 154, the user is prompted to select, using a handheld device, data to be displayed. At 156, the results of the selection are displayed on a screen and the computer 10 is able to export the data to a spread sheet application. At 158, the computer 10 displays the results of the analysis on a screen. At 160, the results are saved to a database.

Reference 162 generally indicates a flow chart representing the possible steps subsequent to a "second phase analysis" tab being selected. At 164, the computer 10 loads a new session. At 166, the computer 10 allows the user to select a doctor or a database and

also to select a patient and data relating to the patient. At 168, the computer 10 sets parameters and adds relevant mathematical calculations to assist the analysis. Also at 168, channels representing data from different regions sensed by the monitor 13 can be compared. Also, at 168, the computer 10 can add further channels for analysis. At 170, the computer 10
5 allows the user to select the data to be displayed with a handheld device. At 172, the computer 10 displays the results of the selection on a screen. This can be a full replay of the collected data or modified data.

Reference 174 generally indicates a flow chart representing the possible steps subsequent to a "compare" tab being selected. At 176, the computer 10 displays two or more
10 of the channels such that the data represented by the channels can be compared. At 178, the computer 10 allows the user to select a doctor or a database and also to select a patient and data relating to the patient. At 180, the computer 10 allows an option to add a mathematical calculation or algorithm to change the data displayed. At 182, the computer 10 allows the user to select data to be displayed with a handheld device. At 184, the computer 10 displays
15 the results of the selection on screens. As before, this can be a full replay of the collected data or it can be modified data.

In figure 9, reference 190 generally indicates a flow chart representing the possible steps subsequent to an "import/export" tab being selected

At 192, the computer 10 queries whether or not data should be imported. If the
20 response is positive, the computer 10 requests the user to select a source, such as a thumb drive, CD or DVD, at 194. At 196, the computer 10 queries as to whether or not the relevant source is present. If the answer is negative, the user is prompted to engage the relevant source with the computer 10, at 198. If the answer is positive, the computer 10 imports the relevant data, in this case data relating to the subject, at 200. At 202, the computer 10 detects
25 whether or not encryption is present in the source and carries out a decryption process. At 204, the computer 10 confirms successful importation.

If the response to the query at 192 is negative, the computer 10 prompts the user to select a source, such as a thumb drive, CD or DVD, at 206. At 208, the computer 10 queries as to whether or not the relevant source is present. If the answer is negative, the user is
30 prompted to engage the relevant source with the computer 10, at 198. If the answer is positive, the computer 10 exports the relevant data, in this case data relating to the subject, at 210, to the relevant source. At 212, the computer 10 confirms that the data has been exported. At 214, the computer queries whether or not encryption of the data is required. If

the answer is positive, the computer 10 carries out an encryption process at 216. At 218, the computer 10 confirms successful exportation. At 220, the user is prompted to remove the relevant source.

In figure 10, reference 222 generally indicates a flow chart representing the possible steps taken by the computer 10 when an "e-mail" tab is selected. At 224, the computer 10 opens an e-mail form in which a current data result is represented. At 226, the computer 10 prepares the e-mail form for sending, once it has been completed. At 228, the computer 10 queries as to whether or not an e-mail system has been configured. If the response is negative, the computer 10 carries out an e-mail form configuration process at 230, and queries, at 232, as to whether or not the form should be encrypted. If the response is positive, the computer 10 moves directly to the query at 232. If the response to the query at 232 is positive, the computer 10 carries out an encryption process on the form at 234 and sends the e-mail form at 236. If the response to the query is negative, the computer 10 moves directly to the step of sending the e-mail form at 236.

Reference 260 generally indicates a step taken when a "print" tab is selected. At 262, the computer 10 prints or exports currently displayed data to a printer or to a further document.

In figure 11, reference 240 generally indicates a flow chart representing the possible steps taken by the computer 10 when a "program setup" tab is selected. At 242, the computer 10 queries whether or not a communications port has been detected. If the response is negative, the user is prompted to ensure that the monitor is properly attached at 244. If the response is positive, the user is prompted to select the communications port and the monitor system, at 246. At 248, the computer 10 selects relevant system settings for data compatibility. At 250, the computer 10 adds doctor or site data. At 252, the computer 10 writes the setup data to a system configuration file.

In figure 12, reference 260 generally indicates a flow chart representing the possible steps taken by the computer 10 when an "exit program" tab is selected. At 262, the computer 10 queries whether or not a backup of the data should be created. If the response is positive, the computer 10 prompts the user, at 264, to insert the relevant removable media to which the data to be backed up is to be written. Also at 264, the data to be backed up is written to the removable media. The computer 10 exits the program at 266. If the response is negative, the computer 10 moves directly to the step at 266.

Reference 270 shows the possible step taken when a "program help" tab is selected. The computer 10 generates a detailed HTML help system that is itemised with training videos, troubleshooting and setup instructions, at 272.

The invention may be useful in the treatment of diverse pathophysiologic fluid
5 volume states including, for example, the management of increased intracranial pressure following trauma, the treatment of disequilibrium and hypotension during renal dialysis, the monitoring of the hydrational state of premature infants, and the investigation and diagnosis of orthostatic intolerance associated with dysautonomia.

The impedance/doppler system can be used to assess the possible compartment
10 changes monitoring two body segments at the same time. In this way, it will provide information regarding the fluid volume redistribution between two body segments in addition to the extent of intra/extravascular fluid shifts within a single body segment. In order to achieve this, the software product of the invention can be configured to be executed by the monitor 13. Thus, the monitor 13 can be configured to cooperate with other
15 equipment to administer treatment to the subject. An example of this would be a dosage meter. In one embodiment, all computer programming will be applied to a small, portable system that can be used to monitor the intra/extravascular compartment volumes.

By continuous measurements of segmental blood flow and fluid volume changes, it will be possible to assess all of the individual fluid compartments of the body in terms of
20 intracellular volume, interstitial volume, and intravascular volume.

Other areas of potential application of the invention include the hydration state of premature infants and burn patients, quantification of segmental and cerebral fluid shifts that take place during orthostatic tests and exposure to microgravity, and the assessment of various countermeasures designed to reduce the stress of re-entry.

25 The methodology explained above can be used with an alternative monitor in the form of a rheoencephalograph. Normally, at least a portion of the montage of electrodes are provide on a head band or similar attachment method adapted to be worn continuously by a test subject for the data collection period. The head band may further include positioning portions to ensure as much as possible that the electrodes are positioned correctly on the
30 subject's head for maximal data collection and accuracy.

Figure 13 shows, broadly, a system, in accordance with the invention, for measuring physiological aspects of a body. The system includes a computer 10 that defines a computational device and a data output device of the invention. Output data 11 generated by

the computer 10 can be graphs displayed on a screen of the computer 10, but may take any suitable form, such as graphs, tables or metrics. The computer 10 is connected to a rheoencephalograph 8. The computer 10 can be a stationary desktop model or preferably a laptop computer for portability. For the sake of convenience, the rheoencephalograph will be referred to as the monitor 8.

In the embodiment shown in figure 13, the cable 12 is connected to the computer 10 using a universal serial bus (USB) interface, but it is envisaged that other interfaces could be used, such as wireless or Bluetooth.

Different frequencies can be selected for use by the monitor 8, however 16Khz, 100Khz, and 200Khz have been found to be the most suitable for the R1, R2 and C calculations. Where the monitor(s) is a bio-impedance monitor, it uses a constant current transformer coupled excitation stage in conjunction with a digital demodulation stage to supply both resistive and reactive impedance components. Thus, the monitor 8 can be configured to generate monitor signals relating to fluid characteristics in the head or body; in this example, said fluid characteristics being resistive and reactive impedance components. The microprocessor system 14 stores data in the form of impedance parameters and signal waveform segments carried by the monitor signals prior to communicating the data to the computer 10 for processing to generate characterizing data for on-line near real time analysis and display.

The software in accordance with the invention, when executed by the computer 10, uses a de-convolution algorithm applied to the impedance parameters and signal waveform segments to obtain parameters for an R-C equivalent circuit used to model the intravascular, interstitial, and intracellular fluid spaces.

The rheoencephalograph 8 is connected to a montage 15 having multiple electrodes 16. As depicted in figure 13, a suitable electrode montage is provided which attaches to the head and can also be configured to attach to the body segments for segmental blood flows and volume change analysis.

The system illustrated in Figure 13 shows a system, in accordance with the invention, for measuring physiological characteristics configured for laboratory examination and proof of concept. Specifically, the montage 15 is connected to a rheoencephalograph system 1801 but also to a TCD 1800 (transcranial doppler) system with a dedicated laptop for the TCD. The waveform segment from the rheoencephalograph and the doppler are combined in a

transforming process to create a new unique wave which is then used to generate additional data and display and save this data for comparative analysis.

The rheoencephalograph laptop with the software for collating, calculating and displaying the physiological data is provided in association with the rheoencephalograph system but separately from the TCD in order to provide separate waveform captures for combination and further calculation of desired physiological characteristics. Other measurements can be taken such as through use of an electroencephalogram or EEG as illustrated.

Figure 14 shows a portable configuration wherein the rheoencephalograph is battery powered, as is the portable computer, touchpad or smartphone.

Both devices in this example are battery powered. The rheoencephalograph in this example is using the automated calculation function in the software to perform the necessary calculations on this data and compute values for R1, R2 and C from this data and plot the changes during any single selected cardiac cycle.

The software is capable of being deployed on multiple platforms and can convey data feeds to a network for further analysis by a laboratory or display the subject's physiological data on its own screen.

Impedance data can be recorded from the head and body segments in near real time and within a clinical environment or in a field location. The data once saved to the database can be used to produce a calculation on selected parameters, produce spectrum and CVR graphs, and provide an interface whereby the user can view comparative tests or weigh the subject's results against a cumulative database to detect anomalous results.

The rheoencephalograph has the capacity to record steady state resistance on each frequency as well as the pulsing wave on 3 frequencies. The steady state resistance values will be received at a frequency of 100 times per cardiac cycle. Software has been automated to perform the necessary calculations on this data and compute values for R1, R2 and C from this data and plot the changes during any single selected cardiac cycle. The software product of this invention allows for configuration of the rheoencephalograph, control of the frequency selection, and retrieval, display and storage of the impedance data in a configurable graphed or tabled format.

The software is capable of exporting and importing data from other systems, automating backup procedures, capturing additional data for subjects using forms, has

provision for administrators to create new test protocols and can create a cumulative database.

Example output results from the software are shown in Figure 16 selected wave segment with calculated data displayed including these details:

- 5 · Test Identifier
- Subject Identifier
- Test Type
- Systolic Graph
- Diastolic graph
- 10 · CCe
- Angle of systolic
- Frequency of captured test
- CSFm
- Delta T
- 15 · Time of the test (taken from recording track)
- CBF
- p_i

Figure 17 shows a Spectral Analysis example including details:

- Primary Cardiac
- 20 · Respiratory
- Slow fluctuation
- 2nd Harmonic

Figure 18 shows the software graphical user interface screen for test selection and allows for "Filtering" of subjects so that a comparative display of tests can be arranged. The
25 "Test Summary" portion displays the tests that have been performed for this subject.

Figure 20 displays an output table of CVR (physical) test results. CVR (Chemical) test results can be obtained also by selecting that function in the software.

Figure 19, shows the resultant figures generated for R1, R2, and C (capacitance) from the information provided in the table in Figure 20.

30

It is to be understood that the terminology employed above is for the purpose of description and should not be regarded as limiting. The foregoing embodiments are intended

to be illustrative of the invention, without limiting the scope thereof. The invention is capable of being practised with various modifications and additions as will readily occur to those skilled in the art.

Accordingly, it is to be understood that the scope of the invention is not to be limited
5 to the exact construction and operation described and illustrated, but only by the following claims which are intended, where the applicable law permits, to include all suitable modifications and equivalents within the spirit and concept of the invention.

It is envisaged that, although the invention has been described with particular reference to humans, it may also be applied to other bodies, such as animals.

10 Throughout this specification, including the claims, where the context permits, the term "comprise" and variants thereof such as "comprises" or "comprising" are to be interpreted as including the stated integer or integers without necessarily excluding any other integers.

CLAIMS

1. A system for measuring physiological aspects, the system comprising:
 - a. a non-invasive monitor consisting of and configured to capture impedance data on at least three different frequencies;
 - 5 b. a computational device operatively connected to the monitor and configured to process the impedance data to generate characterizing data relating to at least one of regional fluid volumes, intra/extracellular fluid volume ratios and blood flow; and
 - 10 c. a data output device connected to the computational device and configured to output the characterizing data.
2. The system as claimed in claim 1, which includes at least one excitation electrode for providing an electrical stimulus across selected head or body areas.
3. The system as claimed in claim 1, in which the monitor comprises a number of electrodes that are configured to be placed in a non-invasive manner into operative engagement with the head, body or the head or body, such that at least one electrode engages each of a number of respective segments of the head and the body.
- 15 4. The system as claimed in claim 1, in which the monitor is configured to record steady state resistance on each frequency as well as pulsing wave resistance on at least three different frequencies.
5. The system as claimed in claim 1, in which the monitor is configured to use at least three different frequencies between 16 and 400 kHz.
- 20 6. The system as claimed in claim 1, in which the monitor operates to capture impedance data on at least three different frequencies simultaneously.
7. The system as claimed in claim 1, in which the monitor is electronically switched automatically between the at least three frequencies at an adjustable rate to capture impedance data on at least three different frequencies.
- 25 8. The system as claimed in claim 1, in which the impedance data includes capacitance and resistance for different tissue structures.
9. The system as claimed in claim 1, in which the data output device is configured to:
display characterizing data for head and body segments;
process the waveform from the rheoencephalograph and the doppler; and

create a new unique waveform from which additional physiological data can be calculated.

10. The system as claimed in claim 1, in which the system is configured to store data in the form of impedance parameters, signal waveform segments, computed tabled data, raw
5 data, graphed data and provide cumulative analysis using a database with extended functionality designed for the purpose of grouping and displaying anomalous tests when weighted against the database mean and averaged results of groups within said database.

11. The system as claimed in claim 1, in which the data output device is configured to output the characterizing data in one or more of the following forms:

- 10 a) near real-time;
b) re-play of previously recorded characterising data;
c) mathematically reconstructed waveforms.

12. The system as claimed in claim 4, wherein the steady state resistance values are captured at a rate of 100 times per cardiac cycle.

15 13. The system as claimed in claim 1, wherein the non-invasive monitor separately monitors the left hemisphere and the right hemisphere of the head.

14. The system as claimed in claim 1, wherein the at least three frequencies used are 16Khz, 100Khz and 200Khz.

20 15. A method for measuring physiological characteristics, the method comprising the steps of:

- a. engaging at least one non-invasive monitors with a body, the non-invasive monitor being configured to capture impedance data relating to the body on at least three different frequencies;
b. processing the captured impedance data to generate characterizing data relating
25 to at least one of regional fluid volumes, intra/extracellular fluid volume ratios and blood flow; and
c. outputting the characterizing data.

30 16. The method as claimed in claim 15, in which the step of engaging the at least one non-invasive monitors with a body includes the step of engaging an electrode montage with the head or body such that at least two of several segments of the head or body are monitored, with at least a head segment monitored and the other of at least one segment chosen from the group including a chest segment, a splanchnic segment, a pelvic segment, a leg segment or an arm segment.

17. The method as claimed in claim 16, in which the electrode montage includes at least two electrodes placed into engagement with each of a head segment and at least one other segment.

18. The method as claimed in claim 15, in which the step of processing the monitor
5 signals includes the step of processing the captured impedance data to generate resistance and reactive capacitance data and to process that data to generate the characterizing data.

19. The method as claimed in claim 15, in which the step of outputting the characterizing data includes the step of normalizing the data and displaying the data visually.

20. The method as claimed in claim 15, in which the characterizing data is outputted in at
10 least one of the following forms:

- a) near real-time;
- b) a re-play of previously recorded characterizing data;
- c) in combination with mathematically reconstructed waveforms.

21. A computer program product comprising a computer useable medium including a
15 computer readable program for measuring physiological aspects, wherein the computer readable program, when executed on a computer, causes the computer to:

- a. process data received from a non-invasive monitor engaged with a body to generate characterizing data relating to at least one of regional fluid volumes, intra/extracellular fluid volume ratios and blood flow; and
- 20 b. output the characterizing data.

22. The computer program product as claimed in claim 21, wherein the data received from the non-invasive monitor is impedance data captured at least three different frequencies.

23. The computer program product as claimed in claim 21, in which the computer readable program, when executed on a computer, causes the computer to output the
25 characterizing data in one of the following forms:

- a.) near real-time;
- b) a re-play of previously recorded characterizing data;
- c) in combination with mathematically reconstructed waveforms.

24. The computer program product as claimed in claim 21, wherein the software enables
30 recording, calculation and display of the characterizing data in a tabled, graphed, or raw data format which can be exported and imported in such a fashion as to allow a cumulative database of impedance test results for examination and analysis.

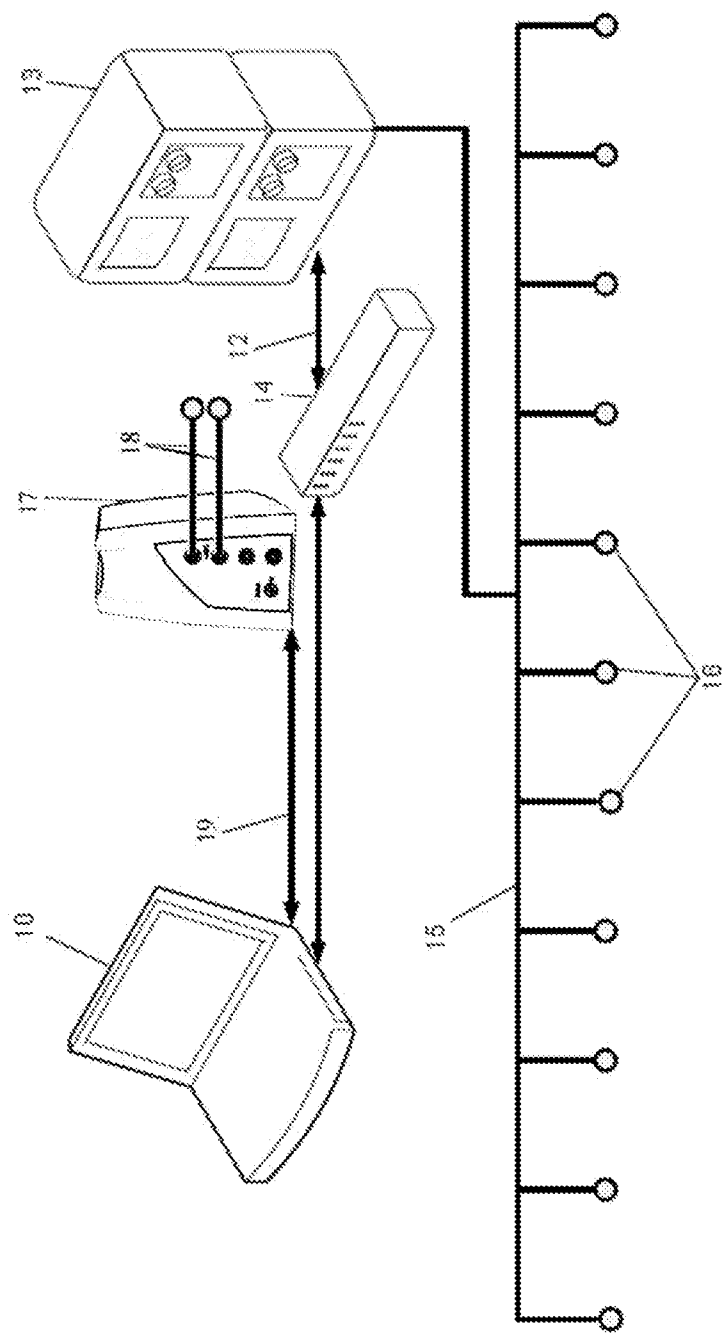


Figure 1

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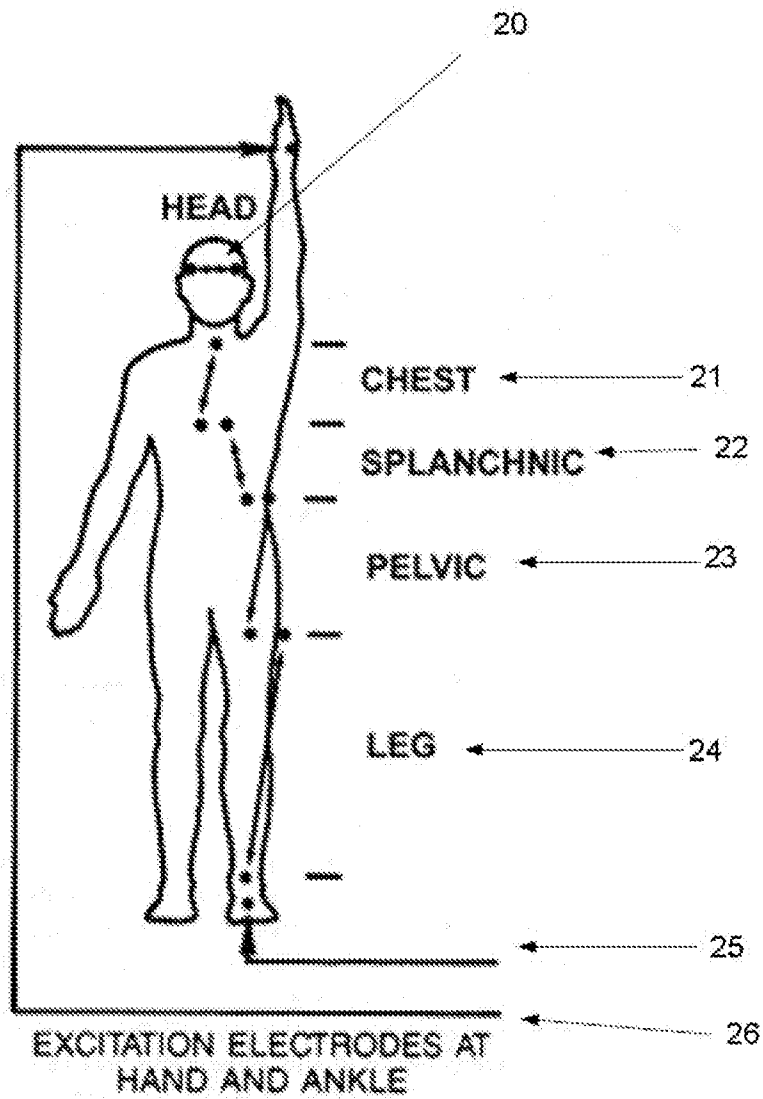


Figure 2

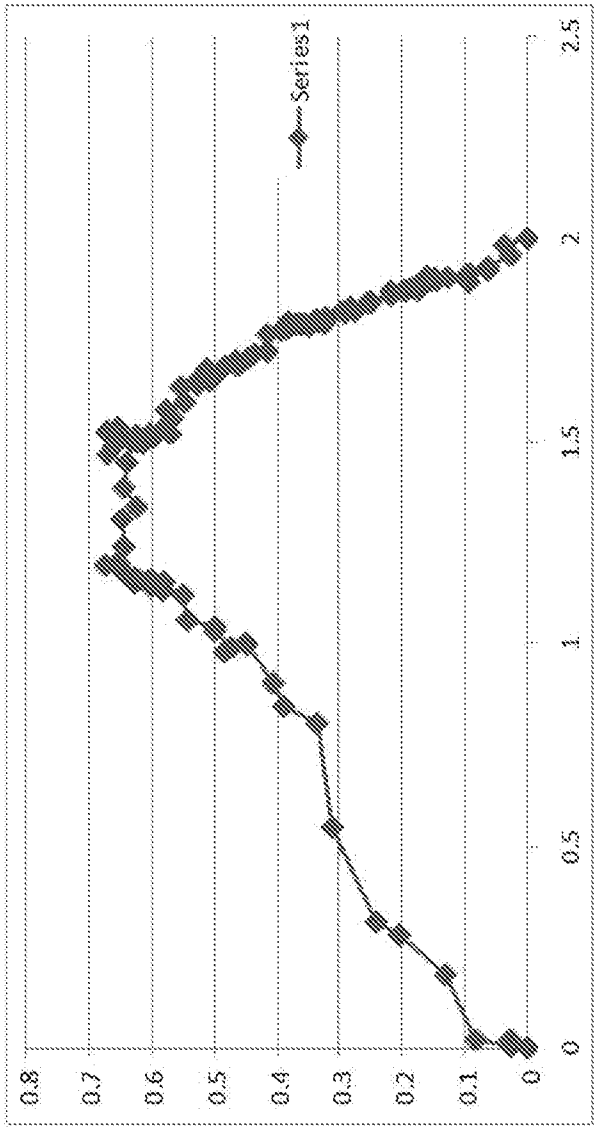


Figure 3

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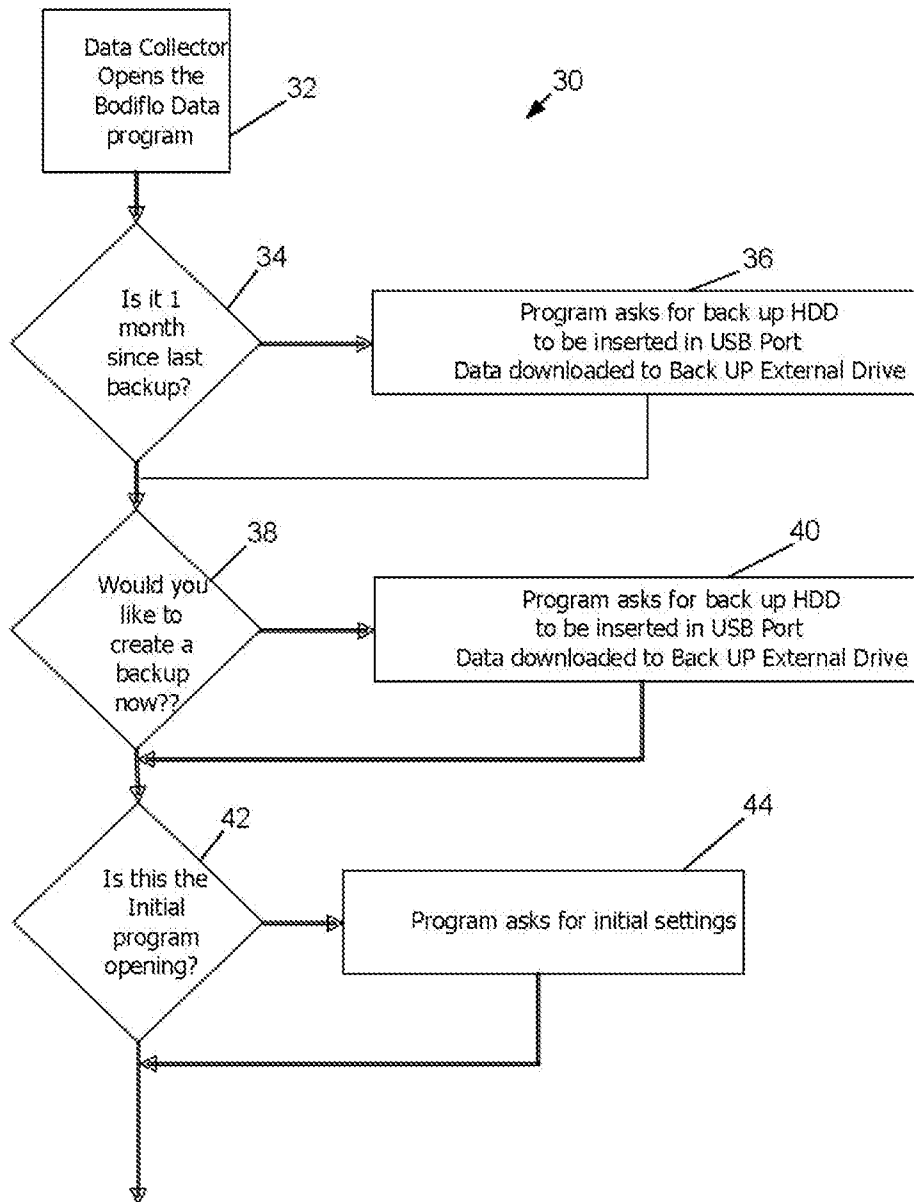


FIGURE 4

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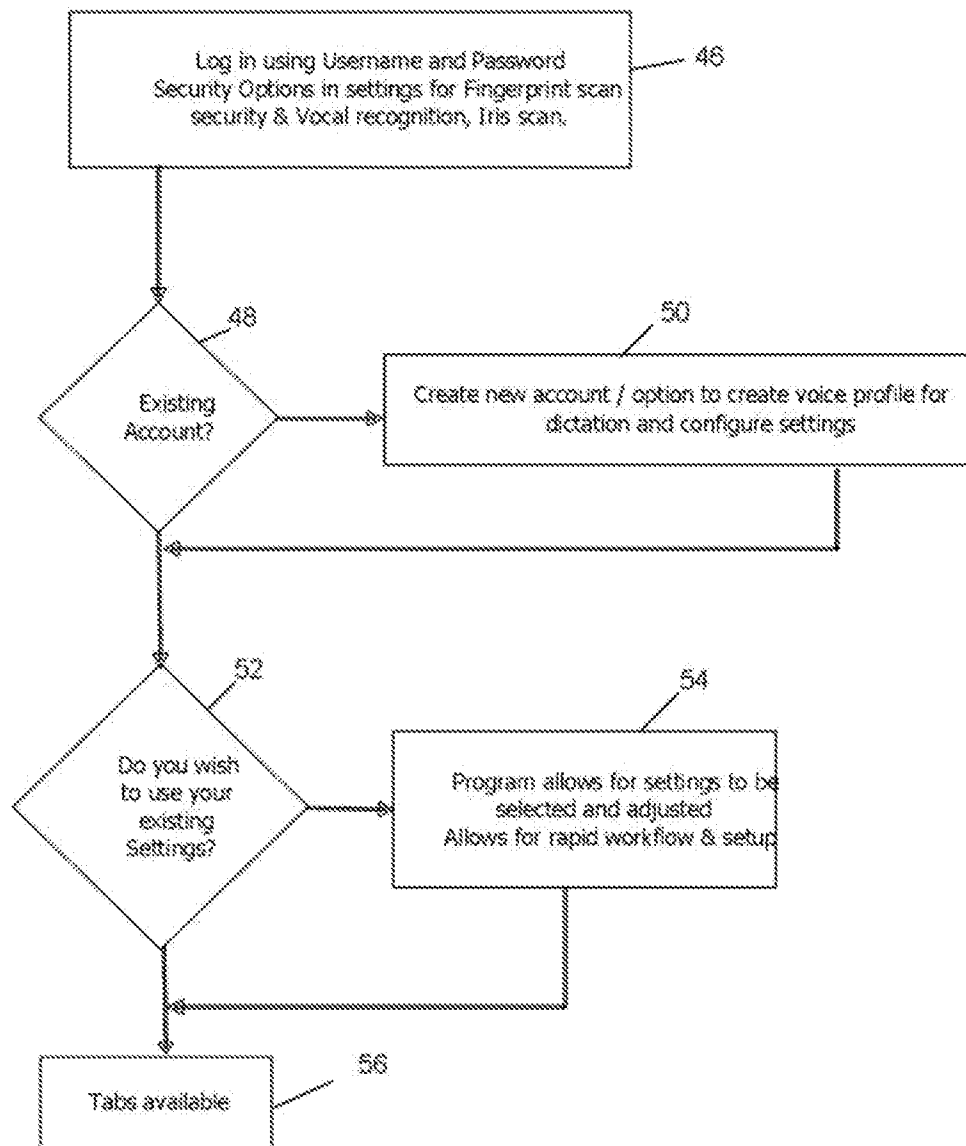


FIGURE 5

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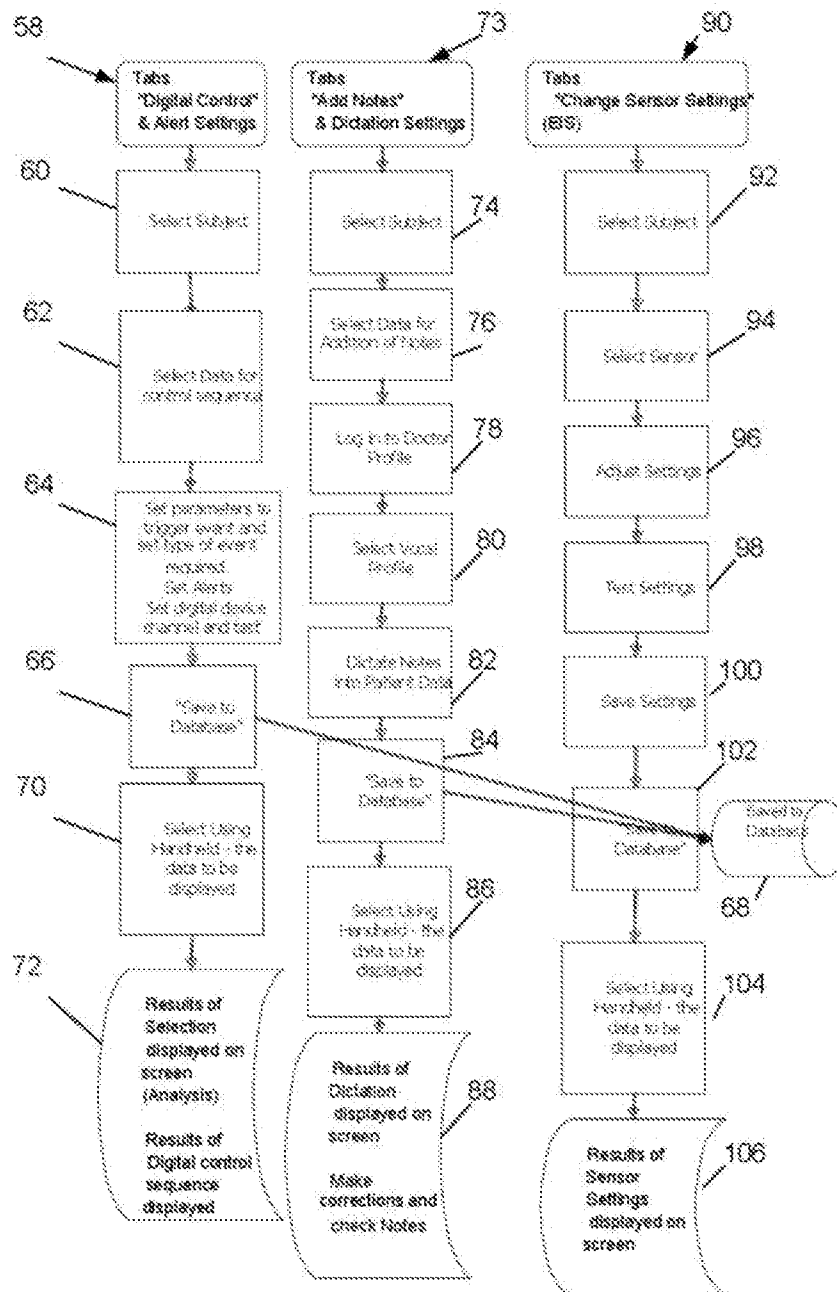


FIGURE 6

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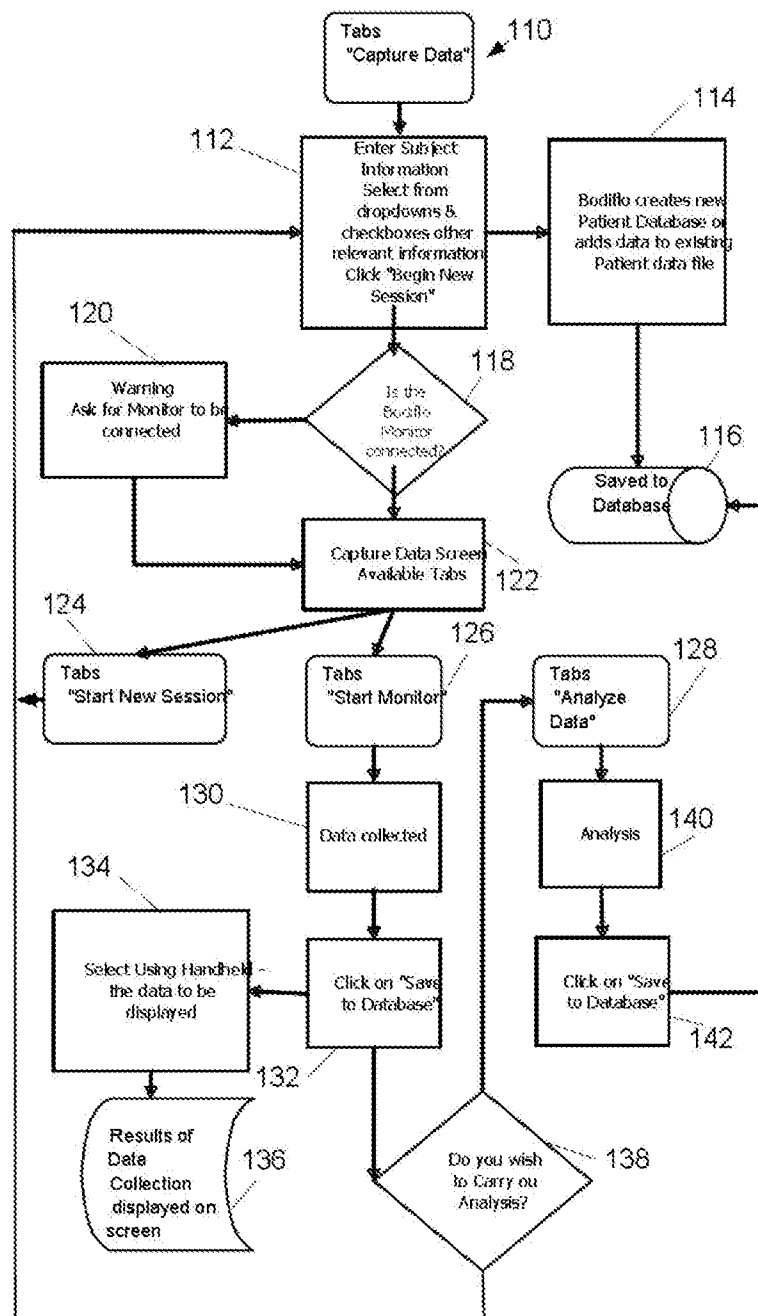


FIGURE 7

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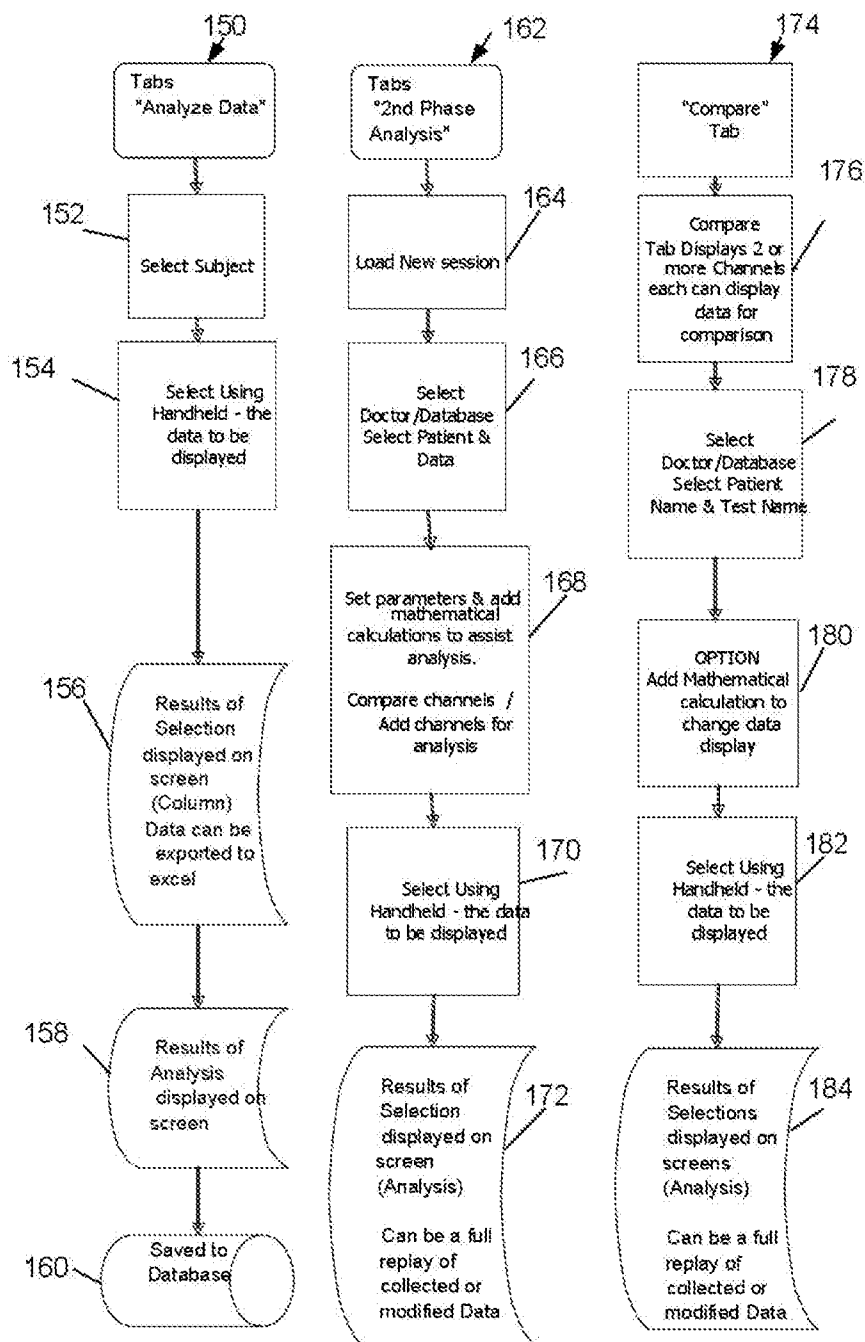


FIGURE 8

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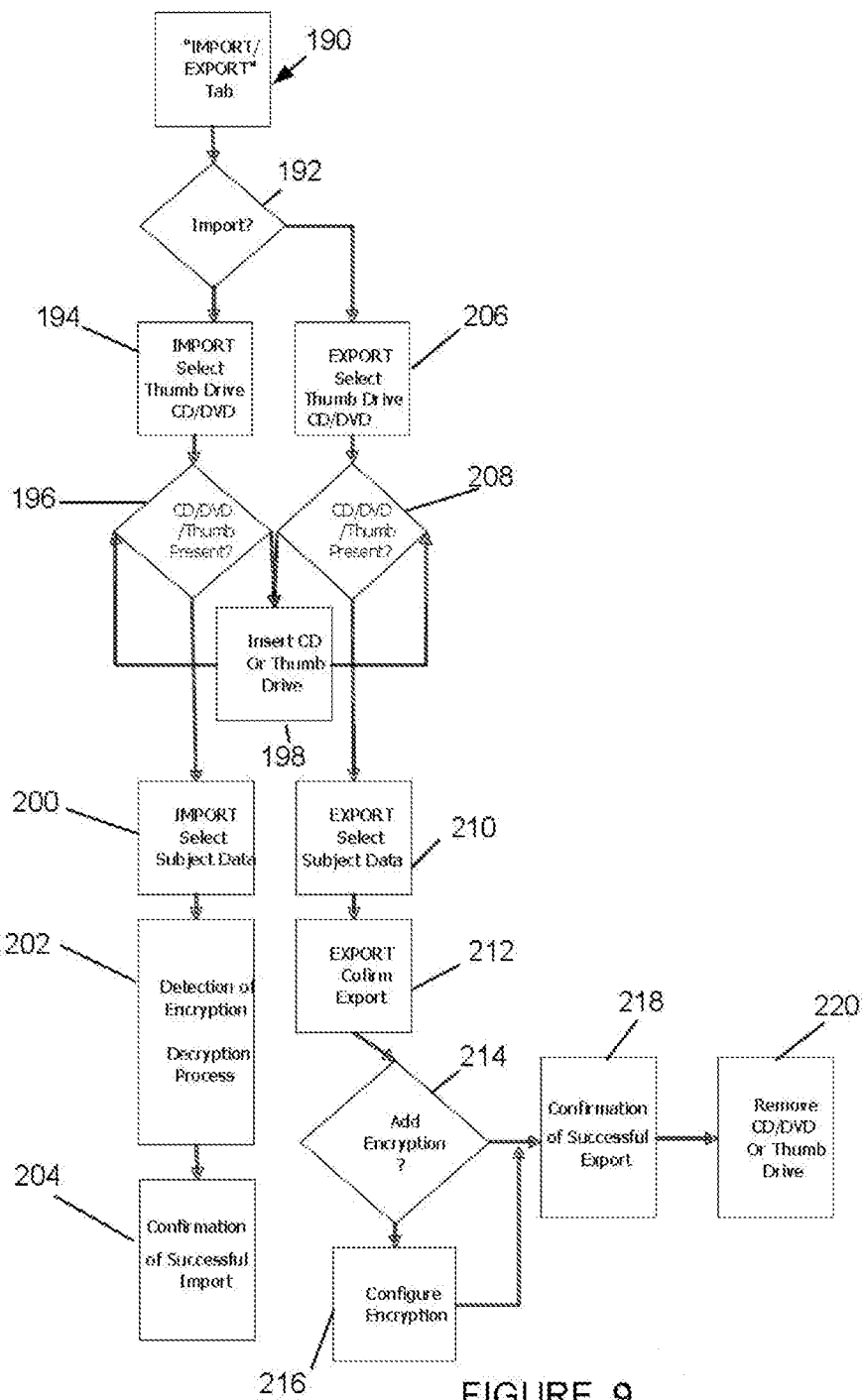


FIGURE 9

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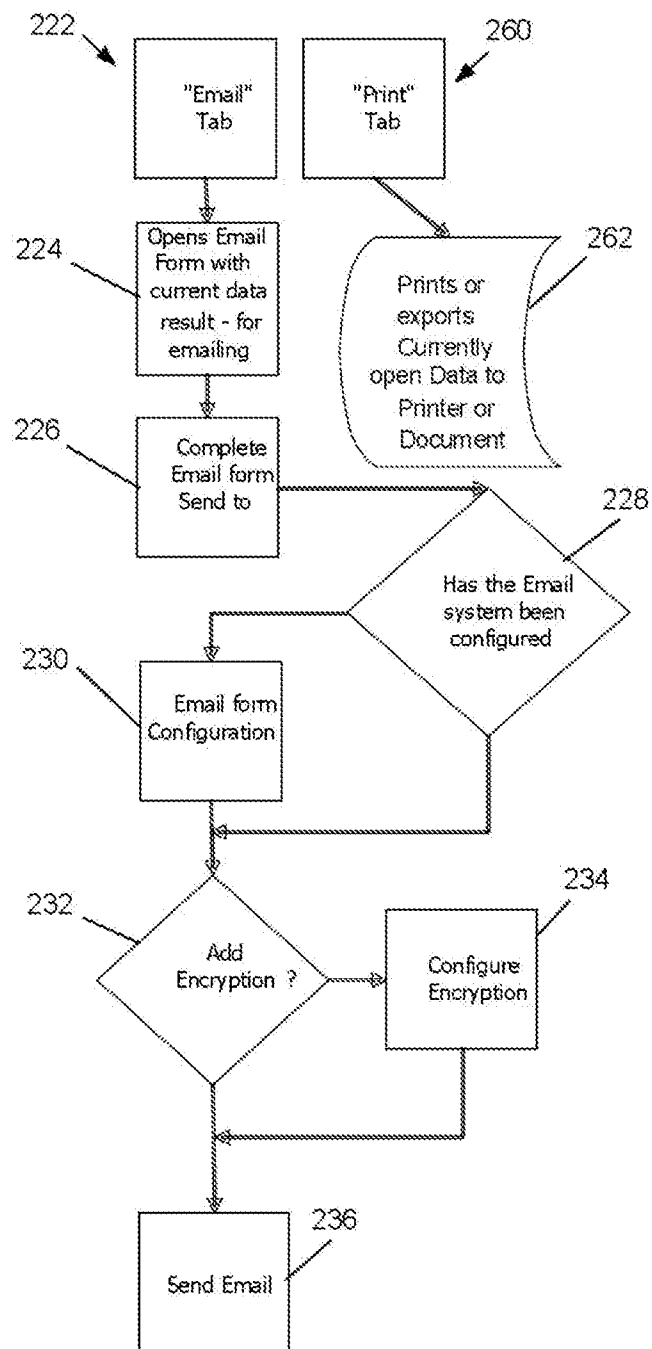


FIGURE 10

11/20

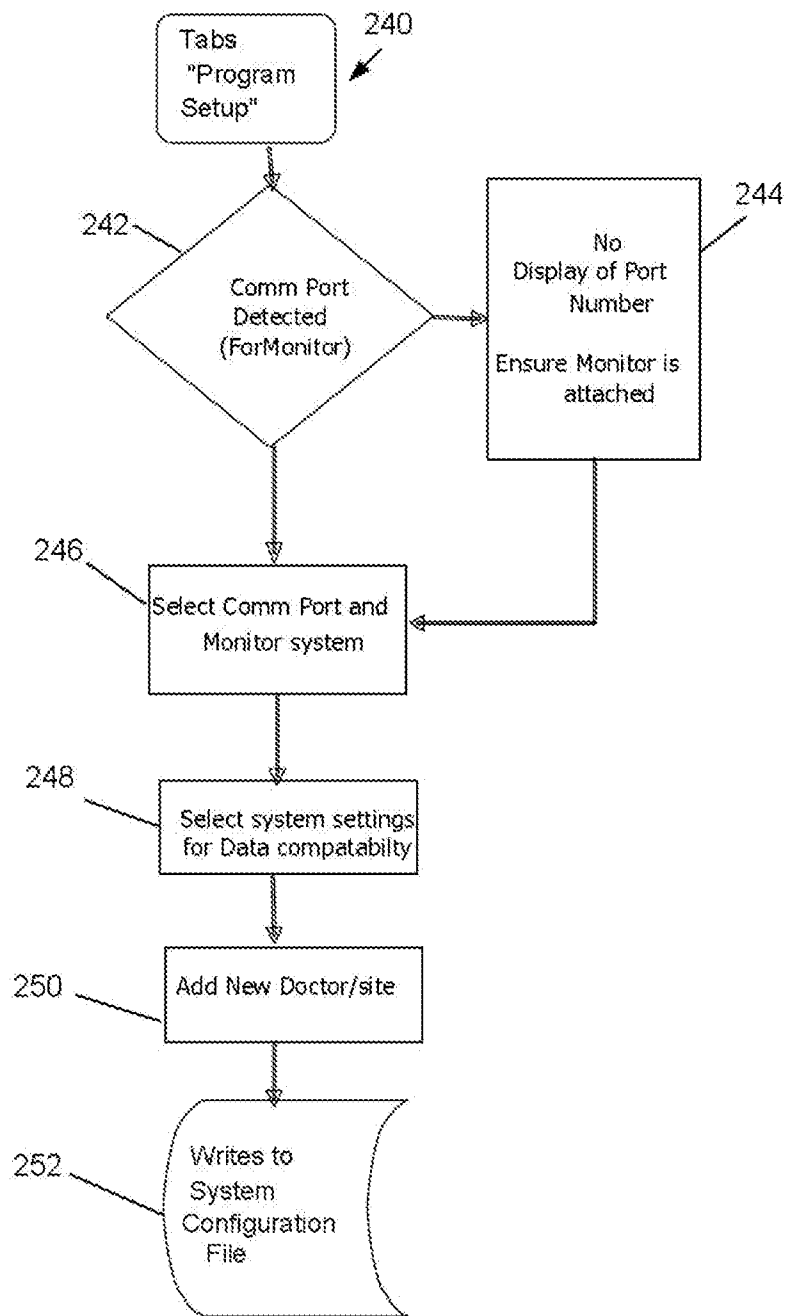


FIGURE 11

12/20

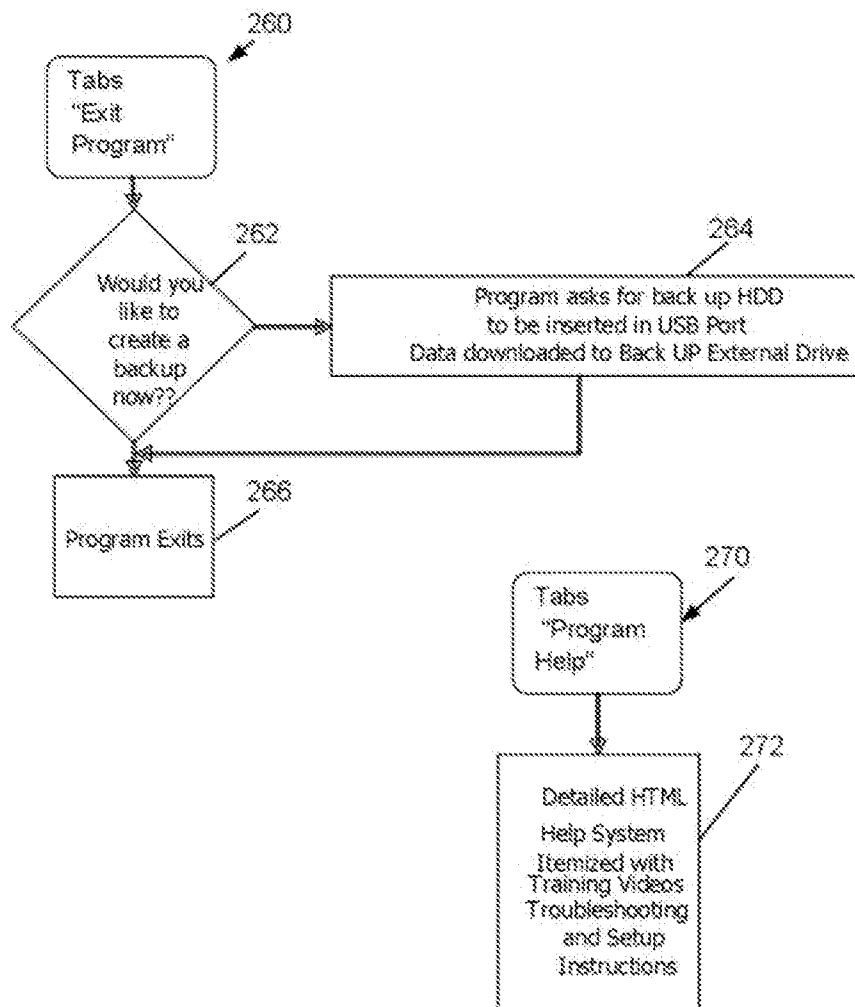


FIGURE 12

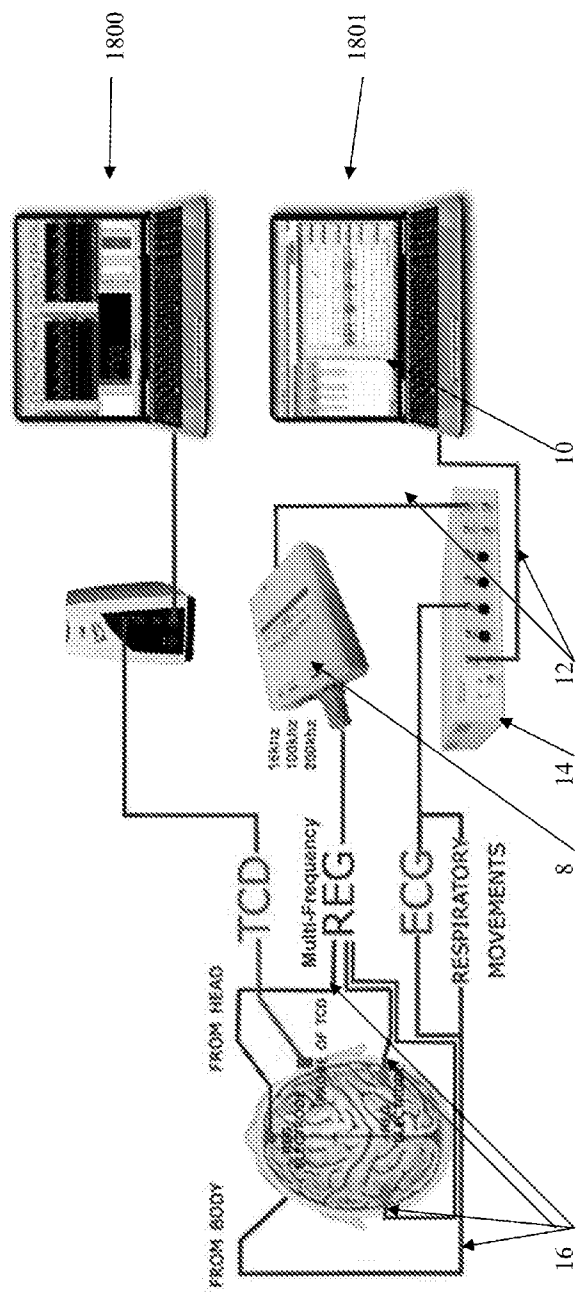


Figure 13

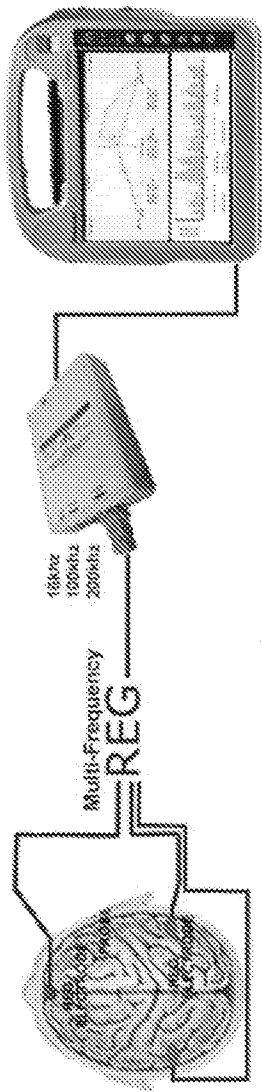


Figure 14

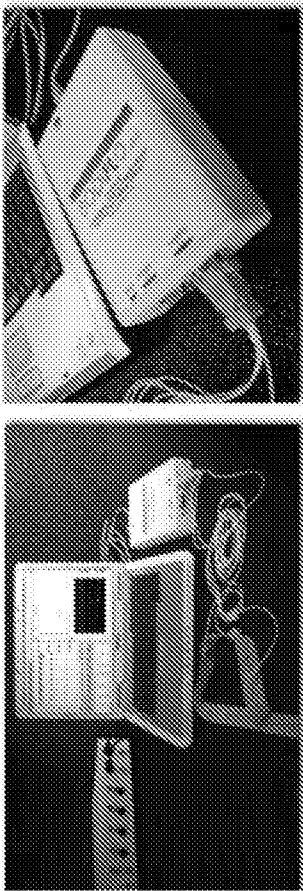


Figure 15

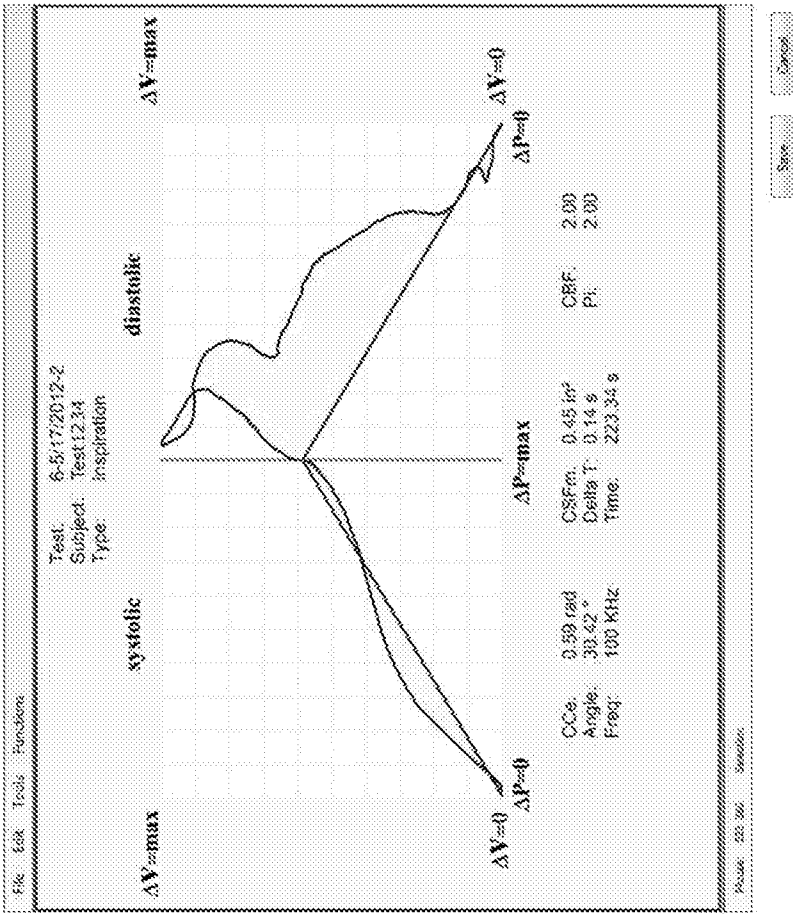


Figure 16

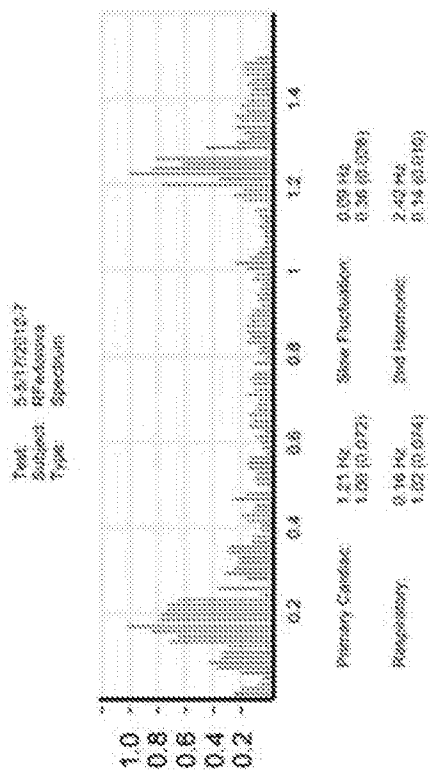


Figure 17

Form with various input fields and sections including:

- General Information**
 - Subject Group: [Dropdown]
 - Subject: [Dropdown]
 - Study ID: [Text]
 - Study Type: [Dropdown]
 - Study Date: [Text]
 - Study Status: [Dropdown]
- Subject Information**
 - Subject ID: [Text]
 - Subject Name: [Text]
 - Subject Date: [Text]
 - Subject Status: [Dropdown]
- Test Parameters**
 - Test ID: [Text]
 - Test Name: [Text]
 - Test Date: [Text]
 - Test Status: [Dropdown]
- Test Results**
 - Test ID: [Text]
 - Test Name: [Text]
 - Test Date: [Text]
 - Test Status: [Dropdown]
 - Test Results: [Table]

Figure 18

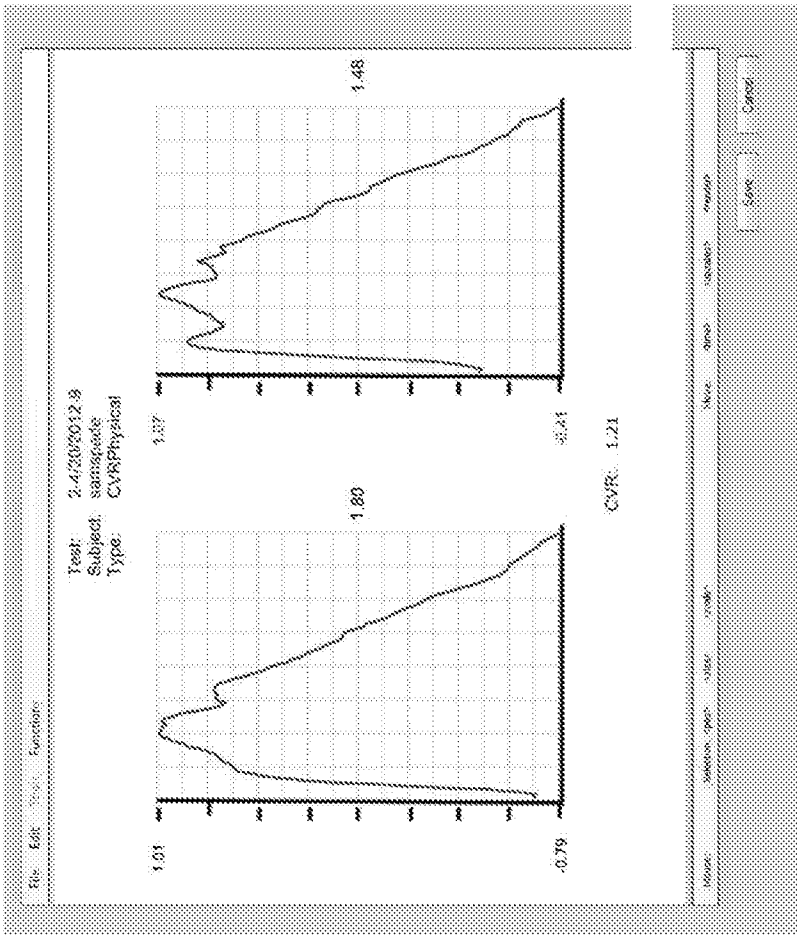
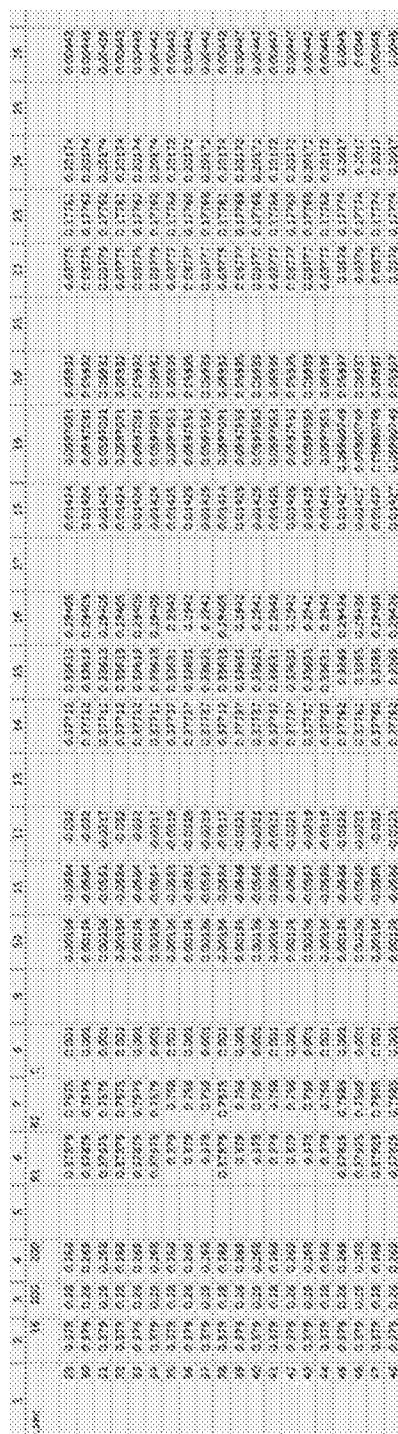


Figure 19



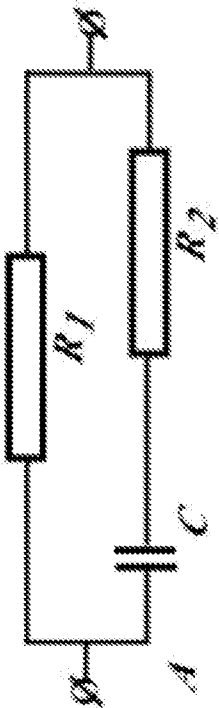


Figure 21

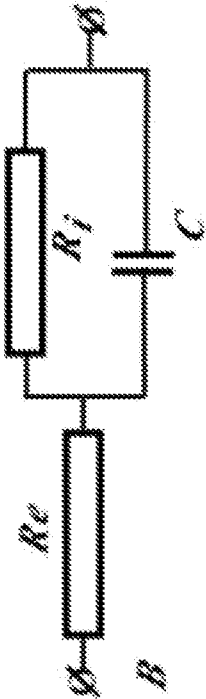


Figure 22

A. CLASSIFICATION OF SUBJECT MATTER**A61B 5/053 (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)

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)

WPI, EPODOC and A61B 5/053/ic, A61B 5/053+/cc and keywords: impedance and multiple and simultaneous and frequency and doppler and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	



Further documents are listed in the continuation of Box C



See patent family annex

* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 17 June 2014	Date of mailing of the international search report 17 June 2014
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustalia.gov.au	Authorised officer David Melhuish AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. 0262832426

INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/AU2014/000298
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	Moskalenko Y, et al. Multifrequency REG: Fundamental Background, Informational Meaning and Ways of Data Analysis and Automation. American Journal of Biomedical Engineering, 2(4) pp 163-174, 2012. paragraphs 1.4, 2.2, 2.4, 2.5 paragraphs 1.4, 2.2, 2.4, 2.5	1, 2, 4 - 15, 18 - 24 3, 16, 17
X Y	US 2005/0177062 A1 (SKRABAL et al.) 11 August 2005 paragraphs 37, 55, 3, 64, 190 paragraphs 37, 55, 3, 64, 190	1 - 3, 5 - 8, 10, 11, 13 - 18, 20 - 24 9
X	WO 2004/047635 A1 (IMPEDIMED PTY LTD) 10 June 2004 page 9 lines 13 to 17	1, 2, 6, 8, 10, 11, 13 - 15, 18, 20 - 24
Y	WO 2003/003920 A2 (GEDEVANISHVILI) 16 January 2003 Figure 1	3, 16, 17
Y	WO 2005/010640 A2 (TSOGLIN et al.) 03 February 2005 Figure 3C	3, 16, 17
Y	Moskalenko Y, et al. Changes of Circulatory-Metabolic Indices and Skull Biomechanics with Brain Activity during Ageing. Journal of Integrative Neuroscience, Vol. 10, No. 2 (2011) pp 131-160. Paragraph 2.5 and Figure 1	9
X	US 2009/0264776 A1 (VARDY) 22 October 2009 paragraphs 5 to 8 and 18	1 - 3, 5 - 8, 10, 11, 13 - 24
P.X	WO 2013/153454 A2 (BEN-ARI et al.) 17 October 2013 paragraphs 8, 37, 46 and 72, claim 27	1, 2, 4 - 8, 10 - 15, 18 - 24

INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/AU2014/000298	
This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.			
Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	Publication Date	Publication Number	Publication Date
US 2005/0177062 A1	11 August 2005	US 7783345 B2	24 Aug 2010
		WO 2004030535 A1	15 Apr 2004
		AT A15172002 A	15 May 2005
		AT 413189 B	15 Dec 2005
		AU 2003266809 A1	23 Apr 2004
		CN 1703165 A	30 Nov 2005
		CN 1703165 B	28 Apr 2010
		EP 1551290 A1	13 Jul 2005
		EP 1551290 B1	27 Aug 2008
		JP 2006501892 A	19 Jan 2006
WO 2004/047635 A1	10 June 2004	AU 2003283079 A1	18 Jun 2004
		CA 2537451 A1	10 Jun 2004
		EP 1565105 A1	24 Aug 2005
		JP 2006507057 A	02 Mar 2006
		US 2006004300 A1	05 Jan 2006
WO 2003/003920 A2	16 January 2003	GE P20032908 B	10 Oct 2002
WO 2005/010640 A2	03 February 2005	EP 1648297 A2	26 Apr 2006
		US 2008009757 A1	10 Jan 2008
		US 8682424 B2	25 Mar 2014
US 2009/0264776 A1	22 October 2009	AU 2009200473 A1	05 Nov 2009
		AU 2013201734 A1	11 Apr 2013
WO 2013/153454 A2	17 October 2013	US 2013274615 A1	17 Oct 2013
End of Annex			
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.			

专利名称(译)	生理特征的测量		
公开(公告)号	EP2976009A4	公开(公告)日	2016-11-30
申请号	EP2014770793	申请日	2014-03-20
[标]申请(专利权)人(译)	VARDY TERENCE		
申请(专利权)人(译)	VARDY , TERENCE		
当前申请(专利权)人(译)	VARDY TERENCE		
[标]发明人	VARDY TERENCE		
发明人	VARDY, TERENCE		
IPC分类号	A61B5/053 A61B5/00 A61B5/0295		
CPC分类号	A61B5/4064 A61B5/026 A61B5/0295 A61B5/0537 A61B5/6814 A61B5/7235 A61B5/742		
优先权	2013201734 2013-03-20 AU		
其他公开文献	EP2976009A1		
外部链接	Espacenet		

摘要(译)

一种用于测量生理方面的系统具有被配置为产生与头部和身体中的流体特性相关的监控信号的非侵入式监控器。计算装置可操作地连接到监测器并且被配置为处理监测信号以产生与区域流体体积，胞内/细胞外液体体积比和血流中的至少一个有关的特征数据。数据输出设备连接到计算设备并且被配置为输出表征数据。还提供了用于记录，测量和显示生理特征的方法和计算机程序产品。