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(54) **METHOD FOR DETERMINING WATER DEFICIENCY IN A PERSON'S BODY**

(57) Determining a state of water deficiency in a human body during daily life activities is done by measuring an impedance of a portion of the human body at a low frequency and at a high frequency. An amount of fluid in the body tissues in the volume under study is assessed based on the impedance at the high frequency. A current amount of extracellular fluid in the tissues in the volume is assessed based on the impedance at the low frequency. A reference value of the assessed amount of extracellular fluid in the tissues is preselected at the start of measurements. A correction value is determined based on the changes in blood amount in the volume at the current measurement time. A corrected assessment value is the determined. Using the corrected assessment value, the onset of water deficiency is determined.

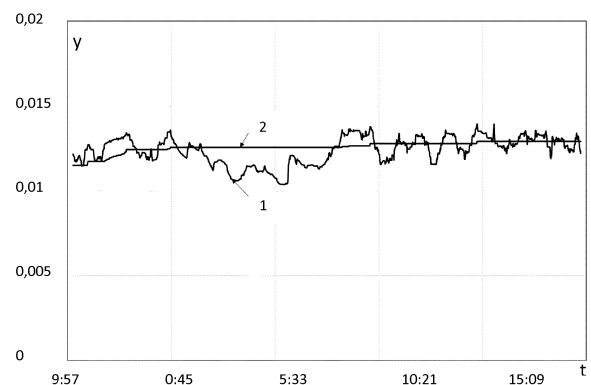


FIG. 5

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Description**FIELD OF THE INVENTION**

[0001] The invention relates to diagnostics, in particular, to determining a state of water deficiency in a human body during daily life activities by measuring an impedance value of a portion of the human body.

BACKGROUND OF THE INVENTION

[0002] The authors are unaware of other methods of determining the need to replenish the supply of water in a human body during daily life activities by measuring the impedance of a portion of the human body.

[0003] Various methods are known to be used for measuring a balance and distribution of water in a human body, mainly for medical purposes.

[0004] For example, US Pat. No. 5,469,859 published on November 28, 1995 (IPC A61B 5/085) discloses a method for determining basic cardiorespiratory parameters of a human body. The parameters are determined by applying electrodes to the patient's hands and feet to measure an amount of extracellular fluid and its balance in the entire patient's body. The measurements are made for medical purposes. The above patent does not teach determining a state of water deficiency in a human body during daily life activities.

[0005] RU Pat. No. 2314750 published on 20.01.2008 (IPC A61B 5/05) teaches a method for system-related evaluation of blood and fluid dynamics in a human body. According to that method, electrodes are applied to patient's head and extremities for measuring the impedance of various portions of the human body. Slow and violent changes in the impedance are registered and blood and fluid dynamics in peripheral parts and the entire human body is calculating based on those measurements. The method is intended for medical purposes, including monitoring of patient's health condition and selecting medical treatment methods.

[0006] US Pat. No. 8,406,865 published on March 26, 2013 (IPC A61B5/00) discloses a system for determining physiological parameters of a human body by measuring an impedance of human body portions via applied electrodes and consequent data processing, which is the closest to the present invention. The primary object of this invention is to determine cardiac and respiratory performance based on impedance measurements. The system enables determination of a water fraction in the lean body mass (i.e. total body mass minus the mass of body fat), a total volume of extracellular fluid, as well as a fluid balance index in the entire patient's body. The system is intended for medical use and does not provide for determining a state of water deficiency in a human body during daily life activities.

[0007] A limitation common to those methods is that they are intended for medical purposes only and provide for determining an amount of bodily fluid based on im-

pedance measurements of different portions of a human body.

[0008] Since the above methods are primarily used for making measurements in a hospital environment, when the patient is in a quiescent state, they are not applicable for making measurements in everyday life, during work, sports activities, etc.

[0009] The applicants are unaware of any methods allowing for determining a state of water deficiency in a human body during daily life activities to warn of the need to replenish water supplies in the body.

SUMMARY OF THE INVENTION

[0010] The technical result of the claimed invention is to determine a state of water deficiency in a human body during daily life activities by measuring an impedance value of a portion of a human body. The above technical result is achieved by assessing a fluid amount in the portion of the human body under study while taking into account changes in the amount of blood in the same body portion caused by a redistribution of fluids in various body portions due to temporary or accidental causes during daily life activities.

[0011] The above mentioned technical result is achieved as follows.

[0012] The method for detecting water deficiency of in a human body involves the following steps:

Measuring an impedance value of a portion of the human body at a low frequency and at a high frequency. Assessing an amount of fluid in body tissues in a volume under study based on the impedance value measured at the high frequency, at a current measurement time. Assessing an amount of extracellular fluid in the volume under study at the current measurement time based on the impedance value measured at the low frequency. Preselecting a reference assessment value of an amount of extracellular fluid in the volume under study at a reference measurement time. Next, a correction value is determined associated with a change of a blood amount in the volume under study at the current measurement time. Further, determining a corrected assessment value of the amount of fluid in the body tissues in the volume under study, wherein the corrected assessment value is associated with the change of the blood amount in the volume under study at the current measurement time. Using the corrected assessment value of the fluid amount in the volume under study to make a conclusion regarding an onset of water deficiency in the human body.

[0013] As known in the art, impedance measurements at a low frequency allow for assessment of an amount of extracellular fluid in a volume under study, whereas impedance measurements at a high frequency allow for assessment of a total amount of fluid in volume under study. The method of the invention allows to make a conclusion regarding an onset of a state of water deficiency in a human body by taking into account a change of a blood amount in the volume under study at the current

measurement time. The method allows to eliminate the influence of the change in blood amount in a given body portion caused, for example, by physical exercise or other temporary or random factors on the measurement results, and to make a corrected assessment of the amount of fluid in the body tissues in the volume under study. The latter allows to make a conclusion regarding an onset of water deficiency in the human body.

[0014] In a particular embodiment, the impedance values of the portion of the human body are measured using spaced-apart electrodes attached to the human body.

[0015] In a specific embodiment, a hematocrit value is taken into consideration for determining the corrected assessment value of the fluid amount in the volume under study associated with change of blood amount in said volume.

[0016] In particular, the conclusion regarding the onset of the state of water deficiency in the human body is made based on a maximum value of corrected assessment value of the fluid amount in the body tissues in the volume under study associated with the change of the blood amount in said volume at the current measurement time.

[0017] In particular, the impedance values of the portion of the human body at the low and high frequencies are corrected using the readings of a human body temperature sensor.

[0018] In addition, the reference measurement time is preselected succeeding a termination of a transition time, which is necessary to adapt the human body to measurement sensors.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The method for detecting water deficiency in human body is illustrated by the following drawings:

Fig. 1 shows time dependencies of impedance values measured at different frequencies.

Fig. 2 shows time dependencies of measured impedance values after median filtering with the use of a median filter.

Fig. 3 shows time dependencies of conductivity, which correspond to the amount of fluid in the body tissues in the volume under study; and to the amount of extracellular fluid in the body tissues in said volume.

Fig. 4 shows time dependencies of conductivity at different frequencies, which correspond to the amount of intra- and extracellular fluid in the body tissues in the volume under study, as well as the conductivity, which corresponds to the amount of fluid in the body tissues of said volume minus the change in the blood amount at the current measurement time.

Fig. 5 shows time dependence of conductivity that corresponds to the amount of fluid in the body tissues in the volume under study minus the change in the blood amount since the reference measurement

time, as well as the time dependence of conductivity value considered as a threshold for the water deficiency state.

5 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0020] The method for detecting water deficiency in a human body is implemented as follows.

10 **[0021]** First, electrodes are attached to the human body. In particular, attachment of two electrodes to a portion of a body is sufficient. Tests have demonstrated that this method provides for determining of an onset of a state of water deficiency in the human body with electrodes attached, for example, to a person's wrist, though this part of the body is not the most suitable for implementing the method. However, the sensor readings of

impedance values Z_i^0 at a low frequency f_0 as well as

20 readings Z_i^3 at a high frequency f_3 for a given small portion of the human body enable the determination of the water deficiency onset in the body. The most efficient sampling rate for measuring impedance values at different frequencies is found to be about 1 to 4 times per minute.

[0022] Fig. 1 shows the time dependencies of measured impedance values Z_{init}^3 at high frequency f_3

30 (curve 1) and Z_{init}^0 at low frequency f_0 (curve 2).

[0023] To avoid any interference, it is beneficial to use filtration of measured impedance values. Various types of filtration are suitable for this purpose, with the so-called "median filter" applied in this specific case.

[0024] Fig. 2 shows the time dependencies of impedance values measured after they were processed using a median filter: Z_{init}^3 at high frequency f_3 (curve 1) and

40 Z_{init}^0 at low frequency f_0 (curve 2). Fig. 2 shows that the filtered impedance values contain practically no outliers caused by random factors.

[0025] The method can be implemented ignoring the human body temperature. However, the accuracy of the method increases when the body temperature is taken

into account. The impedance values Z_i^0 measured at

low frequency f_0 and Z_i^3 at high frequency f_3 are corrected to take into account the temperature sensor readings by using the following dependencies:

$$Z_{i\text{corr}}^0 = Z_i^0 \times (1 + k_T \times (T_i - T_0)),$$

$$55 \quad Z_{i\text{corr}}^3 = Z_i^3 \times (1 + k_T \times (T_i - T_0)),$$

where:

Z_i^0 and Z_i^3 are instantaneous impedance values at frequency f_0 and at frequency f_3 ;

$Z_{i\text{corr}}^0$ and $Z_{i\text{corr}}^3$ are instantaneous corrected impedance values at frequency f_0 and at frequency f_3 ;

T_i is an instantaneous value of the human body temperature in the impedance measurement area;

T_0 is a reference value of the human body temperature in the impedance measurement area;

k_T is a temperature resistance coefficient of the tissue, through which a measuring current passes used for measuring impedance values.

[0026] The temperature value at a start of measurements may be selected as the reference value T_0 .

[0027] Based on the value of the impedance measured at high frequency f_3 , an assessment value of conductivity y_i^{sum} is acquired, which is proportional to the amount of fluid in the body tissues in the volume under study at the current measurement time:

$$y_i^{\text{sum}} = 1/Z_{i\text{corr}}^3.$$

[0028] Based on the value of the impedance measured at low frequency f_0 , an assessment value of conductivity y_i^{out} is acquired, which is proportional to the amount of extracellular fluid in the body tissues in the volume under study at the current measurement time:

$$y_i^{\text{out}} = 1/Z_{i\text{corr}}^0.$$

[0029] The conductivity characterizing y_i^{sum} (curve 1) - at high frequency f_3 , which corresponds to the amount of fluid in the body tissues in the volume under study, and y_i^{out} (curve 2) - at low frequency f_0 , which corresponds to the amount of extracellular fluid in the body tissues in the volume under study are shown in Fig. 3.

[0030] At the start of measurements a reference value $y_{\text{base}}^{\text{out}}$ is preselected, which is proportional to the amount of extracellular fluid in the volume under study at a reference measurement time.

[0031] The reference measurement time t_{base} is preselected succeeding a termination of a transition time, necessary to adapt the human body to measurement sensors after they are applied.

[0032] Next, value $y_{\text{base}}^{\text{out}}$ is used to determine the val-

ue of correction Δ_i^{bl} that takes into account the change in the amount of blood in the volume under study at the current measurement time:

$$\Delta_i^{\text{bl}} = (y_i^{\text{out}} - y_{\text{base}}^{\text{out}})/(1 - h),$$

where:

h is the hematocrit, i.e. the ratio of the volume of erythrocytes constituting about 99% of blood cells, to the volume of blood plasma; the hematocrit value for females may be considered to be 0.40, whereas for males it may be considered to be 0.46.

[0033] Next, a corrected value $y_i'^{\text{sum}}$ is found, which is proportional to the amount of fluid in the body tissues in the volume under study and is associated with the change of blood amount in the body tissues in said volume at the current measurement time:

$$y_i'^{\text{sum}} = y_i^{\text{sum}} - \Delta_i^{\text{bl}},$$

where: y_i^{sum} - is the assessed conductivity proportional to the current amount of fluid in the body tissues in the volume under study.

[0034] Taking into account changes in the amount of blood in the body tissues in the volume under study enables assessment of both intra- and extracellular fluid amounts in said volume.

[0035] The time dependency of conductivity that corresponds to the amount of fluid in the body tissues in the volume under study minus changes in blood flow at the current measurement time relative to the reference measurement time $y_i'^{\text{sum}}$ (curve 3), is illustrated in Fig.

4. For clarity, the same plot shows time dependencies of the conductivity that corresponds to the amount of fluid

y_i^{sum} in the body tissues in the volume under study (curve 1), and that corresponds to the amount of extracellular fluid in the body tissues in the volume under study

y_i^{out} (curve 2) at the current measurement time relative to the reference measurement time (4).

[0036] As is seen from the plots, the dependency $y_i'^{\text{sum}}$ (curve 3) reflecting the amount of fluid in the body tissues of the volume under study minus blood flow changes observed at the current measurement time does not have any significant ups and downs caused by blood flow changes in the body tissues in the volume under study due to temporary external factors. The latter includes, for example, physical activity or its lack, changes in psychological state, or other factors associated with daily life activities of a human.

[0037] Based on the obtained corrected assessment

values y_i^{sum} proportional to the amount of fluid in the body tissues of the volume under study, the onset of the state of water deficiency in the human body is determined by comparing the above corrected assessment values with a threshold value (Fig. 5).

[0038] Here, the threshold value is taken as the corrected assessment value of the conductivity, which is proportional to the amount of fluid in the of body tissues in the volume under study and is associated with the change in blood amount over a given time period taken into account. The threshold value should be less than the maximum value over the entire preceding measurement time by a certain value:

$$y_{\text{thresh}}^{\text{sum}} = y_{\text{max } k}^{\text{sum}} - \Delta_{\text{thresh}},$$

where:

$y_{\text{thresh}}^{\text{sum}}$ - is the threshold value of conductivity,

$y_{\text{max } k}^{\text{sum}}$ - is the maximum value of conductivity in preceding measurements,

Δ_{thresh} - is a value that determines how smaller the threshold conductivity value must be compared to its maximum value.

[0039] It should be noted that the value $y_{\text{max } k}^{\text{sum}}$ within the first few hours of the device use can grow quite high if the method is applied after the user with water deficiency consumed a required amount of water in the process of drinking and/or eating.

[0040] The plot (Fig. 5) shows the temporal changes in value y_i^{sum} (curve 1) and the threshold value, below which the onset of water deficiency in the body occurs (curve 2).

[0041] The reliability of determining the onset of water deficiency in a human body increases as the observations grow longer, since the threshold value $y_{\text{max } k}^{\text{sum}}$ will more accurately reflect the maximum amount of water necessary to maintain a particular person's water balance during daily life activities.

[0042] The method of the invention is designated to determine current deficiency of water in a healthy human body and may be used to develop various devices or automatic systems for monitoring the state of a human body. The method has been tested on a sufficiently large number of subjects.

Claims

1. A method for detecting water deficiency in a human body, the method comprising:

measuring an impedance value of a portion of the human body at a low frequency and at a high frequency;

assessing an amount of fluid in body tissues in a volume under study based on an impedance measured at the high frequency at a current measurement time;

assessing an amount of extracellular fluid in the volume under study based on an impedance value measured at the low frequency at the current measurement time;

preselecting a reference assessment value of an amount of extracellular fluid in the volume under study at a start of measurements;

determining a correction value associated with a change of a blood amount in the body tissues in the volume under study at the current measurement time;

determining a corrected assessment value of the fluid amount in the body tissues in the volume under study, wherein the corrected assessment value is associated with the change of the blood amount in the body tissues in the volume under study at the current measurement time;

using the corrected assessment value of the fluid amount in the body tissues in the volume under study to determine an onset of a state of water deficiency in the human body.

2. The method of claim 1, further comprising measuring the impedance value of a portion of the human body by using spaced-apart electrodes attached to the human body.

3. The method of claim 1, further comprising using a hematocrit value for determining the corrected assessment value of the fluid amount in the body tissues in the volume under study associated with the change of the blood amount in the body tissues in the volume under study.

4. The method of claim 1, further comprising determining the onset of the state of water deficiency in the human body based on a maximum value of corrected assessment value of the fluid amount in the body tissues in the volume under study associated with the change of the blood amount in the body tissues in the volume under study at the current measurement time.

5. The method of claim 1, further comprising correcting the impedance values of the portion of the human body measured at the low frequency and at the high frequency by using the readings of a body temperature sensor.

6. The method of claim 1, wherein the reference measurement time is preselected succeeding a termina-

tion of a transition time necessary to adapt the human body to measurement sensors.

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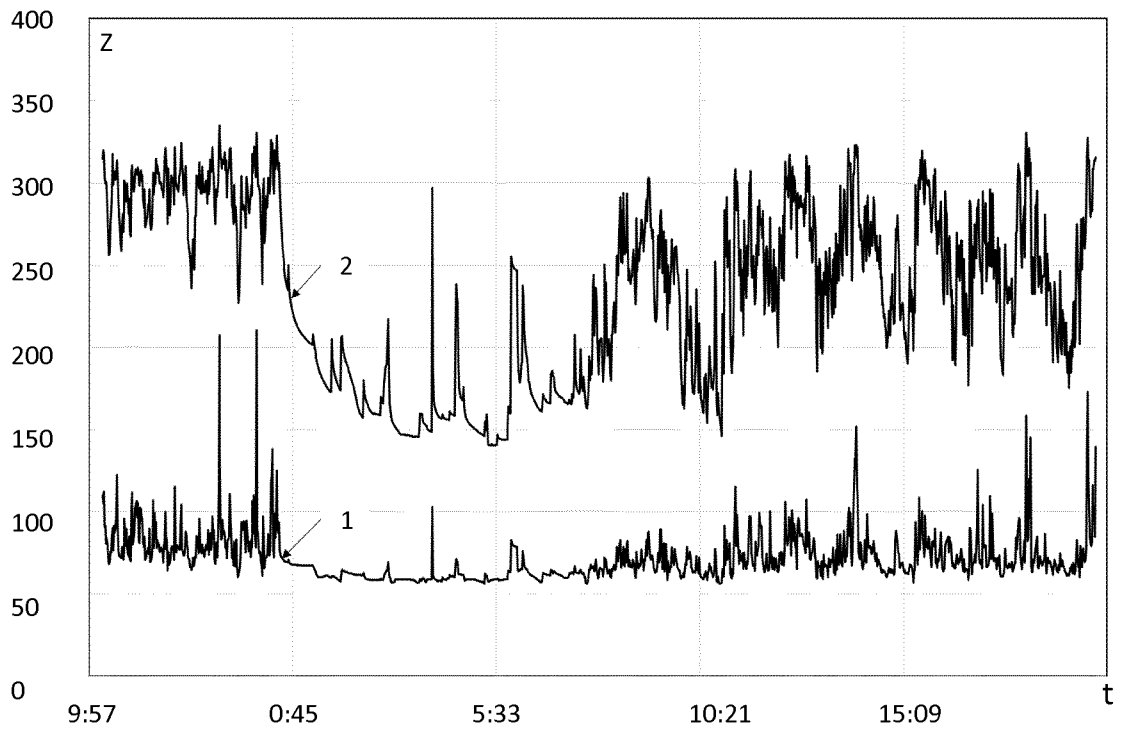


FIG. 1

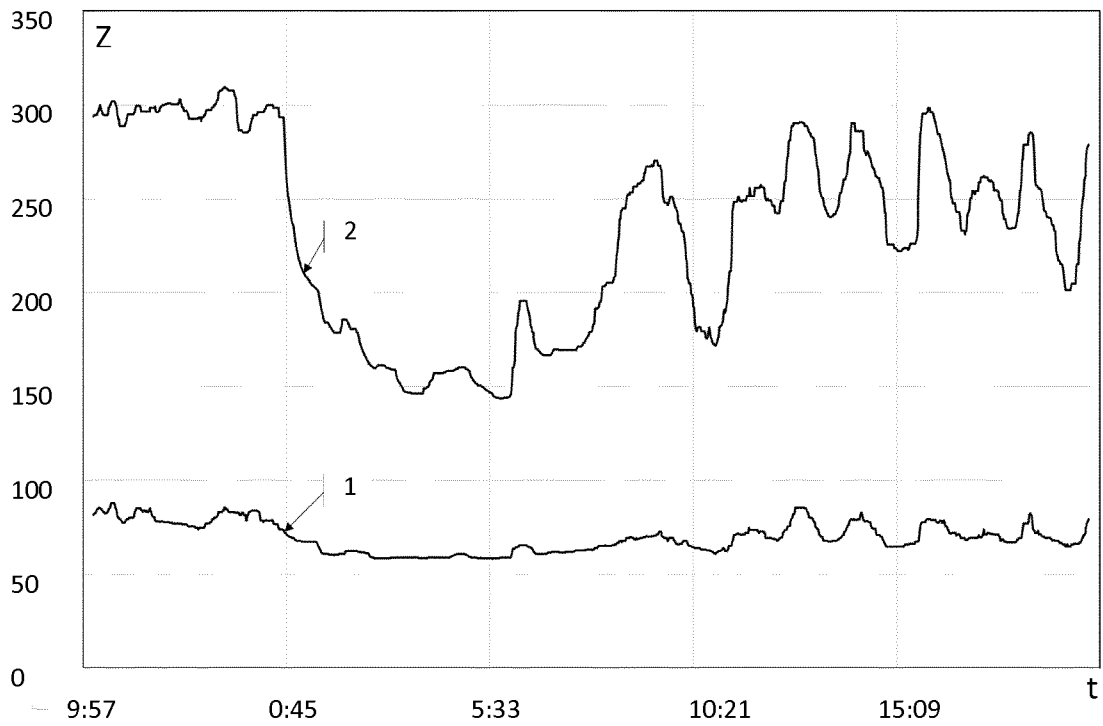


FIG. 2

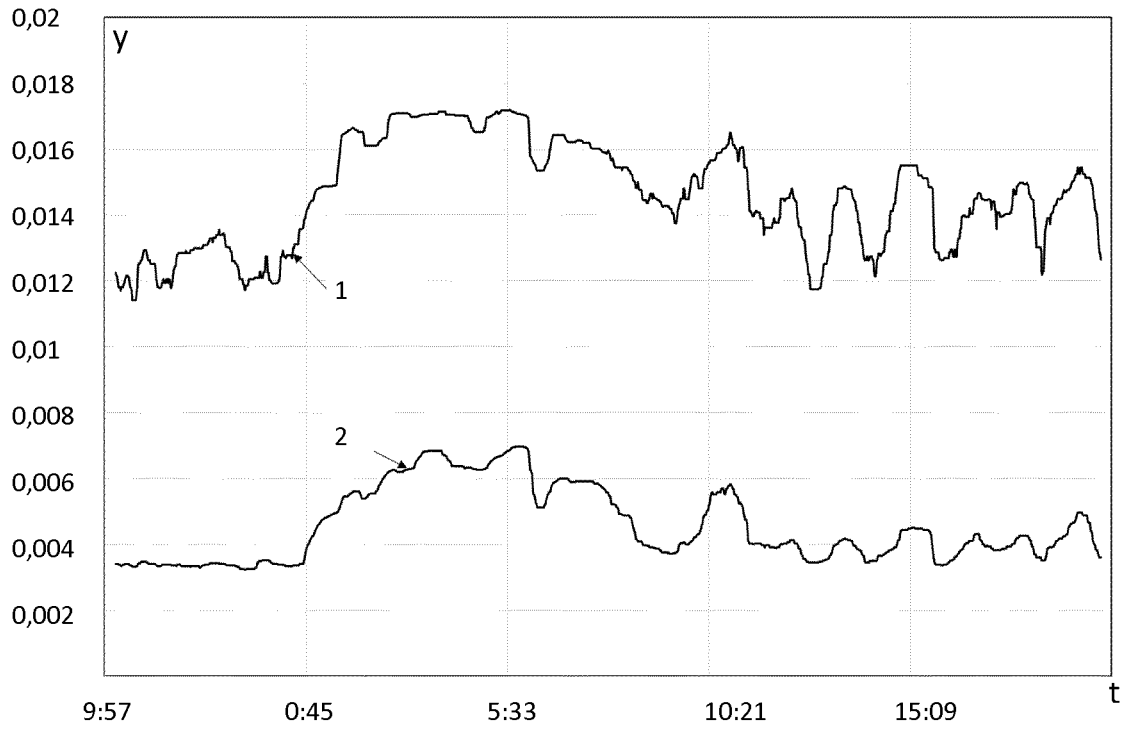


FIG. 3

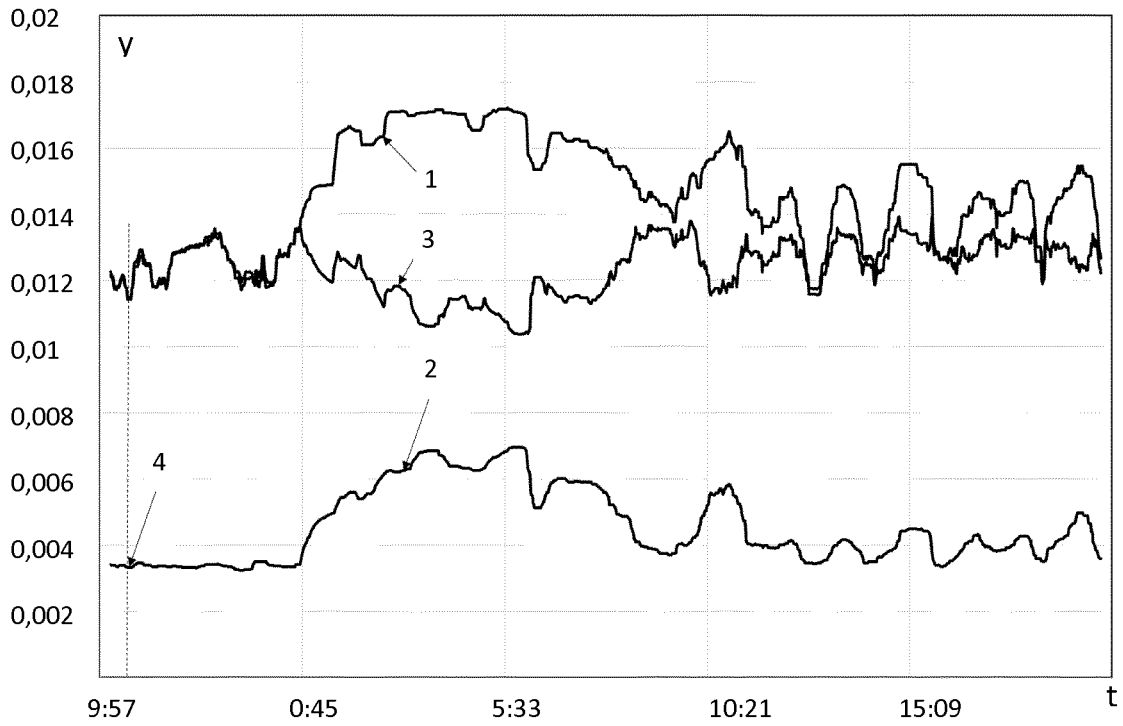


FIG. 4

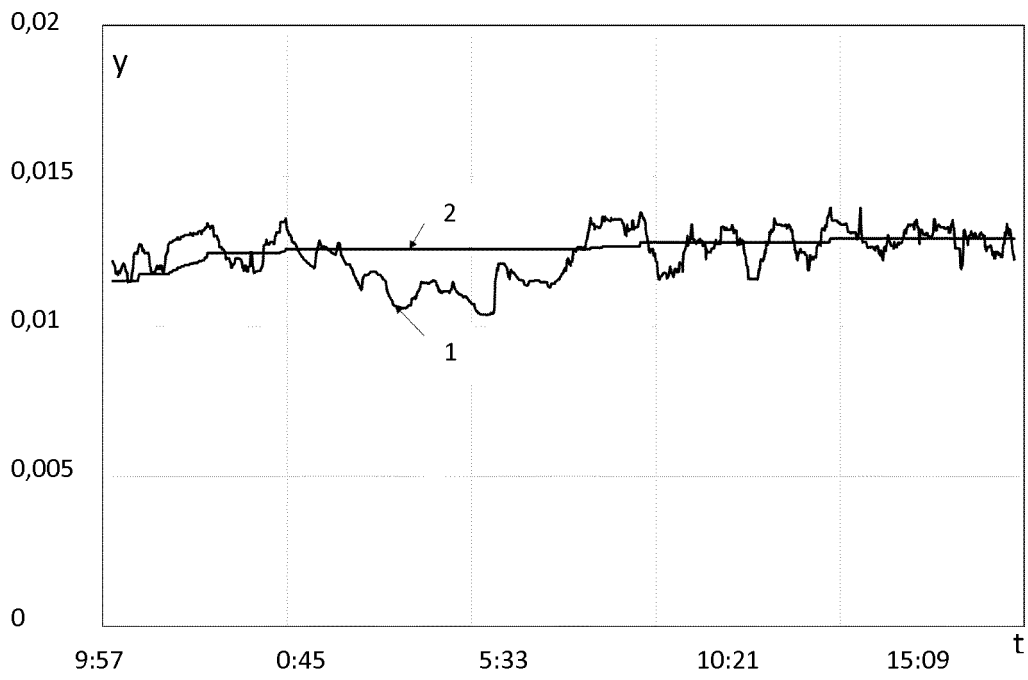


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/RU 2016/000857

5	A. CLASSIFICATION OF SUBJECT MATTER A61B 5/00 (2006.01); 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) A61B 5/053, 5/00 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched	
10	Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) "Rossiiskaya meditsina", EAPATIS, Esp@cenet, Medline, PAJ, Patentscope, PatSearch (RUPTO internal), Rambler, USPTO, Yandex, Benran, VINITI	
15	C. DOCUMENTS CONSIDERED TO BE RELEVANT	
20	Category*	Citation of document, with indication, where appropriate, of the relevant passages
		Relevant to claim No.
25	A	RU 2093069 C1 (VOLKOV IURII NIKOLAEVICH et al.) 20.10.1997
	A	RU 2251387 C1 (KAPITANOV EVGENII NIKOLAEVICH et al.) 10.05.2005
30	D, A	RU 2314750 C1 (TSVETKOV ARKADII ALEKSANDROVICH et al.) 20.01.2008
	D, A	US 8406865 B2 (COVIDIEN LP) 26.03.2013
35	D, A	US 5469859 A (N.I.MEDICAL LTD.) 28.11.1995
	A	US 2004/0230106 A1 (NELLCOR PURITAN BENNETT INCORPORATED) 18.11.2004
40	<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.	
45	* 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 application or patent 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	
50	Date of the actual completion of the international search 07 April 2017 (07.04.2017)	Date of mailing of the international search report 20 April 2017 (20.04.2017)
55	Name and mailing address of the ISA/ RU	Authorized officer
	Facsimile No.	Telephone No.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5469859 A [0004]
- RU 2314750 [0005]
- US 8406865 B [0006]

专利名称(译)	确定人体缺水的方法		
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当前申请(专利权)人(译)	HEALBE CORPORATION		
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CPC分类号	A61B5/0537 A61B5/01 A61B5/14535 A61B5/4875 A61B5/6801		
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其他公开文献	EP3387986A1		
外部链接	Espacenet		

摘要(译)

通过以低频率和高频率测量人体的一部分的阻抗来确定日常生活活动期间人体缺水状态。基于高频阻抗评估研究体积中的身体组织中的流体量。基于低频阻抗评估体积组织中的当前量的细胞外液。在测量开始时预先选择组织中评估的细胞外液量的参考值。基于当前测量时间的体积中的血液量的变化来确定校正值。确定的校正评估值。使用校正的评估值，确定缺水的开始。