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(54) **Device and method for segmental bioimpedance measurements and cardiac output calculation**

Vorrichtung zur segmentellen Bioimpedanz- und Herzzeitvolumenmessung

Dispositif pour des mesures de bioimpédance segmentaire et calcule du débit cardiaque

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## Description

### Field of the Invention

**[0001]** The present invention relates to a device and method that utilize segmental bioimpedance for calculating cardiac output in individuals.

**[0002]** Bioelectrical impedance analysis (BIA) has been recognized as a noninvasive and simple technique to measure body hydration and hydration status (i.e. over-, under- or normal hydration) of subjects for more than twenty years. There is substantial literature on using BIA for the study of dry weight. Kouw *et al* proposed a method to measure changes in regional conductivity, and then to measure regional extracellular volume (ECV) and intracellular volume (ICV) by BIA. *See*, P.M. Kouw, et al, Assessment of post-dialysis dry weight: an application of the conductivity measurement method. Kidney Int. 41:440-444,1992. However, Kouw's method cannot be used to measure interstitial fluid alone as it does not distinguish between interstitial fluid and plasma, both of which make up the ECV compartment. Piccoli published a method of BIA vector analysis which uses the ratio of resistance to reactance to identify dry weight. While this technique could be used to compare the subjects' body hydration, it is unable to predict individual patient's dry weight because of the significant variation in measured values. *See,* Piccoli A: *Identification of operational clues to dry weight prescription in hemodialysis using bioimpedance vector analysis*. Kidney Int. 5 3:1036-1043,1998.

**[0003]** WO 98/51211 discloses a method for calculating cardiac output and a device according to the preamble of claim 3.

**[0004]** To date, a major problem has been how to measure resistivity of blood and tissue separately, in order to estimate the fluid volume in the intravascular compartment and the interstitial compartment, respectively.
Furthermore, there is lacking an easy-operatable device for measuring the heart rate of a patient ant the cardiac output of a patient using BIA.

**[0005]** The invention is defined in the appended claims.

### Brief Description of the Figures

**[0006]**

Figure 1A and 1B each represent a stylized 3-dimensional view of a body segment, that illustrates the principle of measuring resistivity according to one embodiment of the present invention. Figure 1A represents the situation in which no external pressure is applied to the segment and the blood vessels are uncompressed. Figure 1B illustrates the situation in which external pressure is applied to the segment and the blood vessels are compressed.

Figure 2 is a block diagram of a measurement system according to the present invention.

Figure 3 is a graph showing the change is body segment impedance in relation to the change in body segment blood volume due to arterial pulses.

Figure 4 is a graph showing changes in impedance of a limb segment in relationship to pressure cuff pressure.

Figure 5 is a diagram of a pressure cuff for measurement of the circumference of a body segment and for use in measurement of segmental bioimpedance when the body segment is compressed or uncompressed. Shown is a front view with the covering partially cut away, and in Figure 5A, a partial back view showing the conductive plates.

Figure 6 is a block diagram of a device according to the present invention that also provides a means for determining cardiac output.

### Detailed Description of the Invention

**[0007]** The present invention provides a device for determining and monitoring various physiologic parameters of a patient, including but not limited to heart rate (HR) and cardiac output (CO).

**[0008]** One preferred embodiment of the present invention comprises a means to measure the resistivity of a body segment. The body segment may be the whole body, preferably a limb segment, more preferably a leg or arm segment, and most preferably a thigh segment. As shown in Figure 1A, the resistivity of a body segment is measured by the placement of measurement electrodes at points L1 and L2, separated by a distance L. One of skill in the art will appreciate that while distance L may vary, it is preferably about 10 cm, The resistivity between L1 and L2 is denoted as R. Also shown in Figure 1A is a cross-section of the body segment with the interstitial compartment denoted as T and blood

vessels denoted as B. Optionally, a means to compress the body segment is provided, for example a pressure cuff 3 that surrounds the body segment. When the body Segment is not compressed, for example when the pressure cuff 3 is uninflated, the blood vessels are uncompressed and the resistivity R reflects the resistivity of both the interstitial compartment T and the intravascular compartment B. As shown in Figure 1B, when the body segment is compressed, for example by inflating the pressure cuff, to a pressure above about the systolic blood pressure, optionally up to about 240 mmHg, the blood vessels are compressed and substantially all of the blood volume contained within the intravascular compartment of the body segment is forced out of the body segment. When the resistivity between the electrodes placed at L1 and L2 is measured under such circumstances, the resistivity value $\rho_T$ represents the resistivity of the interstitial compartment of the body segment.

**[0009]** The principle of measurement of segmental bioimpedance provides a means to measure segmental resistivity and may be explained with reference to Figures 1A and 1B. Segmental resistivity is calculated using the formula:

**[0010]** Where $\rho_{measure}$ is the measured segmental resistivity; A is the cross-sectional area of the segment ($A = C^2/4\pi$, where C is the circumference of the segment). When no pressure is applied to the body segment the cross sectional area $A_0$ represents the cross sectional area of the body segment including that of the blood vessels, when pressure of at least systolic blood pressure is applied the cross sectional area $A_p$ is that of the body segment minus the cross sectional area of the blood vessels; R is resistance as measured by bioimpedance analysis; and L is the distance between the measurement points (i.e. the distance between measurement electrodes).

The measured resistivity of the body segment depends on a number of factors including the frequency of the injected current and the body mass index (BMI). Preferably a single frequency, optionally multiple frequencies (multi-frequencies) are used. Injected frequencies from about 1 kHz to about 1000 kHz, more preferably from about 1 kHz to about 50 kHz, most preferably from about 1 kHz to about 10 kHz are utilized. BMI reflects fat content, and is defined as the body weight in kg divided by the square of the height in meters (weight/height$^2$) and is typically measured in kg/m$^2$. In order to distinguish between intravascular and interstitial fluid, preferably the body segment is compressed, optionally by a pressure cuff, preferably a blood pressure cuff (BP cuff) to produce a pressure (P) sufficient to squeeze blood volume out of the studied segment over a few seconds. Thus, two resistivity values can be measured: $\rho_0$ (uncompressed body segment, P = 0 mmHg) and pp (body segment is compressed to a pressure from about systolic blood pressure up to $P_{max}$ = 240 mmHg).

The measurement system comprises a high speed, low noise, acquisition and multi-frequency bioimpedance measurement unit, such as is known to one of ordinary skill in the art, preferably a Xitron 4200s (Xitron Technologies, San Diego, CA). Connected to the bioimpedance measurement unit, the system includes an electrical output means attachable to a body segment, the electrical output means preferably comprising at least two injector electrodes for application to a body segment and for the injection of current into the body segment. The system can apply a single frequency of current, or optionally multiple frequencies of electricity (multi-frequencies) ranging from about 1 kHz to about 1000 kHz, more preferably from about 1 kHz to about 50 kHz, most preferably a single frequency from about 1 kHz to about 10 kHz through the injector electrodes. The system further comprises an electrical input means that is adapted to receive the electrical current transmitted from the output means and through the body segment and to then transmit the current to the bioimpedance analysis measurement unit. The input means comprises at least two measurement electrodes for application to the body segment for the receiving and transmission, to the BIA measurement unit, of current transmitted through the selected segment. The electrodes may be made of Ag/AgCl film, conductive rubber, or other appropriate materials which are readily apparent to one of ordinary skill in the art. The injector and measurement electrodes are connected electrically to the BIA measurement unit. This electrical connection may be accomplished by a number of means readily apparent to a person of ordinary skill in the art, but preferably by electrical cables.

**[0011]** In one preferred embodiment of the present invention, the electrodes are incorporated into a pressure cuff suitable for surrounding and compressing the body segment. A single cable optionally may incorporate both the electrical wires to the injector and measurement electrodes and the air tubing connected to the pressure cuff. Such a cable is used to connect the pressure cuff to the measuring unit and an optional air pump. Alternatively, separate electrical cables and a separate air hose may be employed. Optionally, the pressure cuff incorporates a means for electrically measuring the circumference of the body segment. An example of a preferred pressure cuff configuration 3, which is not intended to be limiting in any way is disclosed in Figure 5. The pressure cuff 3 is a blood-pressure cuff type device that comprises a substantially rectangular form suitable for wrapping around a body segment, such that the body segment is encircled by the device. The pressure cuff is composed of a fabric or other flexible material that preferably is capable of being easily cleaned and/or decontaminated. Material that is suitable will be readily apparent to one of ordinary skill in the art. The pressure cuff also includes a means for securing the device on the body segment, such as a Velcro® system or other such securing system 26, as will be readily apparent to one of ordinary skill in the art. Contained within the pressure cuff 3 is a flexible air-bladder 25 or similar means of compressing the body segment, and applying substantially circumferential pressure of at least about systolic blood pressure to the body segment. The air-bladder is connected to an air hose through which air can be moved to inflate or deflate the air-bladder. The pressure cuff preferably includes at least two injector electrodes 9 and at least two measurement electrodes 10 incorporated therein. The injector and measurement

electrodes are electrically connected, preferably by electrical wires 20 and 21 respectively, to a cable connector 27, or other means of electrically connecting the pressure cuff 3 to a bioimpedance measurement unit. At least one, preferably two conductive bands 24 extend substantially the length of the pressure cuff, such that the length of the bands is at least equal to the smallest normal body segment circumference. The bands are composed of a material of stable resistivity. Suitable material includes Cu-Sc alloy or conductive rubber. Other suitable material will be readily apparent to one of ordinary skill in the art. The pressure cuff also comprises at least one and preferably two conductive plates 28 located at the end of the pressure cuff opposite to the end with the securing means 26. The conductive bands 24 and conductive plates 28 are electrically isolated from one another and each is connected, preferably by wires 22 and 23, respectively, to a means of measuring resistivity. The band(s) 24 and plate(s) 28 are arranged on the pressure cuff, such that when the pressure cuff is wrapped around the body segment, the plate(s) 28 electrically connects with the band(s) 24 at a location or locations along the length of the belt such that the distance, measured along the length of the pressure cuff, from the plate(s) 28 to the point of contact on the band(s) 24 is substantially equal to the circumference of the body segment. The circumference of the body segment then can be determined electrically according to the equation:

Where $L_{b1}$ is the length of the band between the end of the pressure cuff 3 closest to the end where the plate(s) is (are) located and the location at which the plate 28 contacts the band 24;

where R1 is the resistivity of the band between its end closest to the end at which the plate(s) is (are) located and the location at which the plate 28 contacts the band;

where Al is the cross-sectional area of the band;

and $\rho$l is the resistivity of this material.

**[0012]** In this manner, by determining the resistivity of the length of the band(s) that substantially equals the circumference of the body segment, the circumference of the body segment can be determined electrically. In this embodiment, it is preferred that the pressure cuff be securely applied prior to each measurement in order to more accurately measure body segment circumference.

**[0013]** Another embodiment comprises a device for controlling a hemodialysis machine. In this and in other embodiments disclosed herein, an example of a hemodialysis machine suitable for use in or with the invention is that disclosed in U.S. Patent No. 5,580,460 to Polaschegg. An example, which is not intended to be limiting in any way, is depicted in Figure 2. In addition to the BIA measurement unit 1, the measurement system also comprises one or more of an air pump 2 to produce pressure to inflate the pressure cuff 3, a control unit 4 to transfer signals from the microprocessor in order to operate the pump, a microprocessor system 5 which is at least a minimal computer with fast data transfer, rapid access and a memory space sufficiently large to permit the manipulation and analysis of the inputted data, a means of communicating with the dialysis machine 6 whereby control signals are sent to and received from the dialysis machine optionally allowing the control of ultrafiltration rate and other hemodialysis parameters according to body hydration status, a display 7 that shows the result of online measurement and an operation interface 8 to input individual patients' parameters to monitor and control dry weight and optionally a means of communication to a standard personal computer (PC) or other device. Optionally, data including, but not limited to, resistance, resistivity, cuff pressure and heart rate is transmitted to the PC by a RS 232 interface or another standard interface in ASCII or other format such that the waveforms of resistivity, pressure values, heart rates and other parameters can be observed, stored, or manipulated on the PC. The block diagram in Figure 2 shows injector electrodes 9 and measurement electrodes 10, optionally incorporated into the pressure cuff 3. The injector and measurement electrodes are attached, preferably by electrical wiring 11, to the to the output sockets $I_a$ and $I_b$ and input (measurement) sockets $V_a$ and $V_b$ of the BIA measurement unit 1, and the air pump 2 is connected to the pressure cuff by an air hose 12.

**[0014]** In this embodiment, various patient specific parameters are input into the microprocessor system 5 by means of the operation interface 8. Inputted data and other data optionally are displayed in the display 7. The microprocessor system 5 is connected to the BIA measurement unit 1 by a means of transmitting signals to the BIA measurement unit and signaling the BIA measurement unit to send electrical current to the injector electrodes 9. When such an electrical current is sent through the injector electrodes into the body segment, the current is detected by the measurement electrodes and transmitted back to the BIA measurement unit for processing, the derived date being transmitted to the microprocessor system. The microprocessor system is also connected to the pump control unit 4 which is capable of sending signals to the air pump 2 to inflate and deflate the pressure cuff 3, allowing bioimpedance measurements to be made with the pressure cuff inflated and/or deflated. The microprocessor system is also connected to the hemodialysis machine by a communication means 6, whereby signals can be sent to the hemodialysis machine permitting changes in the hemodialysis procedure, such that the patient's hydration status may be altered.

**[0015]** Bioimpedance is measured optionally with the body segment uncompressed or preferably, with the body seg-

ment compressed, preferably by inflation of the pressure cuff. The injection and measurement of current is coordinated to correspond with time points when the pressure cuff is substantially fully inflated or substantially deflated.

**[0016]** To measure resistivity, current is injected into the body segment through injector electrodes and the current transmitted through the body segment is received by the measurement electrodes and transmitted to the BIA measurement unit for calculation of the resistivity of the body segment, the derived data optionally being transmitted to the microprocessor system, which, in turn, according to the method disclosed herein.

**[0017]** It is known that the bioimpedance of a body segment changes as the blood pumped by the heart enters and leaves the body segment with each heart beat. By frequent or continuous injection of current and measurement of segmental bioimpedance, a wave form that reflects the pulse can be derived. Based on this information, the present invention provides a means to determine and monitor the heart rate of a patient prior to, during, or after hemodialysis by means of BIA, according to the equation:

$$HR = 60/(T_{i+1} - T_i)$$

where HR is the heart rate in beats per minute; and $T_{i+1} - T_i$ is the time period between peaks of any two successive heart beat induced impedance waves, $T_i$ and $T_{i+1}$, as shown in Figure 3.

**[0018]** In another embodiment of the invention, BIA is optionally used to determine cardiac output in individuals, including, but not limited to healthy subjects, and dialysis patients prior to, during, or following dialysis, Estimation of CO is based on the assumption that there is a high degree of symmetry in the distribution of blood vessels on both sides of the body and the fact that total blood volume per pulse (stroke volume) can be measured in the segments of the arm ($SV_{arm}$) and leg ($SV_{leg}$) using bioimpedance simultaneously (preferably measuring the stroke volume from an arm and an ipsalateral leg (i.e., on the same side of the body)).

**[0019]** The equation used to calculate cardiac output is:

$$CO = 2 \times HR(k_3 \times SV_{arm} + k_4 \times SV_{leg}) \text{ (L/min)}$$

where $SV_{arm}$ and $SV_{leg}$ are the stroke volume in the arm and in the leg respectively;

$SV_{arm}$ and $SV_{leg}$ are calculated using the following formulas:

$$SV_{arm} = \Delta V_A/N_A \text{ and } SV_{leg} = \Delta V_L/N_L$$

where $\Delta V_A$ is the change in blood volume in the arm and $\Delta V_L$ is the change in the blood volume in the leg between the time point of maximal cuff pressure (shown as segment point A in Figure 4, during which time substantially all the blood volume is squeezed from the limb segment) and the time point when the pressure cuff is deflated (Shown as point B in Figure 4, during which time blood volume is refilled by the stroke volume). $N_A$ and $N_L$ are the number of pulses during changes in impedance from peak point (A) to baseline (B) respectively.

**[0020]** The values for $\Delta V_A$ and $\Delta V_L$ are calculated as follows:

$$\Delta V_A = \rho_b L^2 \Delta Z_A / Z_A^2 \text{ and } \Delta V_L = -\rho_b L^2 \Delta Z_L / Z_L^2 \qquad \text{Equation 1}$$

where $\rho_b$ is the resistivity of blood, L is the length of the body or limb segment between the electrodes, and $Z_A$ and $Z_L$ are each respective impedance values. Calculations of $\Delta V_A$ and $\Delta V_L$ are performed according to the method of J. G. Webster in, Medical Instrumention Application and Design, 3rd Ed., Wiley, New York, 1998 pp. 357 - 362, which is hereby incorporated herein by reference, in its entirety.

**[0021]** The coefficients $k_3$ and $k_4$ are coefficients of calibration for individuals in $\Delta V_A$ and $\Delta V_L$ respectively. The calibration is performed by injecting from about 5 ml to about 150 ml into a vein distal to the arm segment in which resistivity is to be measured, while the resistivity is measured continuously in the arm segment. As the wave of increased volume ($\Delta V$) passes through the segment, there is a change in resistance ($\Delta R$) in relation to the volume injected. Using the

relationship between $\Delta V/\Delta R$, $k_3$ and $k_4$ are calibrated.

**[0022]** The calibrating process provides the information about how a change in resistance per ohm is related to a known change in volume ($\Delta V/\Delta R$). By definition, define $k_c = \Delta V/\Delta R$ as a calibration coefficient, where $\Delta V$ is the volume of injected saline (ml) and $\Delta R$ is the change in resistance in the calibrating segment, Thus, $k_3$ is defined by equation as follows:

$$k_3 = k_c \times \Delta Z_A / (N_A \times V_A)$$

**[0023]** Where $\Delta Z_A$ is the change in impedance in the arm, $V_A$ is volume calculated by set, and $N_A$ is number of pulses. Similarly, the equation $k_4 = k_c \times \Delta Z_L/(N_L \times V_L)$ is used to calibrate for changes in the volume of a leg.

**[0024]** One embodiment of a system such as that disclosed in Figure 2, but additionally being capable of measuring cardiac output is shown in Figure 6. Included are two sets of electrodes 9 and 10 and 9' and 10', preferably incorporated into two pressure cuffs 3 and 3' adapted to be attached to a leg segment (not shown) and to an ipsalateral arm segment (not shown), both sets of electrodes being connected to a digital switch, via wiring 11 and 11', capable of rapidly switching between each set of electrodes, so that measurements may be taken from either the leg segment or the arm segment substantially simultaneously. Preferably the digital switch 30 has the capacity to achieve a sampling frequency of at least about 200 Hz and, more preferably, greater than 1 kHz. Optionally, there is a means to send a control signal from a computer 31 to the digital switch so that the sample frequency can be changed as needed.

## Claims

**1.** A method of calculating the cardiac output of a patient in need thereof comprising the steps of:

measuring the stroke volume in an arm segment by bioimpedance analysis:

substantially simultaneously measuring the stroke volume in an ipsalateral leg segment by bioimpedance analysis;
summing the stroke volume in the arm segment and the stroke volume in the leg segment; and
multiplying the sum by twice the heart rate to obtain the cardiac output.

**2.** The method of claim 1., wherein stroke volume of the arm segment is calculated by
applying an external maximum pressure to the arm segment and determining the change in blood volume in the arm segment between the point of maximum pressure and the point at which no external pressure is applied divided by the number of heart beats between the two points in time, and wherein the stroke volume of the leg is calculated by applying an external maximum pressure to the leg segment and determining the change in blood volume in the leg segment between the point of maximum pressure and the point at which no external pressure is applied divided by the number of heart beats between two points in time.

**3.** A device for calculating cardiac output through bioimpedance measurements of a patient comprising:

a bioimpedance measurement unit;
a first electrical output means being in electrical communication with the bioimpedance analysis measurement unit and being attachable to an arm segment, the first electrical output means being adapted to apply electrical current to the arm segment;
a second electrical output means being in electrical communication with the bioimpedance analysis measurement unit and being attachable to a leg segment, the second electrical output means being adapted to apply electrical current to the leg segment;
a first electrical input means being in electrical communication with the bioimpedance analysis measurement unit and being attachable to an arm segment, the electrical input means being adapted to receive the current transmitted through the arm segment and transmit the same to the bioimpedance analysis measurement unit;
a second electrical input means being in electrical communication with the bioimpedance analysis measurement unit and being attachable to a leg segment, the electrical input means being adapted to receive the current transmitted through the leg segment and transmit the same to the bioimpedance analysis measurement unit;
a first pressure applying means for applying a maximum pressure to the arm segment, the first pressure applying means being in electrical communication with the bioimpedance analysis measurement unit;

a second pressure applying means for applying a maximum pressure to the leg segment, the second pressure applying means being in electrical communication with the bioimpedance analysis measurement unit;
a means for selectively electronically connecting the bioimpedance analysis measurement unit between the first electrical input and output means and the second electrical input and output means;
**characterised by** a unit adapted to sum the stroke volume in the arm segment and the stroke volume in the leg segment and to multiply the sum by twice the heart rate to obtain the cardiac output; and
wherein the bioimpedance analysis measurement unit is adapted to selectively measure stroke volume in the arm and leg segments by bioimpedance analysis.

**Patentansprüche**

1. Verfahren zur Berechnung des Herzminutenvolumens eines Patienten, der dieses benötigt, umfassend die Schritte:

Messen des Schlagvolumens in einem Armsegment mittels Bioimpedanzanalyse;
Im Wesentlichen gleichzeitiges Messen des Schlagvolumens in einem ipsilateralen Beinsegment mittels Bioimpedanzanalyse;
Addieren des Schlagvolumens in dem Armsegment und des Schlagvolumens in dem Beinsegment; und
Multiplizieren der Summe mit der zweifachen Herzfrequenz, um das Herzminutenvolumen zu erhalten.

2. Verfahren gemäß Anspruch 1, worin das Schlagvolumen in dem Armsegment **dadurch** berechnet wird, dass an dem Armsegment ein maximaler äußerer Druck angelegt wird und die Änderung des Blutvolumens in dem Armsegment zwischen dem Zeitpunkt des maximalen Drucks und dem Zeitpunkt, an welchem kein externer Druck angewandt wird, durch die Anzahl der Herzschläge zwischen den beiden Zeitpunkten dividiert wird, und worin das Schlagvolumen des Beines **dadurch** berechnet wird, dass ein äußerer maximaler Druck auf das Beinsegment angewandt wird und die Änderung des Blutvolumens in dem Beinsegment zwischen dem Zeitpunkt des maximalen Drucks und dem Zeitpunkt, an welchem kein externer Druck angewandt wird, durch die Anzahl der Herzschläge zwischen diesen beiden Zeitpunkten dividiert wird.

3. Vorrichtung zur Berechnung des Herzminutenvolumens durch Bioimpedanzmessungen eines Patienten, aufweisend :

eine Bioimpedanzmesseinheit;
ein erstes elektrisches Ausgabemittel, welches mit der Bioimpedanzanalyse-Messeinheit in elektrischer Verbindung steht und an einem Armsegment befestigt werden kann, wobei das elektrische Ausgabemittel so eingerichtet ist, dass elektrischer Strom an das Armsegment angelegt werden kann;
eine zweites elektrisches Ausgabemittel, welches mit der Bioimpedanzanalyse-Messeinheit in elektrischer Verbindung steht und an einem Beinsegment befestigt werden kann, wobei das zweite elektrische Ausgabemittel so eingerichtet ist, dass elektrischer Strom an das Beinsegment angelegt werden kann;
ein erstes elektrisches Eingabemittel, welches mit der Bioimpedanzanalyse-Messeinheit in elektrischer Verbindung steht und an einem Armsegment befestigt werden kann, wobei das elektrische Eingabemittel so eingerichtet ist, dass es den Strom aufnehmen kann, der durch das Armsegment übertragen wurde und diesen zu der Bioimpedanzanalyse-Messeinheit übertragen kann;
ein zweites elektrisches Eingabemittel, welches mit der Bioimpedanzanalyse-Messeinheit in elektrischer Verbindung steht und an einem Beinsegment befestigt werden kann, wobei das elektrische Eingabemittel so eingerichtet ist, dass es den Strom aufnehmen kann, der durch das Beinsegment übertragen wurde und diesen zu der Bioimpedanzanalyse-Messeinheit übertragen kann;
ein erstes Druckausübungsmittel zum Anlegen eines maximalen Drucks an das Armsegment, wobei das erste Druckausübungsmittel in elektrischer Verbindung mit der Bioimpedanzanalyse-Messeinrichtung steht;
ein zweites Druckausübungsmittel zum Anlegen eines maximalen Drucks an das Beinsegment, wobei das zweite Druckausübungsmittel in elektrischer Verbindung mit der Bioimpedanzanalyse-Messeinheit steht;
Mittel, um die Bioimpedanzanalyse-Messeinheit selektiv elektronisch zwischen die ersten elektrischen Eingabe- und Ausgabemittel und die zweiten elektrischen Eingabe- und Ausgabemittel zu schalten;
**gekennzeichnet durch** eine Einheit, die angepasst ist, um das Schlagvolumen im Armsegment und das Schlagvolumen im Beinsegment zu addieren und die Summe mit der zweifachen Herzfrequenz zu multiplizieren, um das Herzminutenvolumen zu erhalten; und
worin die Bioimpedanzanalyse-Messeinheit angepasst ist, um selektiv das Schlagvolumen in dem Arm- und Beinsegment mittels Bioimpedanzanalyse zu messen.

## Revendications

1. Procédé pour calculer le débit cardiaque d'un patient en ayant besoin, comprenant les étapes consistant à :

   - mesurer le débit systolique dans un segment de bras par une analyse de bioimpédance ;
   - mesurer sensiblement simultanément le débit systolique dans un segment de jambe ipsilatéral par une analyse de bioimpédance ;
   - additionner le débit systolique dans le segment de bras et le débit systolique dans le segment de jambe ; et
   - multiplier la somme par deux fois la fréquence cardiaque pour obtenir le débit cardiaque.

2. Procédé selon la revendication 1, dans lequel le débit systolique du segment de bras est calculé en appliquant une pression maximum externe sur le segment de bras et en déterminant le changement du débit sanguin dans le segment de bras entre le point de pression maximum et le point auquel aucune pression externe n'est appliquée, divisé par le nombre de battements cardiaques entre les deux points en même temps, et dans lequel le débit systolique de la jambe est calculé en appliquant une pression maximum externe sur le segment de jambe et en déterminant le changement du débit sanguin dans le segment de jambe entre le point de pression maximum et le point auquel aucune pression externe n'est appliqué, divisé par le nombre de battements cardiaques entre les deux points en même temps.

3. Dispositif pour calculer le débit cardiaque par des mesures de bioimpédance d'un patient, comprenant .

   - une unité de mesure de bioimpédance ;
   - des premiers moyens de sortie électrique qui sont en communication électrique avec l'unité de mesure d'analyse de bioimpédance et qui peuvent être fixés sur un segment de bras, les premiers moyens de sortie électrique étant adaptés pour appliquer du courant électrique sur le segment de bras ;
   - des seconds moyens de sortie électrique qui sont en communication électrique avec l'unité de mesure d'analyse de bioimpédance et qui peuvent être fixés sur un segment de jambe, les seconds moyens de sortie électrique étant adaptés pour appliquer du courant électrique sur le segment de jambe ;
   - des premiers moyens d'entrée électrique qui sont en communication électrique avec l'unité de mesure d'analyse de bioimpédance et qui peuvent être fixés sur un segment de bras, les moyens d'entrée électrique étant adaptés pour recevoir le courant transmis par le segment de bras et transmettre ce dernier à l'unité de mesure d'analyse de bioimpédance ;
   - des seconds moyens d'entrée électrique qui sont en communication électrique avec l'unité de mesure d'analyse de bioimpédance et qui peuvent être fixés sur un segment de jambe, les moyens d'entrée électrique étant adaptés pour recevoir le courant transmis par le segment de jambe et transmettre ce dernier à l'unité de mesure d'analyse de bioimpédance ;
   - des premiers moyens d'application de pression pour appliquer une pression maximum sur le segment de bras, les premiers moyens d'application de pression étant en communication électrique avec l'unité de mesure d'analyse de bioimpédance ;
   - des seconds moyens d'application de pression pour appliquer une pression maximum sur le segment de jambe, les seconds moyens d'application de pression étant en communication électrique avec l'unité de mesure d'analyse de bioimpédance ;
   - des moyens pour raccorder sélectivement électroniquement l'unité de mesure d'analyse de bioimpédance entre les premiers moyens d'entrée et de sortie électrique et les seconds moyens d'entrée et de sortie électriques ;

   **caractérisé par** une unité adaptée pour additionner le débit systolique dans le segment de bras et le débit systolique dans le segment de jambe et pour multiplier la somme par deux fois la fréquence cardiaque afin d'obtenir le débit cardiaque ; et
   dans lequel l'unité de mesure d'analyse de bioimpédance est adaptée pour mesurer sélectivement le débit systolique dans les segments de bras et de jambe par l'analyse de bioimpédance.

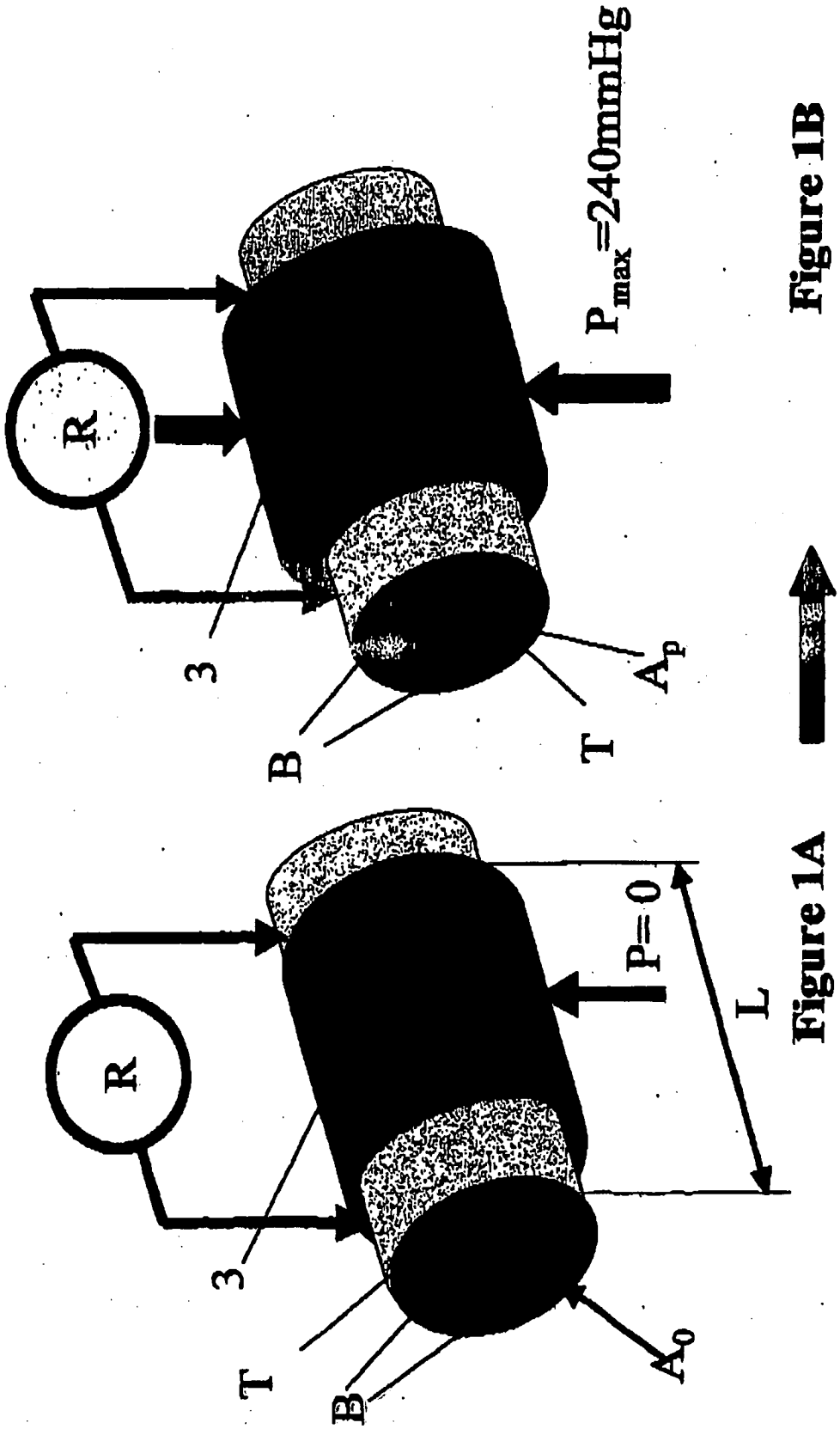


Figure 1B

Figure 1A

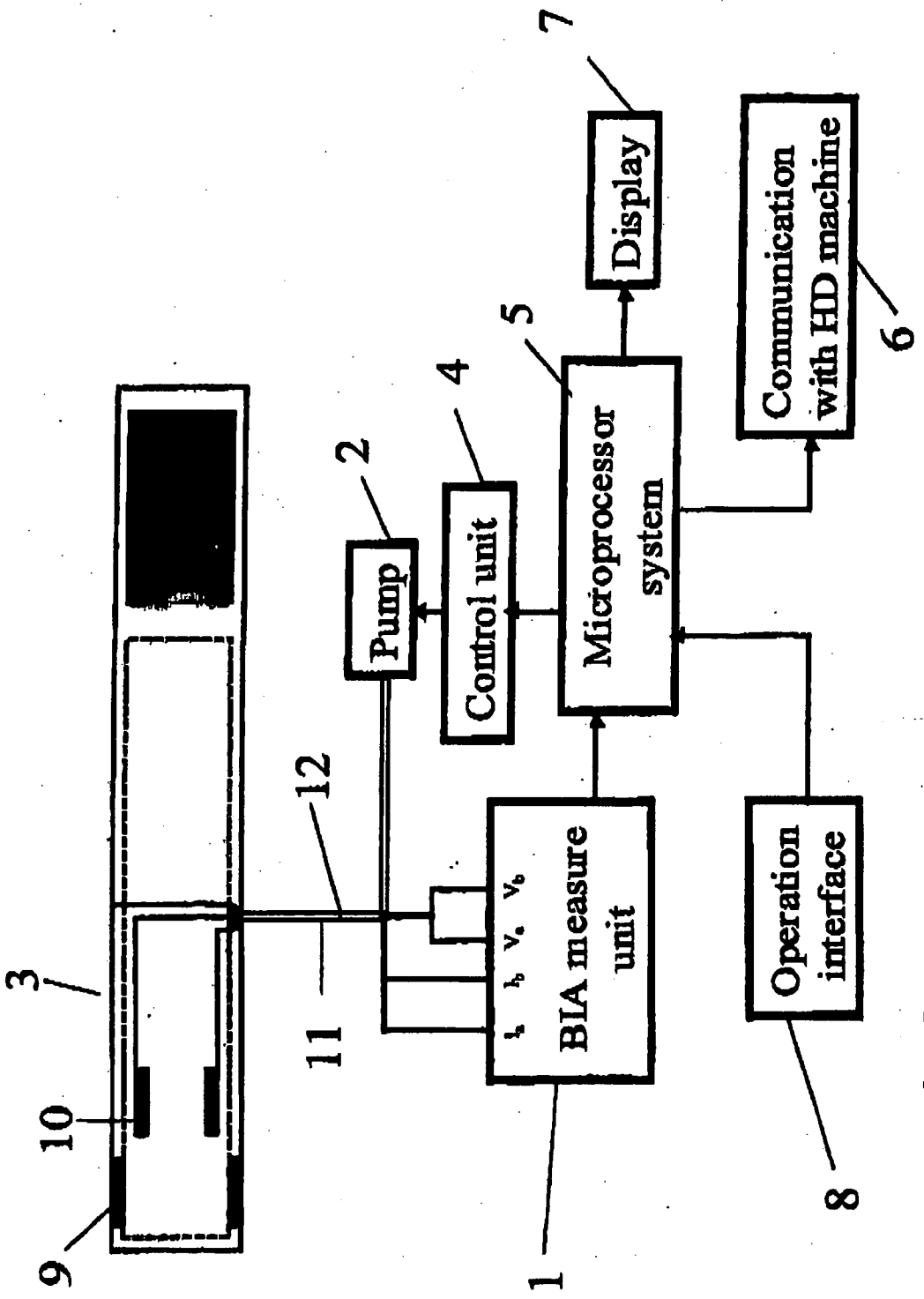
7
Display
Communication with HD machine
6
5
Microprocessor system
4
Control unit
2
Pump
12
11
3
10
9
BIA measure unit
1
Operation interface
8

Fig.2

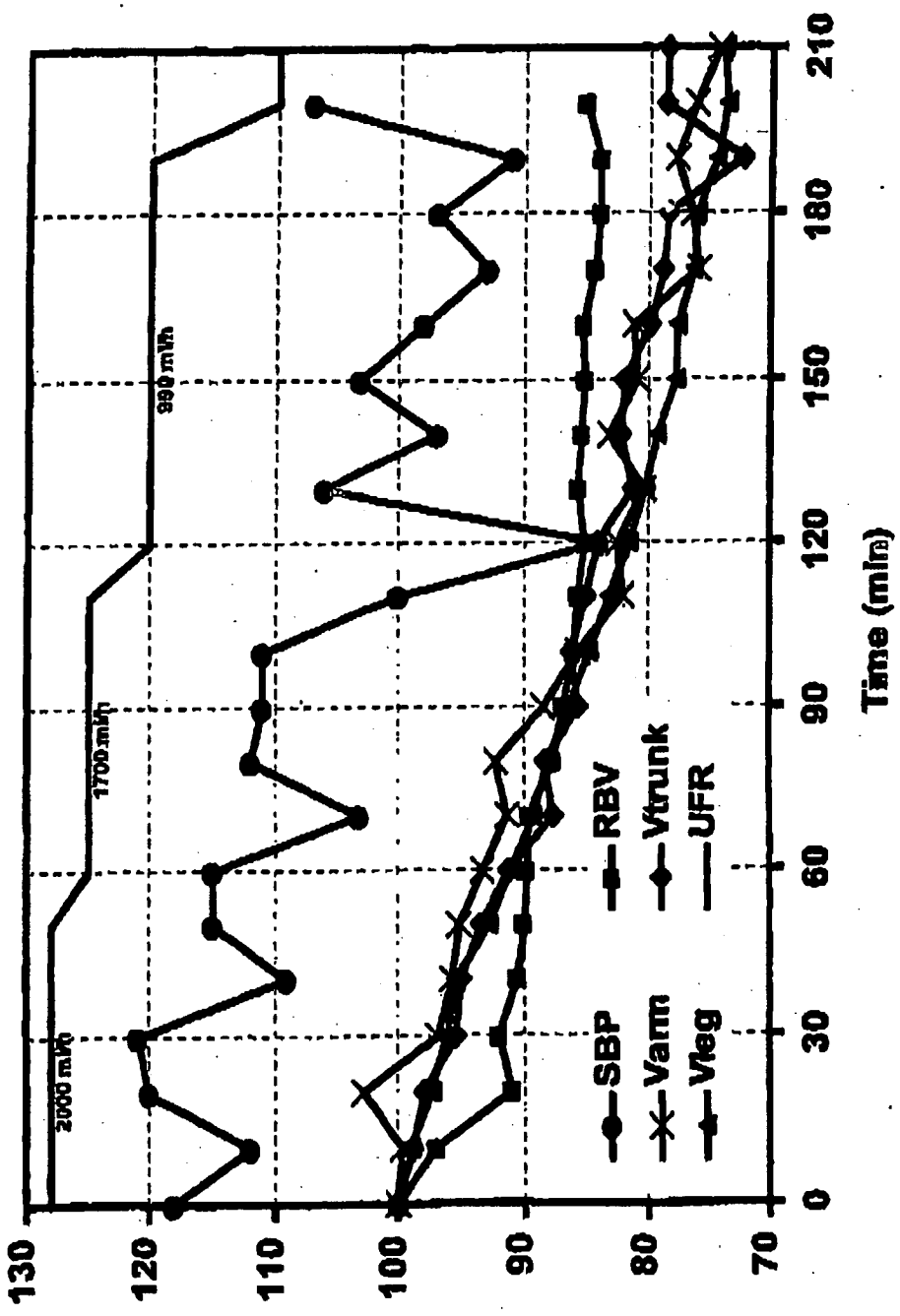
Relative change (%)
130
120
110
100
90
80
70
0
30
60
90
120
150
180
210
Time (min)
2000 mVh
1700 mVh
990 mVh
SBP
Varm
Vreg
RBV
Vtrunk
UFR

Fig. 3

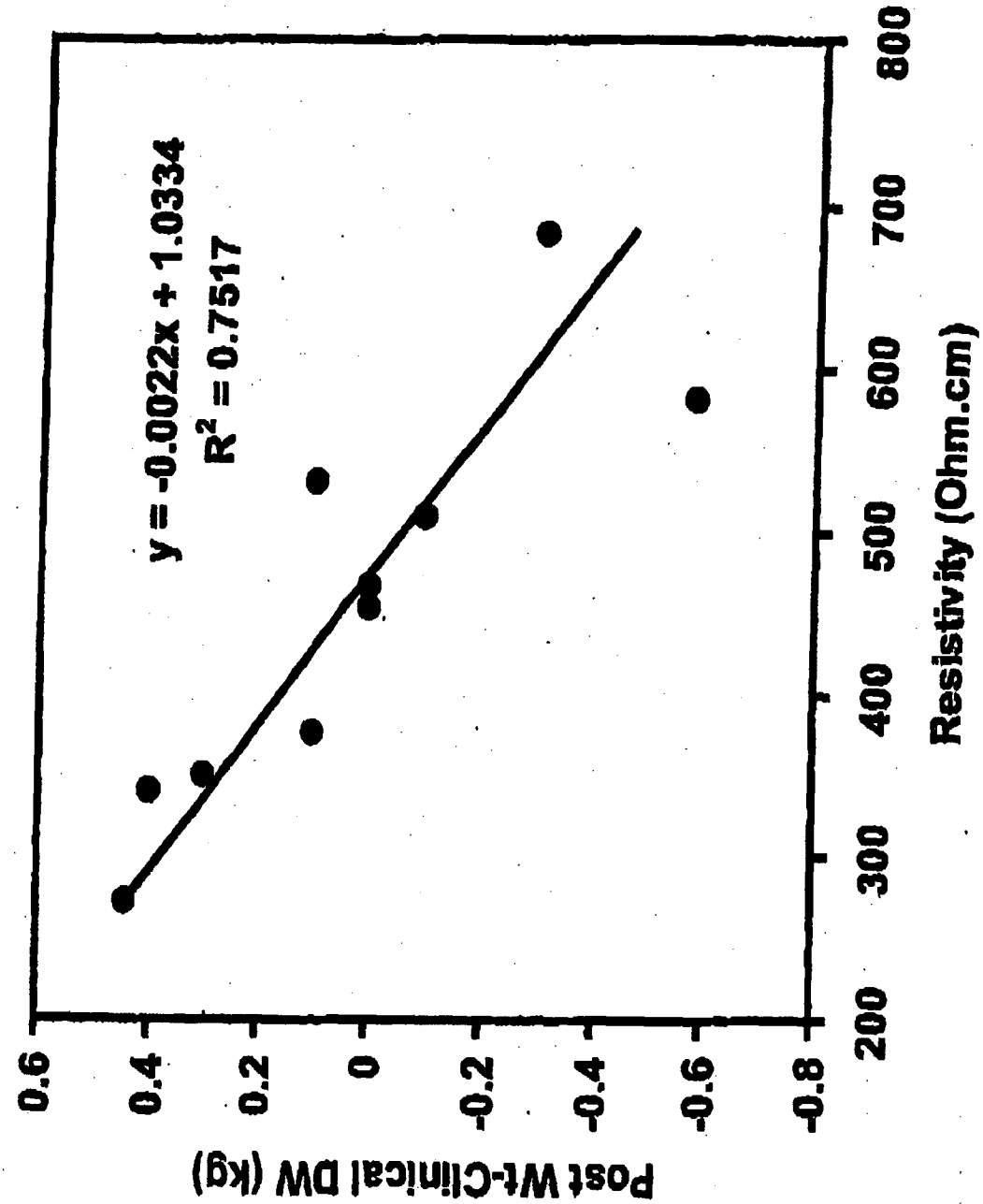
y = -0.0022x + 1.0334
R2 = 0.7517
Post Wt-Clinical DW (kg)
0.6
0.4
0.2
0
-0.2
-0.4
-0.6
-0.8
200
300
400
500
600
700
800
Resistivity (Ohm.cm)

Fig. 4

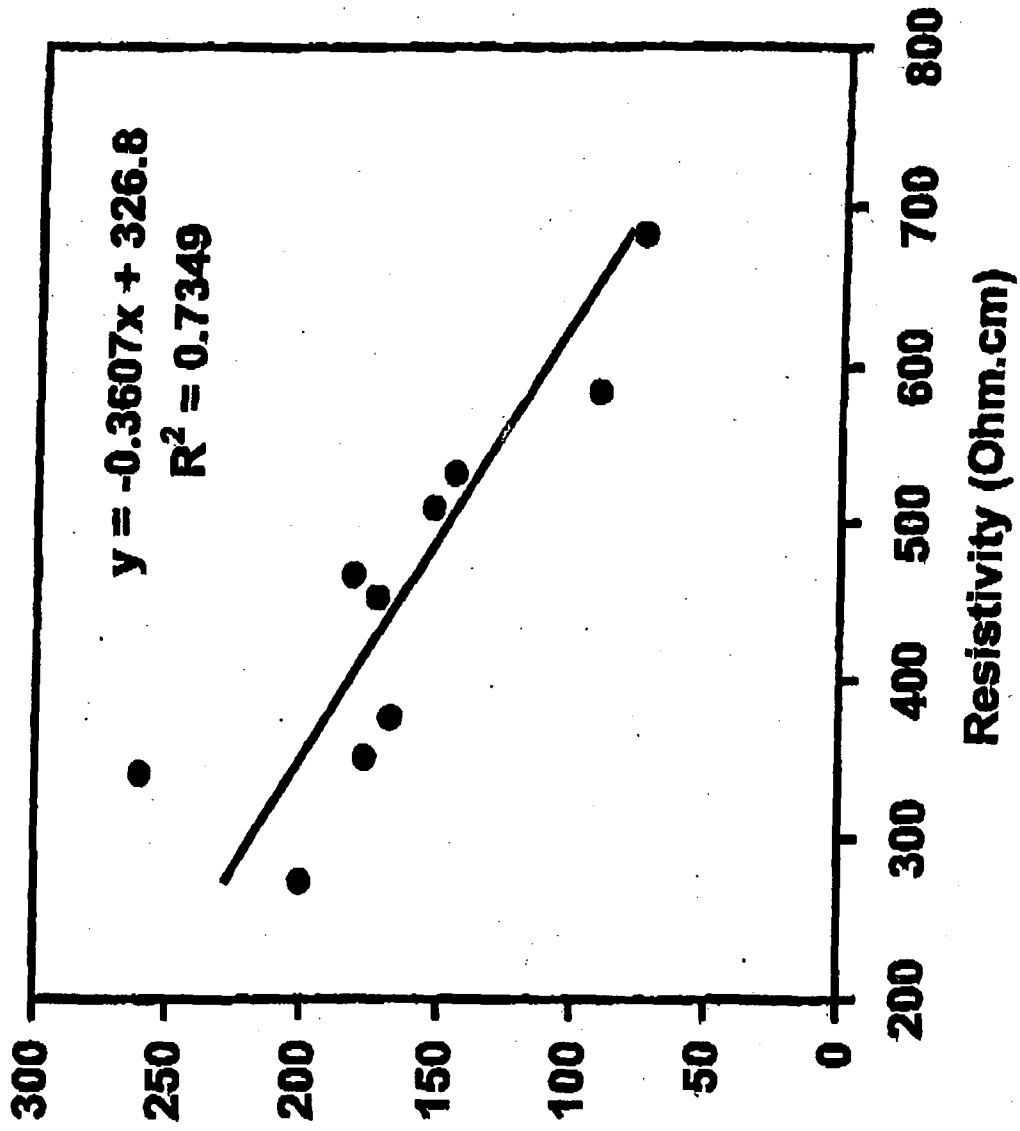
y = -0.3607x + 326.8
R2 = 0.7349
Blood Pressure at end HD (mmHg)
Resistivity (Ohm.cm)
300
250
200
150
100
50
0
200
300
400
500
600
700
800

Fig.5

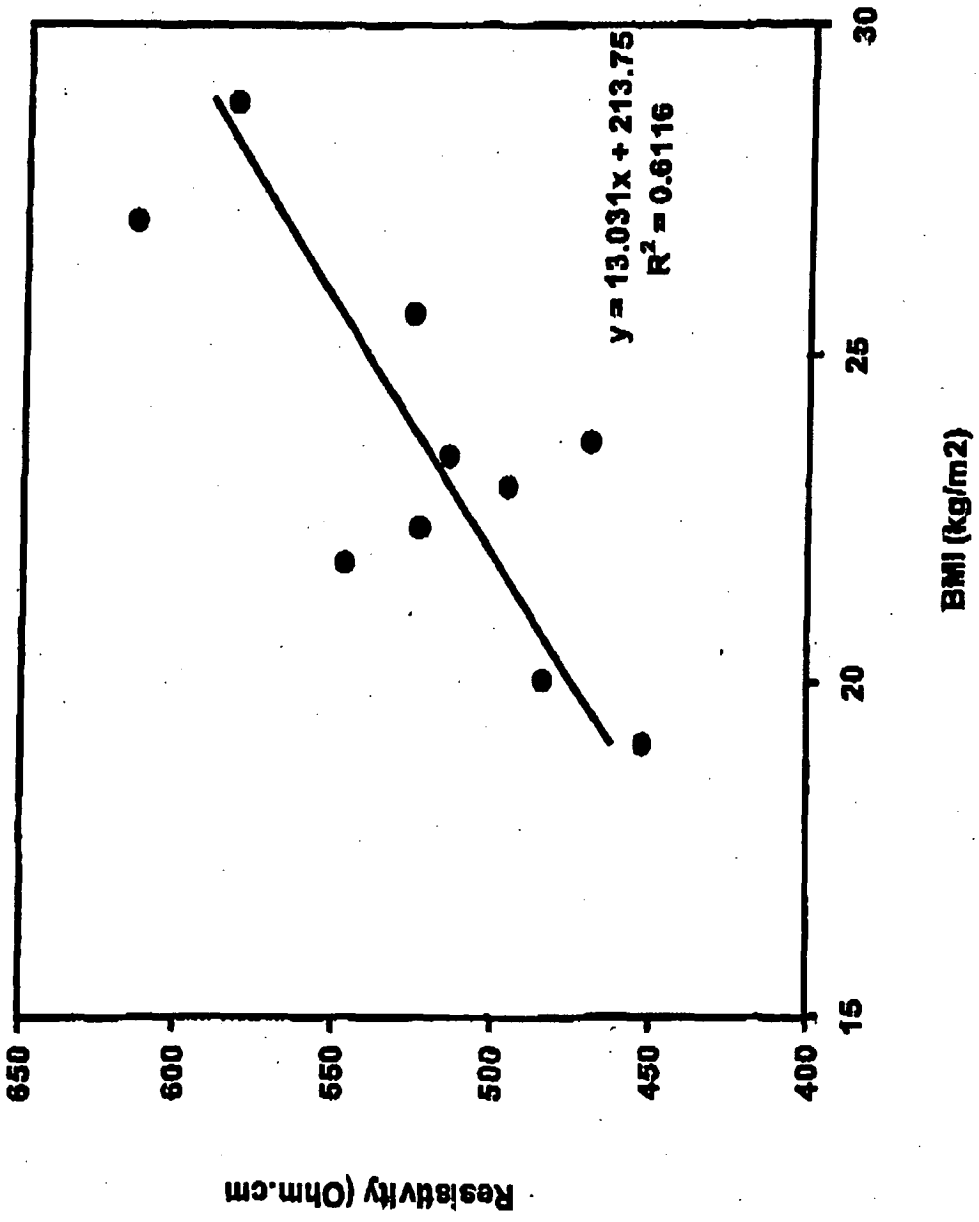
y = 13.031x + 213.75
R2 = 0.6116
Resistivity (Ohm.cm
650
600
550
500
450
400
15
20
25
30
BMI (kg/m2)

Fig. 6

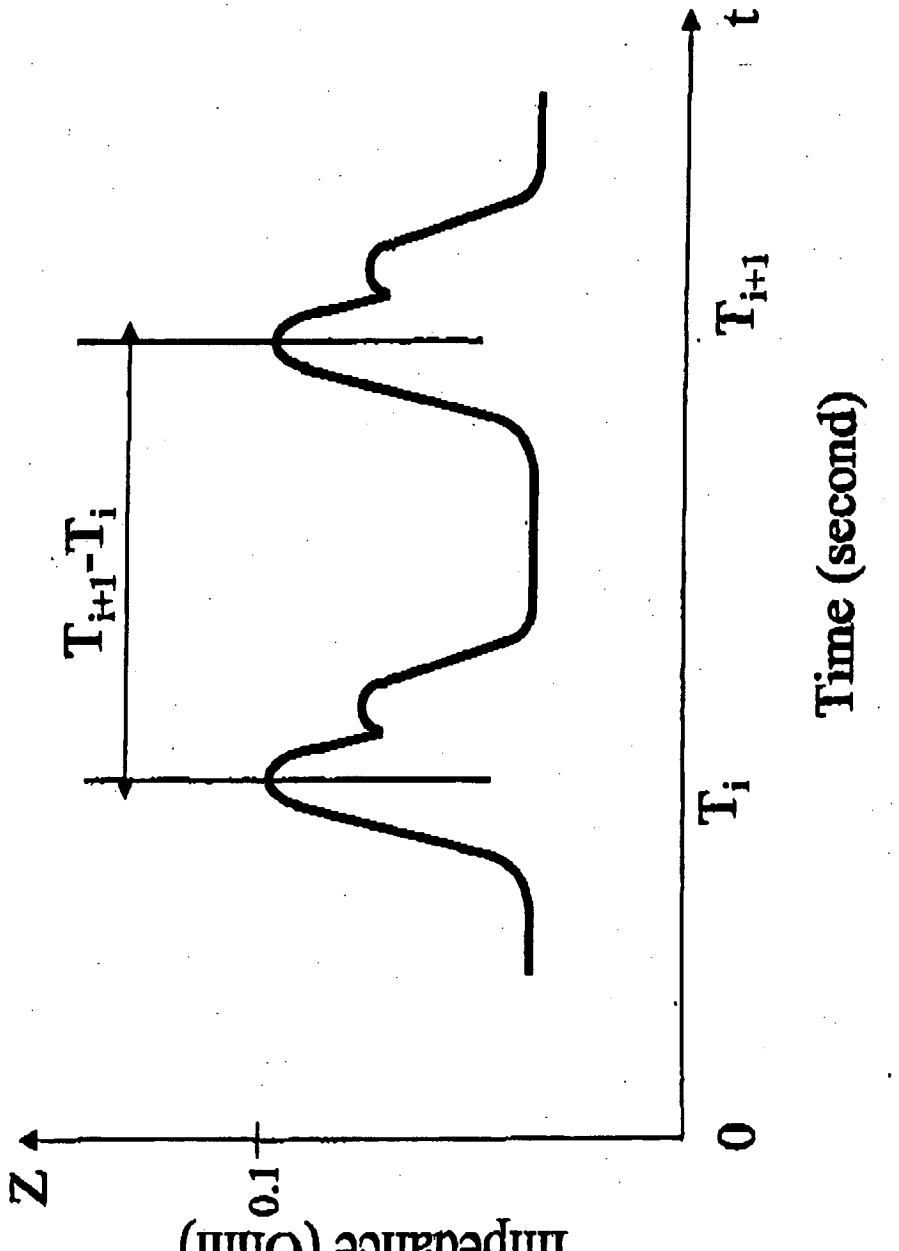


Fig. 7

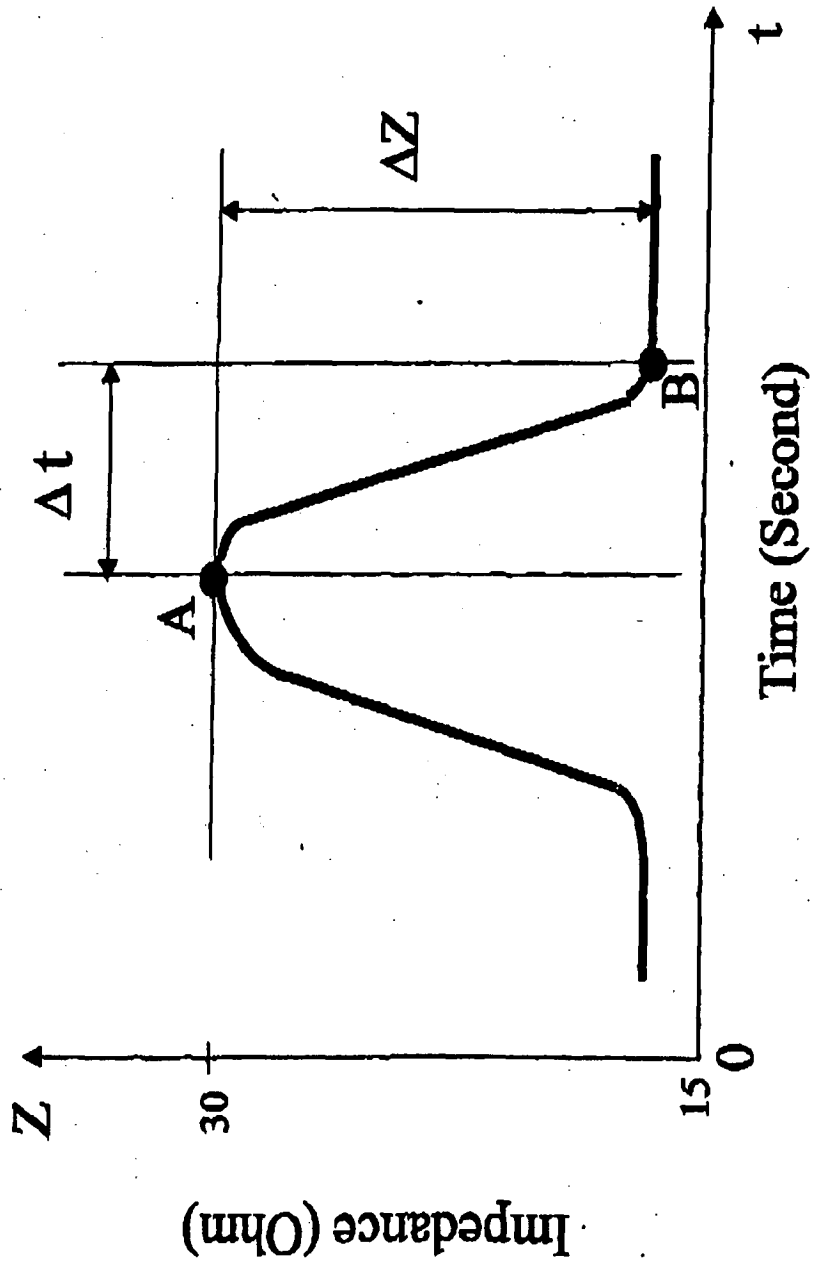


Fig.8

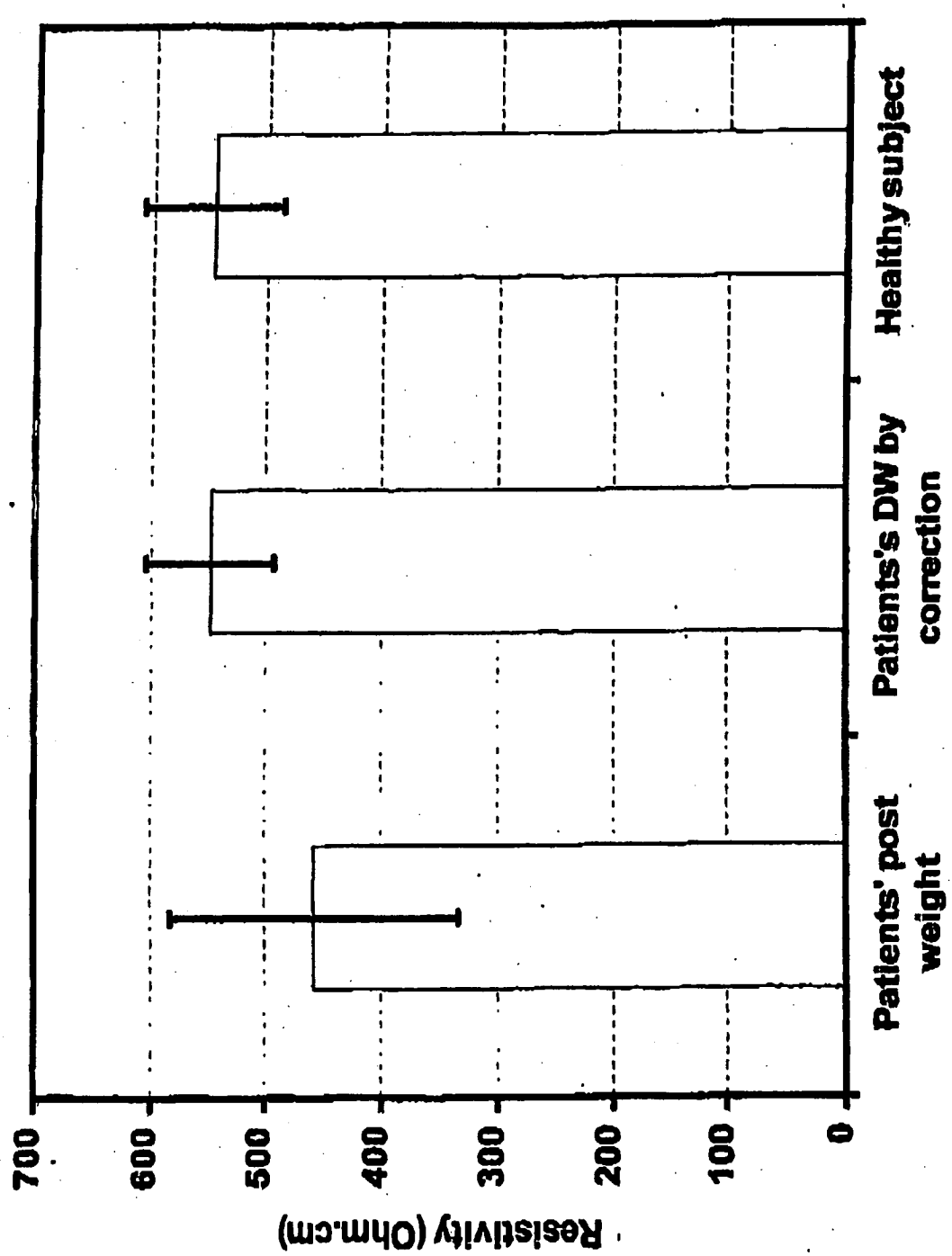
Resistivity (Ohm.cm)
700
600
500
400
300
200
100
0
Patients' post weight
Patients's DW by correction
Healthy subject

Fig.9

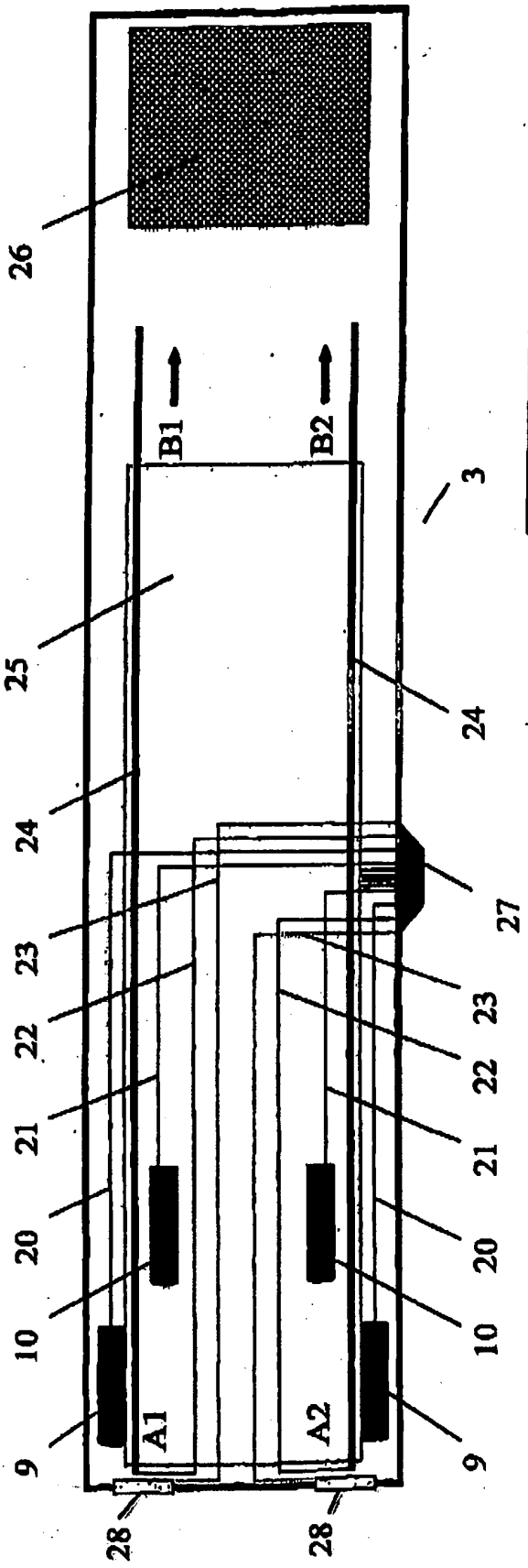


Fig.10

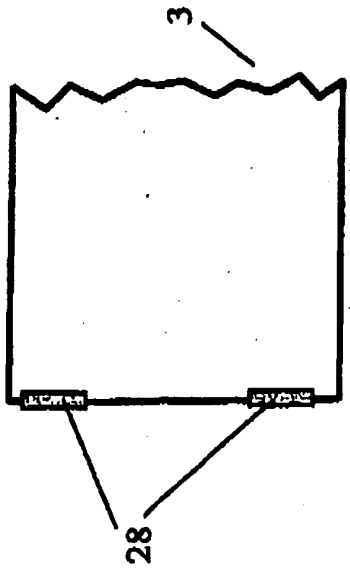


Fig 10A

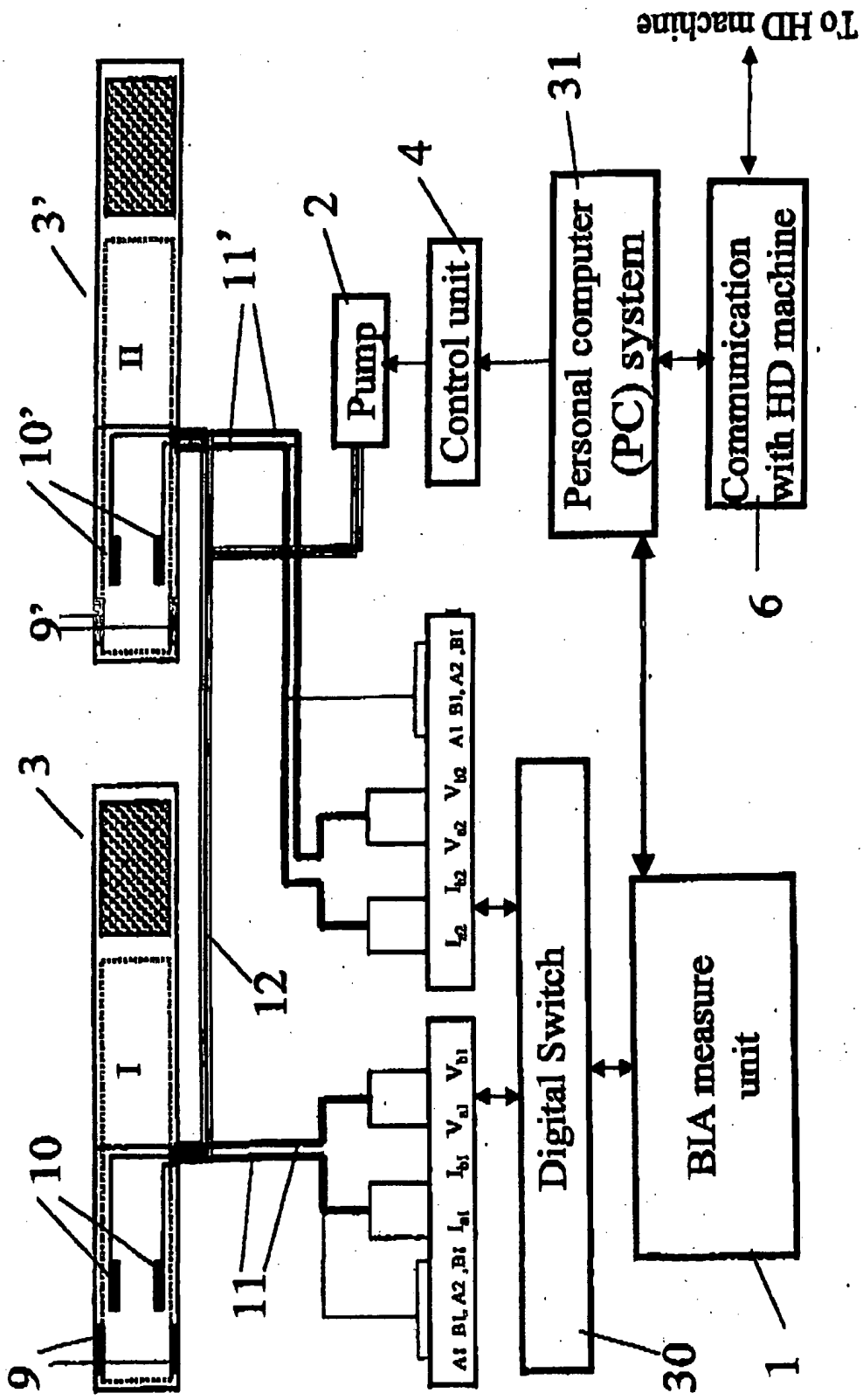
To HD machine
31
4
2
11'
3'
10'
9'
Pump
Control unit
Personal computer (PC) system
Communication with HD machine
6
3
12
I
II
10
9
11
A1 B1, A2 ,B1
$I_{b1}$ $V_{a1}$ $V_{b1}$
$I_{a1}$
$I_{a2}$ $I_{b2}$ $V_{a2}$ $V_{b2}$ A1 B1, A2 ,B1
Digital Switch
BIA measure unit
30
1

Fig. 11

## REFERENCES CITED IN THE DESCRIPTION

*This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.*

### Patent documents cited in the description


- WO 9851211 A **[0003]**
- US 5580460 A, Polaschegg **[0013]**


### Non-patent literature cited in the description


- **P.M. KOUW et al.** Assessment of post-dialysis dry weight: an application of the conductivity measurement method. *Kidney Int.,* 1992, vol. 41, 440-444 **[0002]**
- **J. G. WEBSTER.** Medical Instrumention Application and Design. Wiley, 1998, 357-362 **[0020]**

| | | | |
|---|---|---|---|
| 专利名称(译) | 用于分段生物阻抗测量和心输出量计算的装置和方法 | | |
| 公开(公告)号 | EP1938748B1 | 公开(公告)日 | 2010-08-11 |
| 申请号 | EP2007024513 | 申请日 | 2001-08-13 |
| [标]申请(专利权)人(译) | 肾RES INST | | |
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| 当前申请(专利权)人(译) | 肾脏研究院 | | |
| [标]发明人 | ZHU FANSAN<br>LEVIN NATHAN | | |
| 发明人 | ZHU, FANSAN<br>LEVIN, NATHAN | | |
| IPC分类号 | A61B5/022 A61B5/053 A61B5/00 A61B5/0245 A61B5/026 A61B5/05 A61M1/14 A61M1/16 | | |
| CPC分类号 | A61B5/022 A61B5/0535 A61B5/0537 A61B5/4869 A61M1/16 A61M2205/3393 A61M2205/50 | | |
| 代理机构(译) | 爆竹SCHMIDT，学生和合作伙伴 | | |
| 优先权 | 09/638657 2000-08-14 US | | |
| 其他公开文献 | EP1938748A2<br>EP1938748A3 | | |
| 外部链接 | Espacenet | | |


摘要(译)

本发明包括通过节段生物阻抗分析确定进行透析的患者的干体重的方法。在优选的实施方案中，通过与正常受试者的生物阻抗值比较或通过监测透析期间生物阻抗的变化来确定干体重。本发明的一个实施方案是用于确定透析期间干体重的装置。