(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 June 2011 (16.06.2011)

PCT

(10) International Publication Number
WO 2011/070422 A1

(51) International Patent Classification:
A61B 5/053 (2006.01) *A61B 5/1455* (2006.01)
A61B 5/00 (2006.01)

(21) International Application Number:
PCT/IB2010/003114

(22) International Filing Date:
6 December 2010 (06.12.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/267,510 8 December 2009 (08.12.2009) US
61/267,542 8 December 2009 (08.12.2009) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: MEDICAL DEVICE SYSTEM

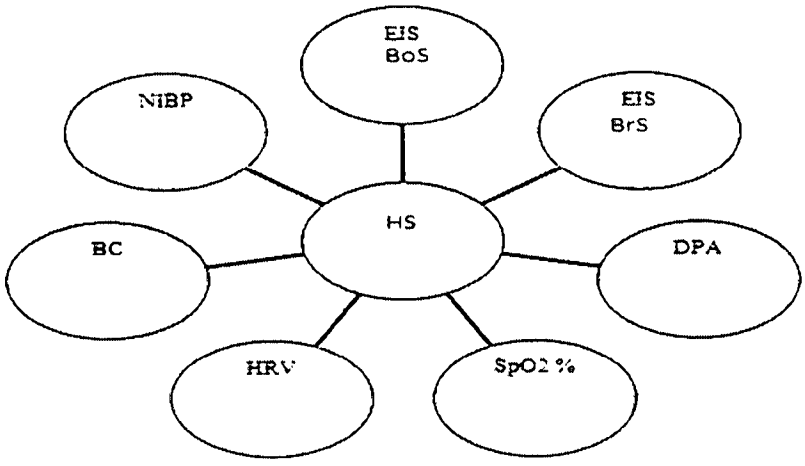

Figure 9

(57) Abstract: The invention provides a medical device system comprising at least two technologies wherein at least one technology is based on bio-impedance measuring and/or at least one technology is based on spectrophotometry measurements wherein software cross analyses the results to assess the homeostasis of an individual. The technologies measure a variety of parameters. In one embodiment the bioimpedance measuring equipment measures in bipolar mode and in tetrapolar mode and the spectophotometer measuring equipment comprises a pulse oximeter. The system and homeostasis score can be used to determine and monitor therapy for a patient.

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Medical Device System

The present invention relates to a medical device system utilising a combination of technologies and software to establish an evaluation. More particularly the device comprises technologies including spectrophotometry and impedance monitoring to establish a measure of homeostasis for a practitioner to determine and monitor treatment.

As stated by Lippincott (Medical encyclopedia): "Disease or death is often the result of dysfunction of internal environment and regulatory mechanisms. Understanding the body's processes, responses and functions is clearly fundamental to the intelligent practice of medicine." At present, the clinical context, the lab tests, functional tests such as EKG or Doppler and imagery provide doctors data to establish diagnoses and treatment plans on predictions based upon statistical averages.

However, these averages do not take into account the overall condition of any individual patient. An overall homeostasis evaluation which represent a patient's potential adaptation to a dysfunction or disease should enhance a treatment plan.

It is an aim of the present invention to provide a device or series of devices comprising different technologies to establish an overall condition of the patient. It is a further aim to assign a score to be known as the homeostasis score.

The homeostasis score provides a fast overview of a patient's homeostasis processes and responses with the key indicators, to understand the patient's potential adaptation to lifestyle, disorders, diseases or current treatment.

The healthy subject is not identified as such simply because he does not have any disease, but because his homeostasis score is acceptable and therefore his body can adapt and remain healthy when challenged. The homeostasis score cannot be used as diagnosis.

The proposed technology and its analysis aims to provide low cost therapeutic follow up. Therefore, with the adjunct of the homeostasis evaluation, a doctor should be able to test how the planned treatment would affect a patient, save time and as the possibilities of treating diseases improve, it is important to choose the right treatment for each individual patient.

According to the present invention there is provided a device wherein at least one technology is based on bio-impedance measuring and/or at least one technology is based on spectrophotometry measurements and software cross analyses the results to assess the homeostasis of an individual.

Medical device monitoring systems tend to measure one parameter or set of parameters in isolation. This has disadvantages for the patient in that other conditions or aggravating issues could be overlooked.

The present invention provides a medical device and or a series of medical devices measuring a variety of parameters using different technologies and software to provide a homeostasis score.

According to the present invention there is provided a medical device comprising at least a pulse oximeter which provides a vascular waveform.in combination with other biosensors and software.

The devices combined in one or more devices comprising a system (to calculate the homeostasis score) may include EKG, blood glucose meter, spirometer and a variety of other known and new technologies.

In one particular preferred embodiment the system is a combination of 4 biosensor technologies with 6 features and signal processing analysis managed by software.

Preferred technologies include a) bioimpedance in bipolar mode (EIS sensor), b) bioimpedance in tetrapolar mode (ES-BC sensor), c) the spectrophotometry (ESO sensor) and d) oscillometric measurements. (NIBP sensor)

Preferred bio impedance biosensor features:

The bio impedance in bipolar mode sensor (such as the EIS (electro interstitial scan) sensor) feature evaluates the segmental and general conductivity of the human body with low frequencies via at least 4 to 8 tactile electrodes. The signal processing analysis of the measurement provides estimated parameters related to living tissue : interstitial fluid sodium ion related to the Na+/K+ATPase pump activity (NAKA), interstitial fluid negative ions (chloride ions and bicarbonate) and morphology of the interstitial fluid space.

The bio impedance in tetra polar mode (ES-BC (electro scan body composition) sensor) feature evaluates the resistance and the reactance of the human body using a mono frequency (50 KHz) via 4 tactile electrodes, to estimate body composition parameters (total body water (TWB), fat free mass, fat mass) according to predictive equations as commonly seen in peer reviews. (WC Chumlea, SS Guo, RJ Kuczmarski, KM Flegal, CL Johnson, SB Heymsfield, HC Lukaski, K Friedl and VS Hubbard Body composition estimates from NHANES III bioelectrical impedance data. International Journal of Obesity (2002) 26, 1596-1609)

Preferred spectrophotometry measurement features:
The pulse oximeter (ESO sensor) displays SpO2%, pulse rate value and vertical bar graph pulse amplitude.

The photoelectrical plethysmograph or digital pulse analysis (DPA) feature is the signal processing analysis of the pulse waveform provided by the oximeter. The mathematical analyses

provide indicators to estimate the artery stiffness, associated with the heart rate detection the cardiac output and associated with the NIBP sensor, the systemic vascular resistance and means arterial pressure.

The Heart Rate Variability feature (HRV), both in the time domain and in the frequency domain (spectral analysis). Each QRS complex is detected and the so-called normal-to-normal (NN) or Rate-to-Rate (RR) intervals between adjacent QRS complexes are the result of sinus node depolarization. The signal processing analysis of the measurement provides indicators to estimate the ANS (Autonomic Nervous System) activity.

Preferred oscillometric measurements.
The non invasive blood pressure device (NIBP sensor) feature is the measurement of the systolic and diastolic pressure.

The invention will now be described with reference to the accompany non-limiting figures wherein

Figure 1 shows the EIS process
Figure 2 shows a graph of conductivity against time for an individual EIS measurement
Figure 3 shows the pathways of the individual EIS measurements
Figure 4 shows the HRV signal and time domain and frequency domain analysis
Figure 5 shows the body system tissue diagram with zones marked to assess risk
Figure 6 shows the brain system tissue diagram with zones marked to assess risk
Figure 7 shows the photoelectrical plesthysmography or DPA class risk
Figure 8 shows class risk from HRV assessment
Figure 9 shows the various elements contributing to the calculation of the homeostasis score

Bio Impedance Bipolar Mode (EIS sensor) technology

General principles
EIS sensor is a programmable electro medical system (PEMS) including:

- USB plug and play hardware devices including interface box , disposable electrodes, reusable plates and reusable cables
- Software installed on a computer.

Successive measurements are typically made with weak Direct Current and very low frequency (700 Hz) between six tactile electrodes placed symmetrically on the left and right forehead, palm of hands, and sole of the feet of the subject.
The hand and foot electrodes are typically at least 250 cm2 and in metal
The forehead electrodes are typically disposable (single use) and preferably in AgAgCl.

Each electrode is alternatively cathode then anode (bipolar mode), which permits in the particular embodiment described the recording of the intensity/ voltage/ resistance and conductivity (Law of Ohm) of 11 segments (segments means interstitial fluid pathways) of the human body.
In this case odd numbered segments are measured from the anode to the cathode and even segments are measured from the cathode to anode.

Features and intended uses

According to the features
The measurements relate to estimations of parameters related to living tissue:

- Estimation of the interstitial fluid sodium ions density related to the Na+/K+ATPase pump activity (NAKA),
- Estimation of the interstitial fluid negative ions density (chloride ions and bicarbonate)
- Estimation of the morphology of the interstitial fluid space.
-

According to the clinical investigations:

- Follow ups of drugs' administrations (thyroid hormone, beta blockers, ACE inhibitors and SSRI treatments)
- Adjunct in diagnosis of ADHD children with the conventional methods
- Adjuct to PSA test and DRI prostate analysis of men

- Estimation of the sympathetic system modulation

The EIS may be used for children (over 5 years) and adult patients.
The device is not intended for use in life support situations and is not for continuous monitoring.
The system should be used by a practitioner taking into account the clinical context of each individual patient.

Data acquisition Diagram: Description for one segment from anode (active electrode) to cathode (passive electrode) Figure 1.

Figure 1 description:

1. Hardware
2. Software installed in PC
3. Communication Protocol via USB
   Sending of the output signal waveform to the active electrode (AE) .The signal waveform is rectangular, is continuous during 1 or 3 seconds / per human body segment located between 2 electrodes. Each electrode is alternatively anode then cathode for each segment/ pathway
   This operation is realized 22 times (11 pathways) according to a programmed sequence.
   Current specification: DC and Frequency 700 Hz, voltage U (output) = or > 1.2 V and I (intensity) = or > 12 μA. Time between each pulse (resolution) = < 30 ms
4. Entrance of the current through the skin via the eccrine sweat gland
5. Pathway of the current into the body located between the 2 electrodes : Interstitial fluid
6. Exit of the current through the skin via the eccrine sweat gland
7. Current transmitted to the passive electrode (PE) and transfers at the measured current to the hardware => ADC cheap=> USB port => Software
8. The software receives 32 or 255 measurements according to the time of current application, converts the intensity and voltage into conductivity according to Ohm's law and generates a graph for each sequence of measurement.

Analysis of the graph of conductivity generated by the software for each sequence of measurement. Figure 2

Figure 2 description :

EPA = First value of measured conductivity for each segment

SPA= Last value of conductivity for each segment

The delta EPA-SPA = Dispersion of the current

The selected conductivity value for each sequence of measurement is the value SPA (After stabilization of the measurement)

The curve can be straight or inverse. This curve is similar to the chronoamperometry measurement which is an electrochemical measurement (intensity related with a chemical substance concentration i.e. below)

Sequence of measurement and pathways between the left and right forehead, hands and feet segments in this embodiment are as shown in Figure 3

Figure 3 description:

The current is sent from the anode to cathode for the odd numbered segments

1/3/5/7/9/11/13/15/17/19/21

The current is sent from the cathode to anode for the even segments

2/4/6/8/10/12/14/16/18/20/22

This sequence is a programmed sequence and can be changed and this change does not affect the results of the device.

Signal processing analysis

1. Domain Analysis: Results analysis for each segment /pathway

a. The full cycle comprises the measurement of the 11 segments/pathways measured in the polarity anode-cathode and in second time in the polarity cathode-anode. This operation is performed 4 times (m1, m2, m3 and m4) 2 measurements in DC and 2 measurements with a very low frequency 700 Hz .The graph is an average of the 4 measurements.

b. SDC + = Conductivity in µS of each odd numbered segment/pathway normal range 8 to 18 µS and pathway brain (segment 9/10) normal range 3.40 to10.33 µS

c. SDC - = Conductivity in μS of each even segment/pathway normal range 8 to 18 μS and pathway brain (segment 9/10) normal range 3.40 to10.33 μS

d. EPA-SPA α parameter = Dispersion in C.U of each segment/pathway pathway body normal range 0.60 to 0.67 and pathway brain normal range 0.65 to 0.70. (Calculation from the Cole- Cole equation)

2. Frequency or spectral analysis : Results

a. The full cycle comprises the measurement of the 11 segments/pathways measured in the polarity anode-cathode and in second time in the polarity cathode-anode. This operation is performed 4 times (m1, m2, m3 and m4) 2 measurements in DC and 2 measurements with a very low frequency 700 Hz .The graph is an average of the 4 measurements. The conductivity measurements are in abscissa and segments in ordinate.

b. Application of the Fast Fourier Transform (FFT) to the entire signal

c. Components of the FFT: EIS HF, EIS LF, EIS VLF.
EIS HF (High frequencies from 0.1875 to 0.50Hz). Normal range from 22 to 34 %.
EIS LF (Low frequencies from 0.05 to 0.1875 Hz). Normal range from 22 to 46%. EIS VLF (Very Low frequencies from 0 to 0.05 Hz). Normal range from 22 to 50 %.
EIS HF/VLF ratio. Normal range from 0.44 to 1.54.

EIS features

a. The entrance and exit of the EIS current are the eccrine sweat glands and the system operates via the large tactile planar electrodes in the parts the body with the higher density of sweat glands (palms of hands, soles of feet and left and right forehead).

b. The EIS Technology uses a very low frequency close to the DC, therefore, the current flows around the cells very close to the cell membrane in the area of the interstitial fluid and does not penetrate the cell in accordance with the fickle circuit and peer reviews related to the BIA (Bio Impedance Analysis). This fact is confirmed by the EIS very high measured resistance (membrane resistance)

c. The EIS current goes deeper in the living tissue interstitial fluid.

d. The electrode reaction is not an oxidation-reduction reaction, but is performed by chronoamperometry (Cottrell equation application) and therefore by physical diffusion of the chemical substance to the electrode surface.

e. EIS provided measurements

The electronic box receives from the passive electrode the measurement of the intensity and voltage after passage into the interstitial fluid of the body and the digital analogic converter microchip transmits the data in numeric form (from 0-100) to the software which converts the data in resistance and conductivity in μSiemens.

f. Calculation in vivo of the interstitial fluid sodium ions density in 11 segments/ pathways of the human body

The Cottrell equation

$$c_0 = \frac{i}{nFA\sqrt{\frac{D}{\pi t}}}$$

i= measured intensity for each measured odd numbered segments

n= atomic number of Na+ =11

F= 96500

A= electrode surface :

Forehead = 15.75 cm2

Hand = 272 cm2

Foot = 330 cm2

D= $\sqrt[3]{\text{atomic mass Na+}}$ => $\sqrt[3]{22.98977}$ = 2.843

л = 3.14

t= time of tension = 1 second.

By the same way , we can calculate the interstitial fluid negative ions density.

g. The intensity and conductivity of the odd numbering segment is therefore proportional to the interstitial fluid Na+ ions density and according to the peer

reviews about Na+/ K+ ATPase pump principle , the conductivity is proportional to the cellular mitochondrial ATP production.

h. The electrical Bioimpedance dispersion of the current (α parameter) is related with the morphology of the extra-cellular spaces.

i. The EIS estimation of the mitochondrial ATP production and the interstitial fluid morphology will be use in the hypoxia / ischemia detection.

ES-BC sensor to estimate the body composition

ES-BC features

This technology is well known.

Following the sending of weak intensity at the mono frequency 50 KHz (to active tactile electrodes), the BIA sensor measures the resistance and reactance between 2 other passive tactile electrodes (tetra-polar mode).

The resistance and reactance calculate will be converting in estimated body composition parameters (TWB, Fat Free mass, fat mass) according to the predictive equations of BIA (Body Impedance Analysis) issue from the peer reviews.

ESO sensor technology

E.S.O Features

The E.S.O system is using the spectrophotometry technology (oximeter) with 3 features and signal processing analysis managed by software.

The Pulse Oximeter (SpO2 sensor) displays SpO2%, pulse rate value and vertical bar graph pulse amplitude.

The Photoelectrical Plethysmography or DPA (Digital Pulse Analysis) feature is the signal processing analysis of the pulse waveform provided by the oximeter.

The mathematical analyses provide indicators to estimate the hemodynamic parameters.

The Heart Rate detection feature

Signal processing analysis of the heart rate variability: analysis both in the time domain and in the frequency domain (spectral analysis). Each QRS complex is detected and the so-called normal-to-normal (NN) or Rate-to-Rate (RR) intervals between adjacent QRS complexes are the result of sinus node depolarization.

The signal processing analysis of the measurement provides indicators to estimate the ANS (Autonomic Nervous System) activity.

SpO2 % measurement:

Pulse Oximeter

This technology is well known.

1) Fearnley, Dr S. J. "Pulse Oximetry." Practical Procedures. Issue 5(1995) Article 2: page 1. Available www.nda.ox.ac.uk/wfsa/html/u05/u05_003.htm
2) "Introduction to the Pulse Oximeter." www.monroecc.edu/depto/pstc/paraspe1.htm

Photoelectrical Plethysmography or DPA

This technology is well known. However this invention provides a new application in the calculation of the cardiac output measurement and hemodynamic indicators.

Estimated cardiac Output (Q) or (CO) Figure 4

The cardiac output is calculated according to the formula =

$$\frac{\left(1-\frac{\sum_{n=2}^{N} FFT^2(f_n)}{\sum_{n=1}^{N} FFT^2(f_n)}\right)}{\left(\frac{S_2}{S_1}\right)}$$

Estimated SV = Stroke Volume

SV = Q/ HR

Where Q= cardiac output and HR= Heart rate

Estimated BV= Blood Volume

Calculation

Normal range according to the Nadler's Formula:

For Males = 0.3669 * Ht in M^3 + 0.03219 * Wt in kgs + 0.6041

For Females = 0.3561 * Ht in M^3 + 0.03308 x Wt in kgs + 0.1833

Note:

* Ht in M = Height in Meters, which is then cubed

* Wt in kgs = Body weight in kilograms

And adjustment with the ECW (extracellular water) estimated from the E.S-Body composition device

CI = Cardiac Index

Cardiac Index (CI) = Q / Body Surface Area (BSA)

BSA (m^2) = ([Height (cm) x Weight (kg)]/ 3600)^{½}

Estimated EDV from the blood volume (BV)

Estimated EF= Ejection Fraction

EF is proportional to the ejection time of the Second derivative PTG as follow:

	ET	ET	EF
EF (Ejection fraction) in %	400	500	35
From Ejection time (ET) SDPTG in ms	350	400	40
	320	350	42
	310	320	45
	305	310	52
	290	305	55
-	280	290	58
-	260	280	60
-	250	260	65
-	240	250	68
-	200	240	70
-	190	200	72
-	180	190	75
-	100	180	80

MAP = Means Arterial Pressure from the Non Invasive blood pressure device

MAP = Diast. Pressure – ((syst.-diast.)/3)

Estimated SVR: Systemic Vascular Resistance

SVR= (MAP/CO) X 80

Heart rate variability (HRV) analysis

This technology is well known and provides indicator of the Autonomic nervous system activity level

Reference:

Task Force of The European Society of Cardiology and The North American Heart rate variability Standards of measurement, physiological interpretation, and clinical use European Heart Journal (1996) 17, 354–381

NIBP Sensor: oscillometric measurements

This type of device is in routine and does not need more clinical data and validation.

Homeostasis Score.

Homeostasis score Using bioimpedance, spectrophotometry and oscillometric technologies : ES Teck Complex

1. Bioimpedance DC and low frequency score calculation

The higher risk is the risk 1

Graphic of the bioimpedance result and class risk

For the body Abscissa = α parameter Ordinate = SDC in scale 0-100 corresponding to the conductivity values related to the body segments .

Body risk: according to the zone number Figure 5

For the brain Abscissa = α parameter Ordinate: SDC in scale 0-100 corresponding to the conductivity value related to the brain segments..

Brain risk: according to the zone number Figure 6

Calculation of the EIS Class Risk = 0.75 Body risk + 0.25 Brain risk
If EIS HF > N => Score -1

2. Photoelectrical plethysmography or DPA Class Risk Figure 7

If SI > N or EF < N => Score -1

3. HRV Class Risk. Figure 8

According to the zone number

4. SpO2 % Class Risk

- SpO2 > =95 Class 5
- SPo2 > =99 % Class 4
- SPo2 < 95 and > =91: class 3
- SPo2 < 91 and > 80 => class 2
- SpO2 < 80 => Class 1

5. Body Composition Class risk

- Normal range Class 5
- FM> N + BMI <= 29: Class 4
- FM < N => Class 3
- FM> N + BMI >29 and <= 35: Class 2
- FM> N + BMI > 35: Class 1

6. Blood pressure Class risk

Systolic <= 120 Diastolic <= 80 => Class 4
Systolic <= 121-139 Diastolic <= 81-89 => Class 3 pre-hypertension
Systolic <= 140-159 Diastolic <= 90 -99 => Class 2 stage 1 hypertension
Systolic <= > 160 Diastolic > 100 => Class 1 stage 2 hypertension

Homeostasis Score Calculation ES Teck Complex

Maximum Score = 30 Figure 9

Very Good = 27-30

Good = 24- 27

Normal = 20-24

Warning = 17-20

Low = 10-17

Poor < 10

Homeostasis score Spectrophotometry / ES –BC and oscillometric technologies : ESO

Same calculation for DPA, BC, HRV and NIBP

Maximum score = 24

Very Good = 21-24

Good = 18- 21

Normal = 15-18

Warning = 12-15

Low = 10-12

Poor < 10

The invention can further comprise additional or alternative monitoring devices to provde a medical device system as described herein.

It will be appreciated that the specific disclosures described and arbitrary scores assigned are illustrative to provide a working example and these can be altered significantly without departing from the essence of the invention as claimed.

Claims

1. A medical device system comprising at least two technologies wherein at least one technology is based on bio-impedance measuring and/or at least one technology is based on spectrophotometry measurements wherein software cross analyses the results to assess the homeostasis of an individual.

2. A system as claimed in Claim 1 wherein a series of medical devices measurie a variety of parameters using different technologies and software compiles the results of these to provide a homeostasis score.

3. A system as claimed in Claim 1 comprising at least a pulse oximeter which provides a vascular waveform.in combination with other biosensors and software.

4. A system as claimed in Claim 1 which further includes EKG monitor, blood glucose meter, spirometer.

5. A system as claimed in claim 1 comprising at least 4 biosensors wherein signal processing analysis is managed by software.

6. A system as claimed in Claim 5 wherein the technologies include a) bioimpedance in bipolar mode (EIS sensor), b) bioimpedance in tetrapolar mode (ES-BC sensor), c) a spectrophotometer (ESO sensor) and d) oscillometric measurements. (NIBP sensor)

7. Use of a system as claimed in any of the proceding claims to establish a homeostasis score for a patient

8. A medical device system to assess the homeostasis of an individual, the system comprising bio impedance measuring equipment and spectophometry measuring equipment and software capable of analyzing both sets of results

9. A medical device system as claimed in Claim 9 wherein the bioimpedance measuring equipment measures bioimpedance in bipolar mode and in tetrapolar mode

10. A medical device system as claimed in Clima 9 wherein the spectophotmeter measuring equipment comprises a pulse oximeter

11. A medical device system as claimed in Claim 8 wherein the software analyzes the results to calculate assess a patient and provides the results as a homeostasis score

12. A score of homeostasis of an individual comprising a series of defined tests including at least bioimpedance and spectrophotometer monitoring.

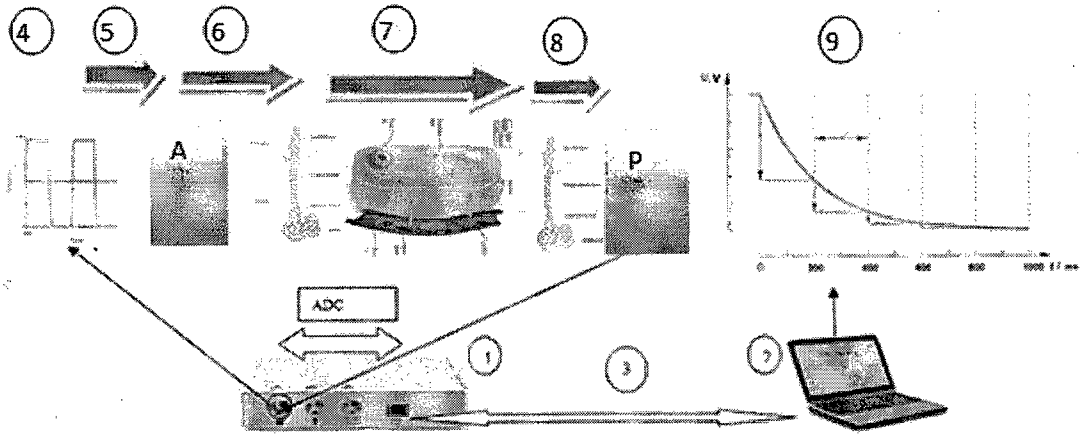

Figure 1

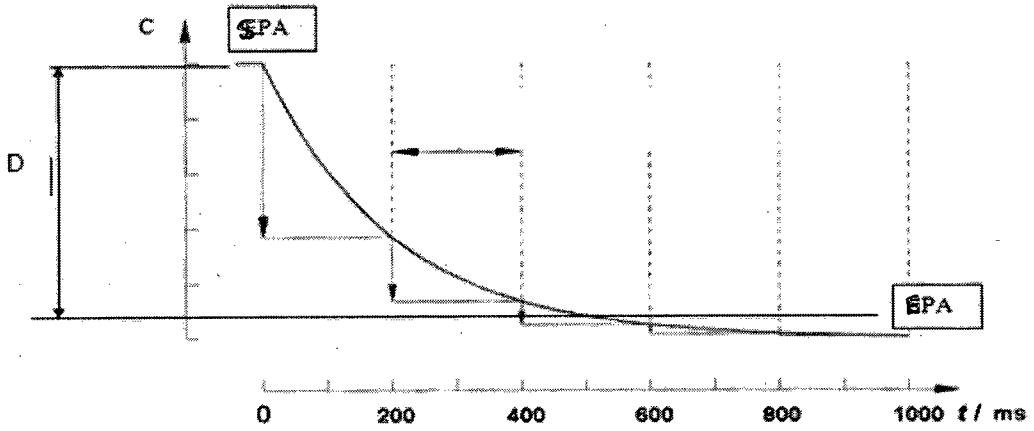

Figure 2

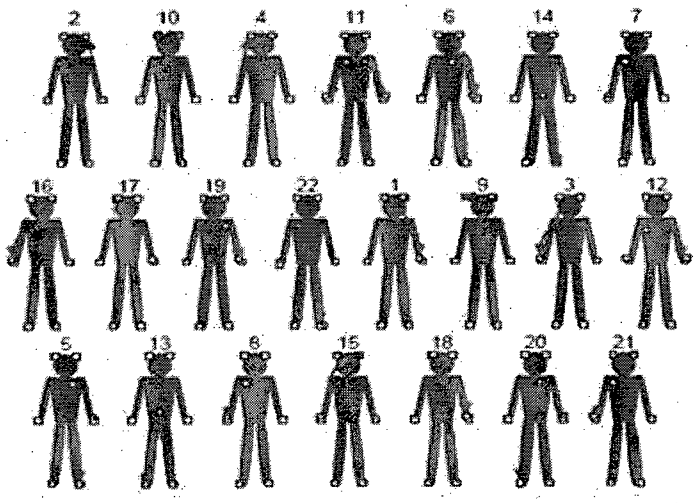

Figure 3

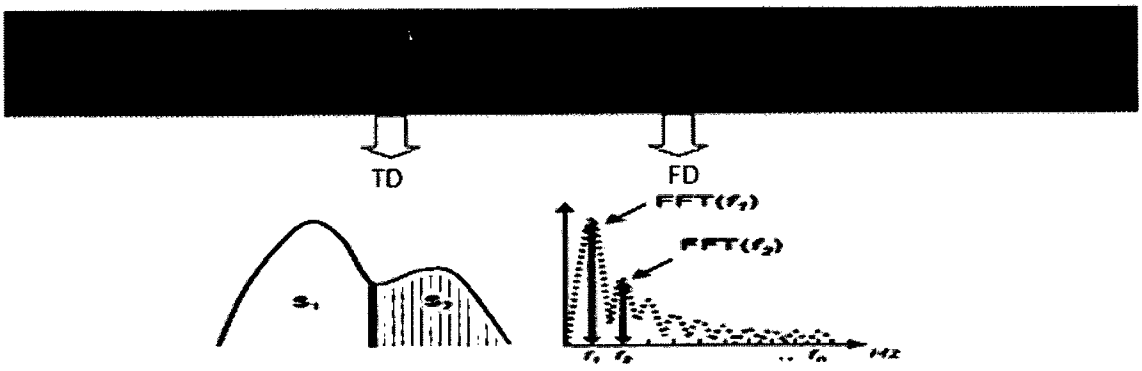

Figure 4

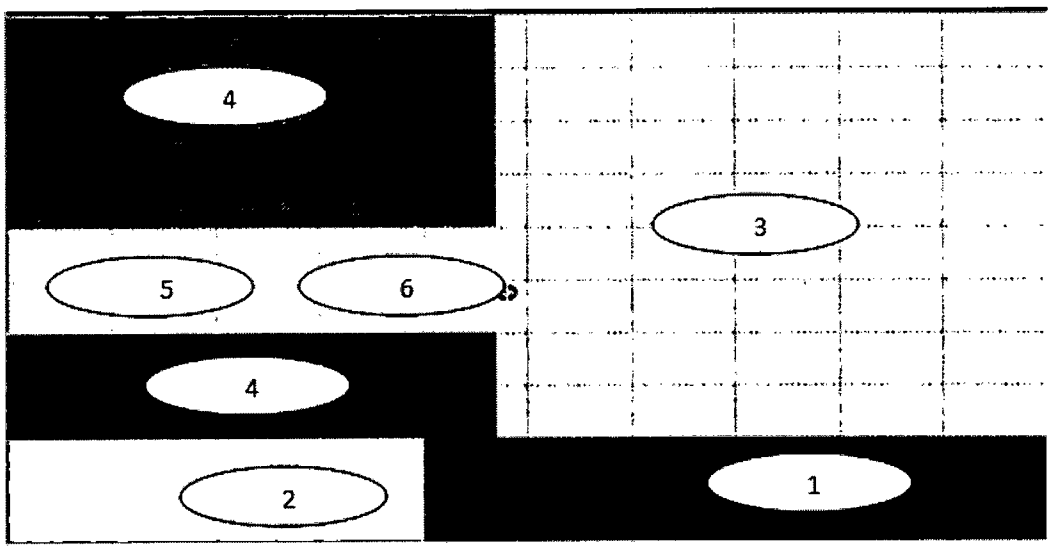

Figure 5

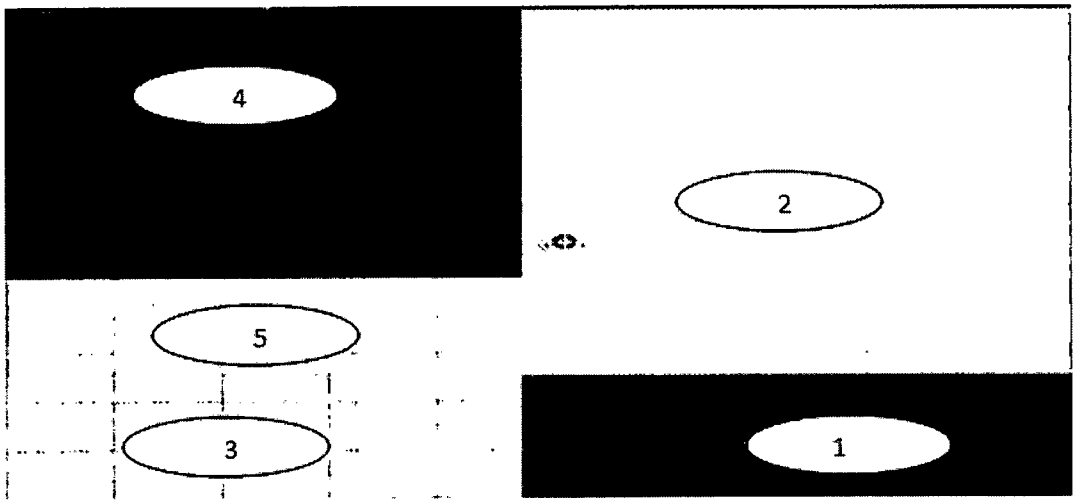

Figure 6

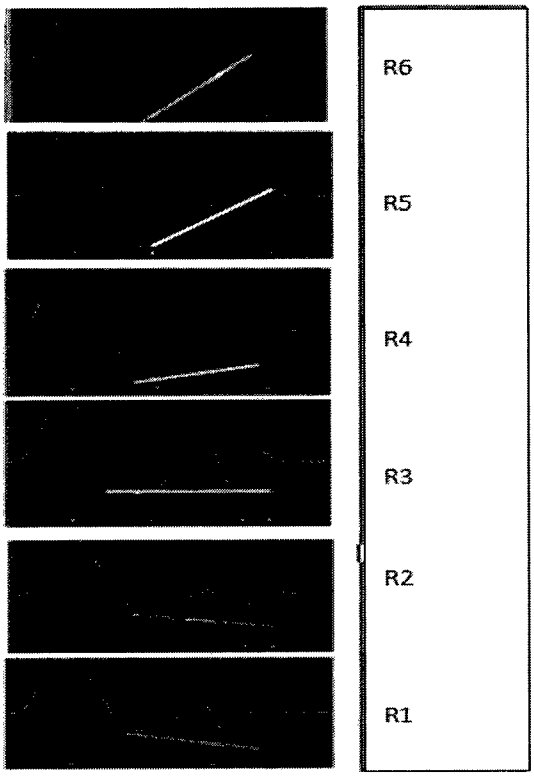

Figure 7

P			
	2	3	DPA e/a = N / > N 2 DPA e/a < N 1
	2	4	DPA e/a = N / > N 2 DPA e/a < N 1
	1	2	DPA e/a = N / > N 2 DPA e/a < N 1

S

Figure 8

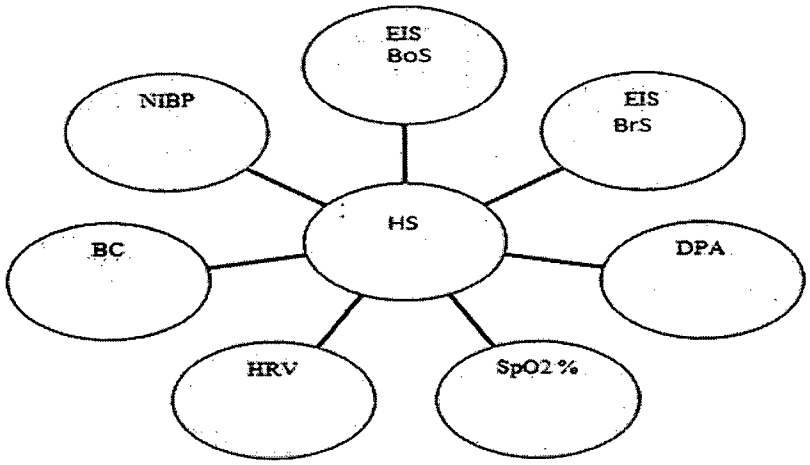

Figure 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2010/003114

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/053 A61B5/00 A61B5/1455
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	"The EIS System, The ES Teck, The ES Teck Complex", , 3 April 2009 (2009-04-03), XP002630895, Retrieved from the Internet: URL:http://replay.waybackmachine.org/20090403074602/http://www.ldteck.com/products.php [retrieved on 2011-03-31] The EIS System - EIS features : http://replay.waybackmachine.org/20090409170613/http://www.ldteck.com/feat.php The ES Teck - Description of the device: http://replay.waybackmachine.org/20090409213131/http://www.ldteck.com/description24.php The EIS Teck Complex - Description of the device : http://replay.waybackmachine.org/20090409 -/--	1,3-6, 8-10

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 March 2011	09/05/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Rosenblatt, Thomas

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2010/003114

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	23837/http://www.ldteck.com/description27.php -----	
X	US 2008/004904 A1 (TRAN BAO Q [US]) 3 January 2008 (2008-01-03) paragraphs [0002], [0005] - [0007], [0013], [0054], [0057], [0059], [0063]; figure 1 paragraphs [0280] - [0289], [0303] - [0318], [0324] - [0364], [0387] - [0389]; figures 6A,6B -----	1,3-6, 8-10
X	WO 2005/077260 A1 (BIOPEAK CORP [CA]; BRYENTON ALAN [CA]; BATKIN IZMAIL [CA]) 25 August 2005 (2005-08-25) paragraphs [0001], [0014] - [0016], [0025] paragraphs [0050], [0051]; figure 1 paragraphs [0063] - [0076]; figures 16,17 paragraphs [0081] - [0087]; figure 19 paragraph [0089]; figure 13 -----	1,3,5,8, 10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2010/003114

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008004904 A1	03-01-2008	NONE	
WO 2005077260 A1	25-08-2005	CA 2555807 A1	25-08-2005
		US 2005192488 A1	01-09-2005
		US 2010004517 A1	07-01-2010

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2010/003114

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [X] Claims Nos.: 2, 7, 11
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 12

Independent claim 12 seeks patent protection for a score of homeostasis of an individual. As such, the claim is directed to a mental or abstract concept, which could be considered as the result of a mathematical or scientific theory (which is moreover not even disclosed in the application, see claims 2, 7, 11). The remaining features of the claim only refer in general to a series of some well known measurement methods, only suggesting that the score is derived by the results obtained from such methods. Therefore it is considered that the parameter referred to in claim 12 is an abstract mental concept, for which according to Article 17(2)a)i) and Rule 39.1i) and iii) PCT, the EPO acting as International Search Authority does not carry out a search.

Continuation of Box II.2

Claims Nos.: 2, 7, 11

The subject-matter of claims 2, 7 and 11 relates to the determination of the parameter "homeostasis score". Whereas "homeostasis" relates to the overall condition of a patient and has a more or less defined meaning, the expression "homeostasis score" apparently suggests to quantify such condition on the basis of some bio-physiological measurements. This expression has however no well defined meaning in the field of medicine. It is already only for this reasons not possible to carry out a search for such an unknown parameter. A meaningful search in general would however be performed if from the application as originally filed it would be clear what is meant by this parameter. However the application refers to the homeostasis score only in very broad statements, without disclosing any well defined and reproducible way to establish this parameter. In the last paragraph of page 2 it is stated which type of measurement may flow into the calculation of the homeostasis score. No way of calculation is disclosed and it is moreover referred, besides of ECG, blood glucose, spriometer, to a variety of other known and new technologies which could contribute to its calculation, underlining already that this score has no well defined underlying concept. Figure 9 and pages 13 to 15 disclose some further information under the heading "Homeostasis Score". On page 14 "Score -1" is found several times as result of some obscure conditional expressions, in which the arguments are completely unclear (eg. "if EIS HF > N => Score -1", what is EIS HF, what is N, where are these defined in the application ?). Furthermore, on page 15 the "Homeostasis Score Calculation ES Teck Complex" is referred to, again without any indication on how to perform such calculation. In summary it is concluded that the application does also not contain sufficient information on how to establish a "homeostasis score". Under these circumstances a meaningful search cannot be carried out for claims 2, 7, 11 relating to the establishment of a homeostasis score (Article

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

17(2)a)ii) PCT).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

专利名称(译)	医疗器械系统		
公开(公告)号	EP2509493A1	公开(公告)日	2012-10-17
申请号	EP2010814724	申请日	2010-12-06
[标]申请(专利权)人(译)	MAAREK ALBERT		
申请(专利权)人(译)	MAAREK，ALBERT		
当前申请(专利权)人(译)	MAAREK，ALBERT		
[标]发明人	MAAREK ALBERT		
发明人	MAAREK, ALBERT		
IPC分类号	A61B5/053 A61B5/00 A61B5/1455		
优先权	61/267510 2009-12-08 US 61/267542 2009-12-08 US		
外部链接	Espacenet		

摘要(译)

本发明提供了一种医疗装置系统，其包括至少两种技术，其中至少一种技术基于生物阻抗测量和/或至少一种技术基于分光光度测量，其中软件交叉分析结果以评估个体的体内平衡。这些技术可以测量各种参数。在一个实施例中，生物阻抗测量设备以双极模式和四极模式测量，并且分光光度计测量设备包括脉冲血氧计。系统和体内平衡评分可用于确定和监测患者的治疗。