



(12) **EUROPEAN PATENT APPLICATION**
published in accordance with Art. 153(4) EPC

(43) Date of publication:
14.03.2018 Bulletin 2018/11

(51) Int Cl.:
A61B 5/053 (2006.01) **A61B 5/024** (2006.01)
A61B 5/00 (2006.01)

(21) Application number: **16789672.9**

(86) International application number:
PCT/RU2016/000269

(22) Date of filing: **04.05.2016**

(87) International publication number:
WO 2016/178602 (10.11.2016 Gazette 2016/45)

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR
Designated Extension States:
BA ME
Designated Validation States:
MA MD

(72) Inventors:
• **RUBIN, Mikhail Semenovich**
St. Petersburg 191119 (RU)
• **MISJUCHENKO, Igor Leonidovich**
St. Petersburg 197371 (RU)
• **GERASIMOV, Oleg Mikhailovich**
Leningradskaya obl.
g. Sertolovo 188650 (RU)
• **STRELNIKOV, Aleksandr Sergeevich**
St. Petersburg 196084 (RU)

(30) Priority: **06.05.2015 RU 2015117066**

(74) Representative: **Reichert & Lindner**
Partnerschaft Patentanwälte
Bismarckplatz 8
93047 Regensburg (DE)

(71) Applicant: **Healbe Corporation**
Redwood City, CA 94063 (US)

(54) **SENSOR UNIT**

(57) [0039] A sensor unit intended for use in devices for simultaneous measurement of human tissue impedance and pressure, which identifies human hemodynamic parameters. The sensor unit of the device attached to skin surface segment includes a base with a recess, in which a piezoelectric element of pressure sensor is installed. The unit also includes a flexible membrane mounted on the base and overlapping said recess. First and second electrodes are attached to the outer surface of the membrane. The first electrode is mounted opposite

the recess and is capable of moving together with the membrane. The second static electrode surrounds the first electrode. A central support is mounted between the first electrode and the piezoelectric element. Being connected to the electrical outputs of said impedance measurement sensor, the first and second electrodes are aligned so as to permit contact with skin surface. Such an embodiment makes the sensor unit smaller in dimensions. At the same time, the operational stability and sensitivity of sensors are increased.

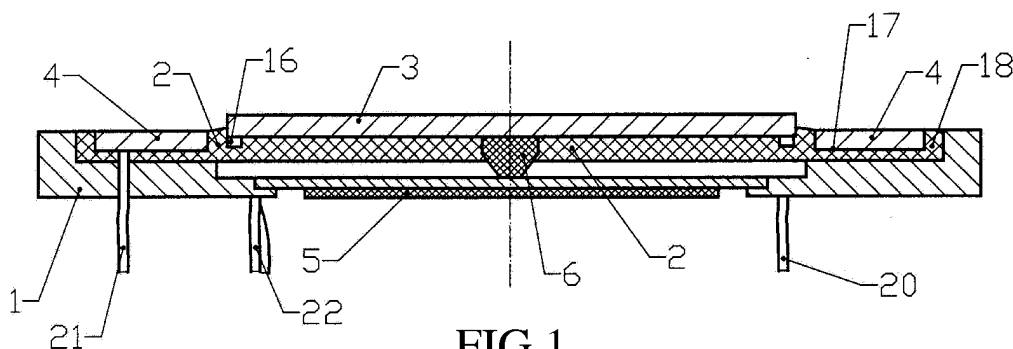


FIG 1

Description

FIELD OF THE INVENTION

[0001] The invention relates to medicine, in particular to measurements made for diagnostic purposes, more specifically, to pressure measurements aimed at identifying human body hemodynamic parameters and measurements of human tissues impedance.

BACKGROUND OF THE INVENTION

[0002] An increasing number of devices for diagnosing human state in the process of natural behavior are developed in recent times. The diagnostics is performed by using several sensors, which monitor various human vital signs, including hemodynamic parameters and impedance of human body tissues.

[0003] Various methods and embodiments of monitoring systems are known, wherein different sensors are used as separate devices.

[0004] For example, application US2004039254 (published 26/02/2004, IPC A61B05 / 00) describes a monitoring device comprising various sensors, which can be installed in a device attached to the forearm. The device can include a body tissue impedance sensor and a pressure sensor for measuring heart rate, which are manufactured separately.

[0005] A lot of other embodiments of pressure and impedance sensors to be implemented separately from each other are known.

[0006] For example, application US20070287923 (published 13/12/2007, IPC A61B5 / 021) describes the embodiment of a pressure sensor mounted on human wrist and intended for plethysmography. The sensor comprises a case with a piezoelectric element mounted therein. A sensitive movable element enabling a skin contact, relays the pressure to the piezoelectric element through a central support, thus causing said piezoelectric element to bend.

[0007] Another embodiment of a sensor for measuring human skin impedance is known from application US20040065158 (published 8/04/2004, IPC G01N1 / 00). The sensor comprises a base with a flat ring electrode mounted thereon; also mounted on the same base inside said ring electrode is a second flat strip electrode, its width being much smaller than its length.

[0008] However, no technical solutions combining a pressure sensor and an impedance sensor in a single unit are known to the applicants.

[0009] Yet, the use of separate sensors enlarges the dimensions of the device in which they are installed, and makes the application of the device more complex.

SUMMARY OF THE INVENTION

[0010] The technical result achieved by the claimed invention consists of reducing the dimensions of sensor

unit by making it smaller compared to a device containing separate sensors. Coincidentally, the operation of sensors combined into one unit becomes more stable, while their sensitivity increases.

[0011] A sensor unit, which makes part of a device attached to skin surface and comprises a pressure sensor and a sensor for measuring the impedance of a skin segment, includes a base with a recess, wherein a piezoelectric element of pressure sensor is fixed. The unit also includes a flexible membrane mounted on the base and overlapping said recess. A first electrode and a second electrode are attached to the outer surface of the membrane. The first electrode is mounted opposite the recess and is capable of moving together with the membrane. The second static electrode surrounds the first electrode. A central support is mounted between the first electrode and the piezoelectric element. The first and second electrodes are aligned so as to permit contact with skin surface, and are connected to the electrical outputs of said impedance measurement sensor.

[0012] This sensor unit structurally integrates a pressure sensor, for example, blood pressure sensor, and a sensor for measuring human tissue impedance, thus making it possible to measure the above parameters simultaneously. Such an embodiment needs a smaller skin surface area for accommodating the sensors due to mutual overlaying of pressure sensor elements and impedance sensor elements, as well as an optimal geometrical alignment of sensor elements. The second electrode surrounds the first movable electrode, thus making the whole device compact at a maximum possible area of its electrodes and the sensing element of pressure sensor, which is represented by the first electrode. Said first movable electrode represents one of the impedance sensor electrodes and, at the same time, an element that senses the skin pressure and transfers it to the piezoelectric element of pressure sensor.

[0013] The sensor unit embodiment affords opportunity to increase the operational stability of each of the two sensors. This result is achieved both by expanding the skin contact area of the sensors and by placing both impedance sensor electrodes on a flexible membrane. The placement of the first movable electrode on the flexible membrane ensures a stable skin contact provided by elastic properties of the membrane. The static sensor is also mounted at the edge of the membrane made of an elastic material attached to the base. The elastic membrane material under the static sensor provides a more stable contact between the electrode surface and the surface of the body.

[0014] The sensitivity of sensors is increased due to the fact that the skin contact area of each sensor is maximized within a given contact area of the sensor unit.

[0015] In a particular case, said recess in the base is surrounded by a groove, which accommodates the flexible membrane, with the second electrode attached thereon and above said recess. Such positioning of the membrane is technologically more effective since it decreases

the transverse dimension of the sensor unit.

[0016] Besides, the membrane can be mounted on the base in a manner that makes the whole sensor unit watertight.

[0017] In one embodiment, an opening for an electric output of the first electrode can be made in the membrane.

[0018] More particularly, the first electrode can be attached to the membrane in a manner that provides a sealed connection, which increases the overall tightness of the sensor unit.

[0019] Thereat, an opening can be made in the membrane for electric output of the first electrode.

[0020] The membrane may also comprise an opening for installing said central support. In this case, the pressure from the first electrode is transferred directly to the piezoelectric element.

[0021] In one embodiment, the flexible membrane is made of a dielectric material.

[0022] The second electrode can be mounted with a gap separating it from the first electrode.

[0023] More particularly, when the sensor is static, the outer surface of the first electrode is raised above the surface of the second electrode by 0.1 - 3 mm.

[0024] Besides, the central support can be mounted roughly at the center of the piezoelectric element.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The invention is illustrated by the following graphic materials:

Fig. 1 shows a sectional view of the sensor unit,

Fig. 2 gives a top view of the sensor unit,

Fig. 3 presents a base drawing (upper view),

Fig. 4 presents a membrane drawing (upper view),

Fig. 5 presents a second electrode drawing (upper view),

Fig. 6 shows a first electrode drawing (upper view),

Fig. 7 presents a central support drawing (side view).

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0026] The sensor unit of the device includes base 1 with recess 8 (Fig. 1, Fig. 2 and Fig. 3), wherein piezoelectric element 5 of pressure sensor is mounted on flange 9; and flexible membrane 2 (Fig. 1, Fig. 2 and Fig. 4) mounted on base 1 and overlapping recess 8. Membrane 2 can be either mounted on the base, or glued to the base in recess 7. First electrode 3 and second electrode 4 are attached to the outer surface of membrane 2 (Fig.

1, Fig. 2, Fig. 5 and Fig. 6). Both electrodes may be glued to membrane 2. Membrane 2 has groove 16 (Fig. 1, Fig. 4) on its movable part, which enhances its flexibility. It provides a sufficient mobility at the spot, where movable electrode 3 is mounted. Movable electrode 3 is glued to membrane 2. Gluing of membrane and electrodes provides the integrity of sensor unit and makes it watertight. Membrane 2 is made of a dielectric material, for example, rubber-based. Membrane 2 also includes groove 23 for mounting static electrode 4. First electrode 3 is mounted opposite recess 8. Second static electrode 4 is glued in groove 10 of membrane 2 around first movable electrode 3. Mounting of the second electrode on a rubber-based material of the membrane provides stability of contact between the second electrode and the skin. Additionally, such an embodiment makes the sensor unit watertight.

[0027] Central support 6 is mounted between first electrode 3 and piezoelectric element 5. Central support 6 has a conical section (Fig. 1 and Fig. 7). The conical section of central support 6 is placed into conical hole 15 (Fig. 4) of membrane 2, which enables a snug fit of central support 6. Central support 6 is made of a dielectric material. Electric terminals 20 and 21 of impedance measurement sensor are connected, respectively, to first electrode 3 and second electrode 4. Pressure sensor terminals 22 are connected to piezoelectric element 5 (Fig. 1). Terminal 20 of first electrode 3 passes through opening 13 in membrane 2 (Fig. 4) and opening 11 in base 1 (Fig. 3). Accordingly, terminal 21 of static electrode 4 passes through opening 14 in membrane 2 and opening 12 in base 1 (Fig. 3 and Fig. 4). When the sensor is static, the outer surface of first movable electrode 3 is raised above the surface of second fixed electrode 4 by 0.1 to 3 mm, which provides a tight contact of electrodes 3 and 4 with skin, and stabilizes the functioning of pressure sensor.

[0028] The sensor unit can be employed in devices that require data on the impedance of skin and subcutaneous layers of a body segment, as well as pressure needed, for example, to identify the hemodynamic parameters of the body. The sensor unit permits fixing on various parts of human body, including cervical spine, chest and extremities. The sensor unit is especially suitable for use in wearable devices attached to limited flat segments of the body, for example, to the wrist.

[0029] The sensor unit can be attached to the body by means of various fastening devices, for example, straps. First electrode 3 and second electrode 4 of the sensor unit must be attached in a manner providing their reliable contact with skin surface. The contact of first electrode 3 and second electrode 4 of impedance sensor with the skin enables measurements of biological tissue impedance using known methods. The contact of first movable electrode 3 with the skin affords possibility to transfer skin pulsations caused, for example, by arterial pressure changes, from the movable electrode to the membrane, central support and piezoelectric element 5, making pressure sensor operation possible.

INDUSTRIAL APPLICABILITY

[0030] The pressure sensor unit has a simple scheme and is technologically efficient. The sensor unit can be employed in various monitoring devices used in medicine and health monitoring due to its small dimensions, water tightness, as well as high sensitivity of its pressure and impedance sensors.

Claims

1. A sensor unit for diagnostic measurements disposed on a body, the sensor unit comprising:

a pressure sensor and a sensor for measuring impedance of segments of the body;
the sensor unit comprises a base with a recess accommodating a piezoelectric element of the pressure sensor, and a flexible membrane mounted on the base and overlapping the recess;

a first electrode and a second electrode disposed at an outer surface of the flexible membrane, the first electrode being positioned opposite of the recess and capable of moving together with the membrane, the second electrode being immovable and surrounding the first electrode;

a central support disposed between the first electrode and a piezoelectric element; and
the first electrode and the second electrode being disposed to permit contact with a skin of the body and being coupled to electrical terminals of the sensor for measuring impedance.

2. The sensor unit of claim 1, wherein the second electrode is disposed on the flexible membrane above the recess.

3. The sensor unit of claim 1, wherein the flexible membrane is hermetically mounted on the base.

4. The sensor unit of claim 3, wherein the membrane comprises an opening for an electrical output of the first electrode.

5. The sensor unit of claim 1, wherein the first electrode is hermetically attached to the flexible membrane.

6. The sensor unit of claim 5, wherein the flexible membrane comprises an opening for an electrical output of the first electrode.

7. The sensor unit of claim 5, wherein the flexible membrane comprises an opening for the central support.

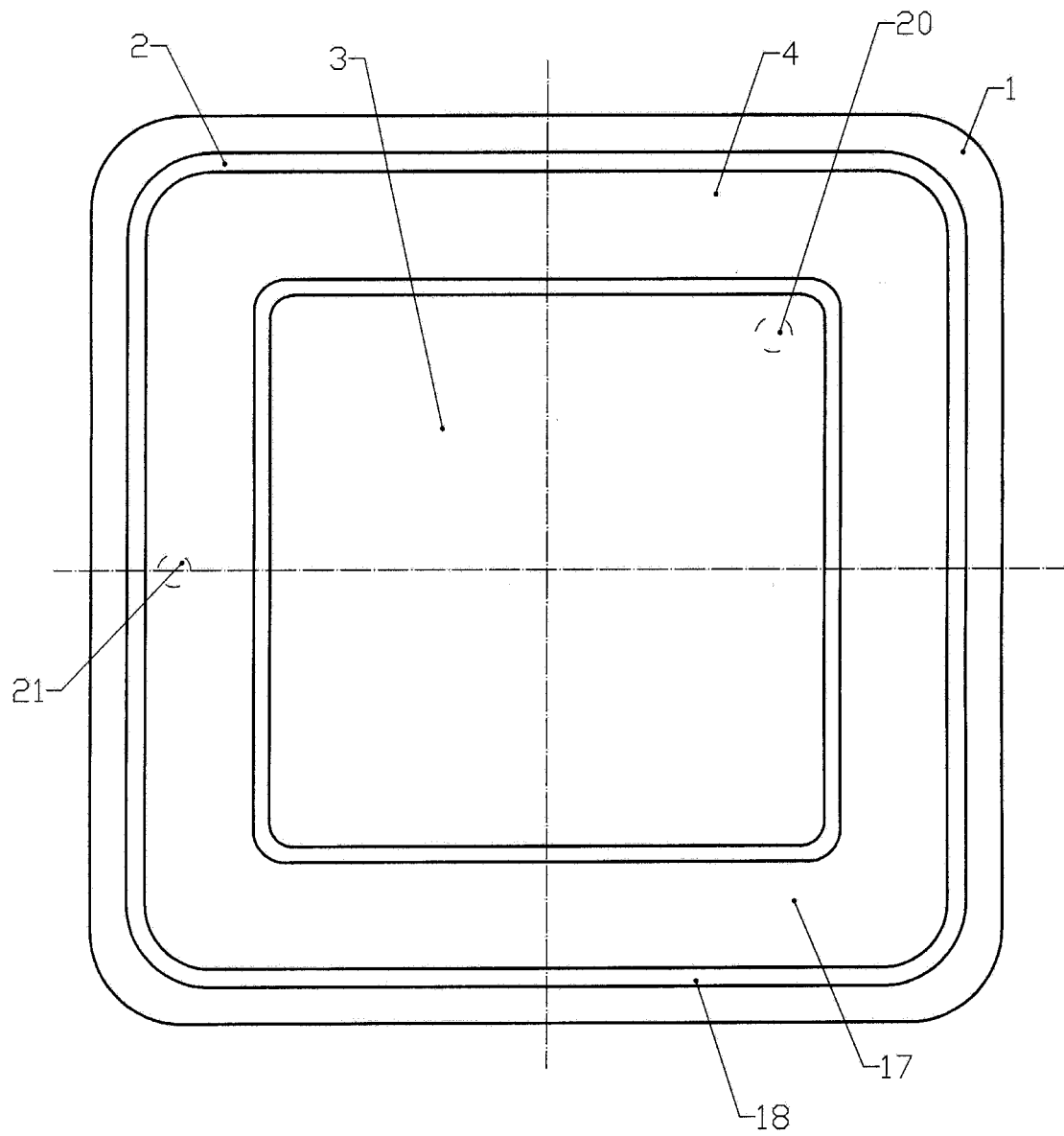
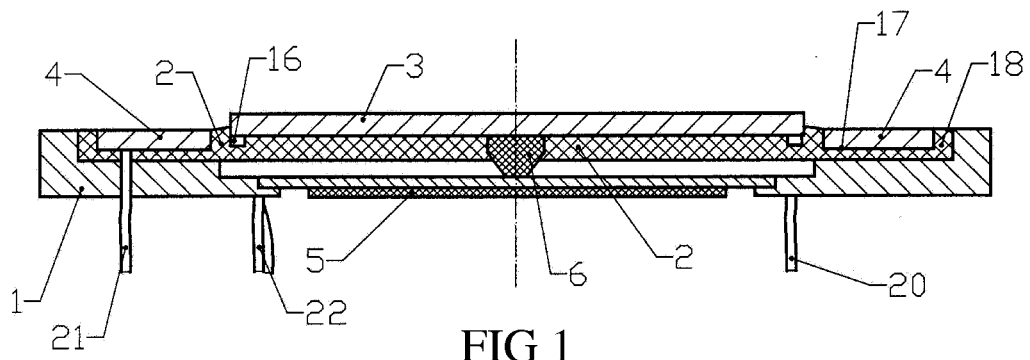
8. The sensor unit of claim 1, wherein the flexible mem-

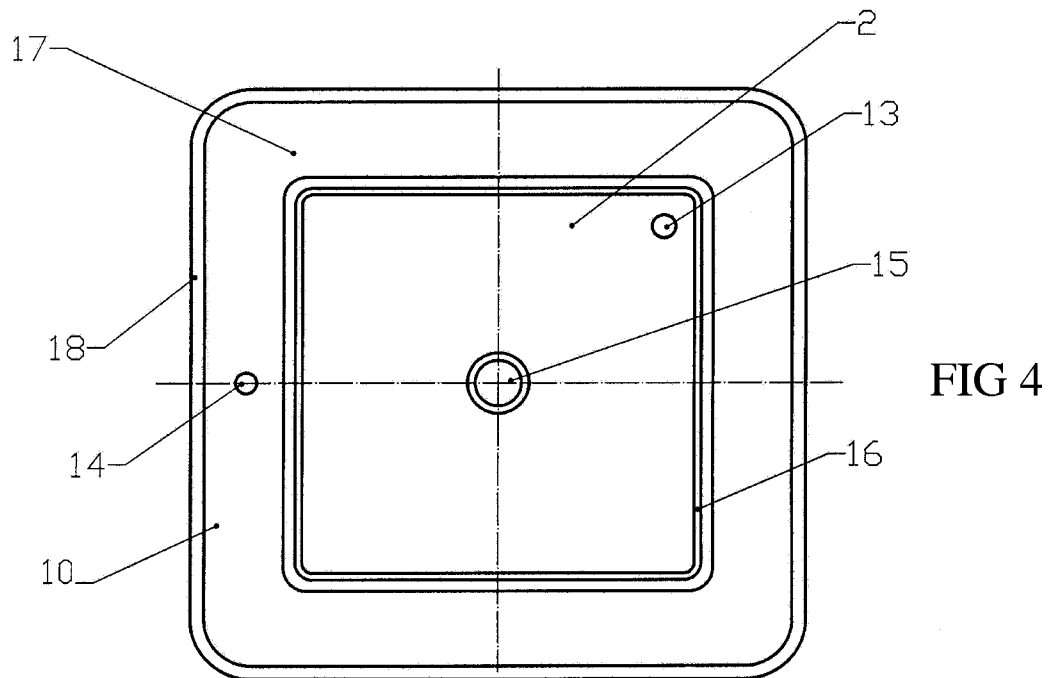
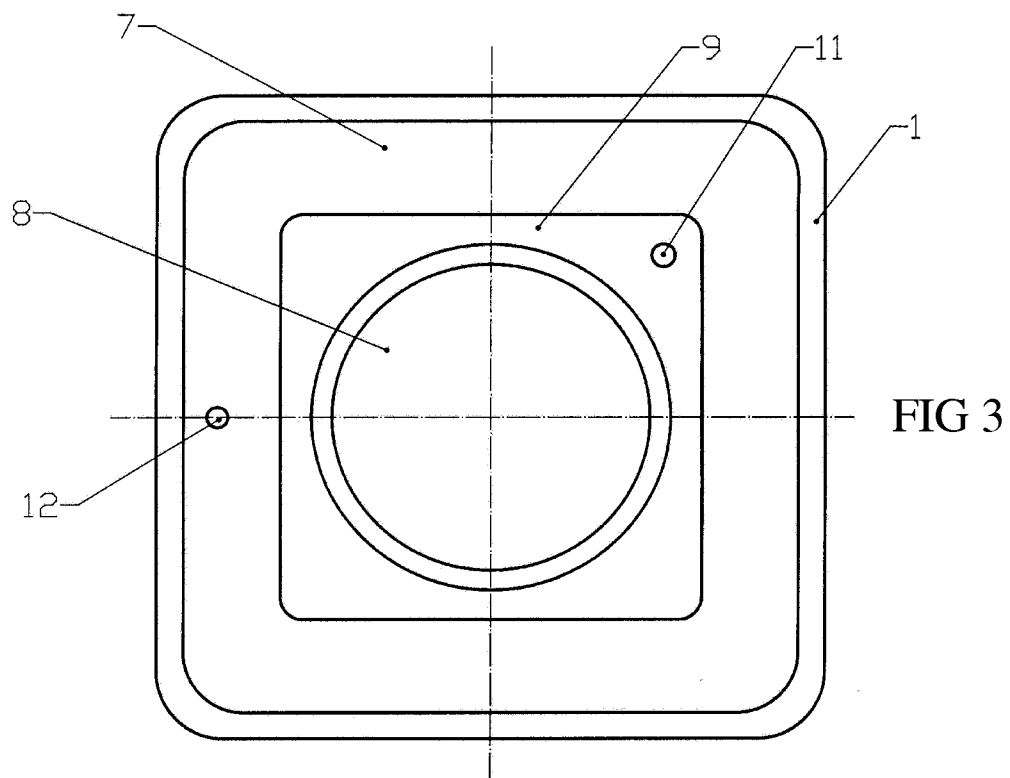
brane is made of a dielectric material.

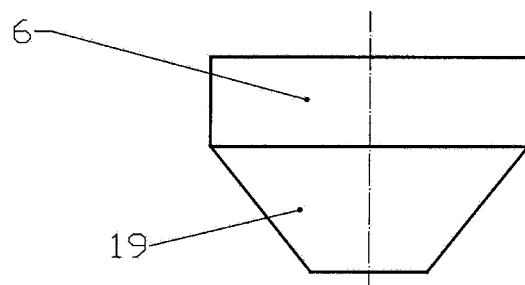
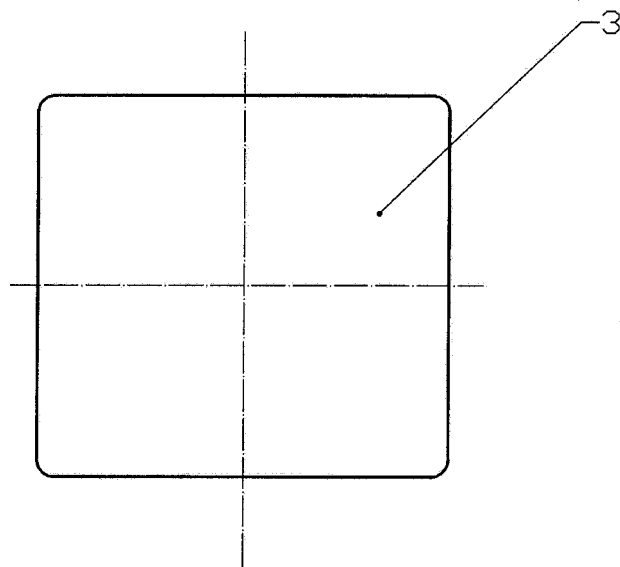
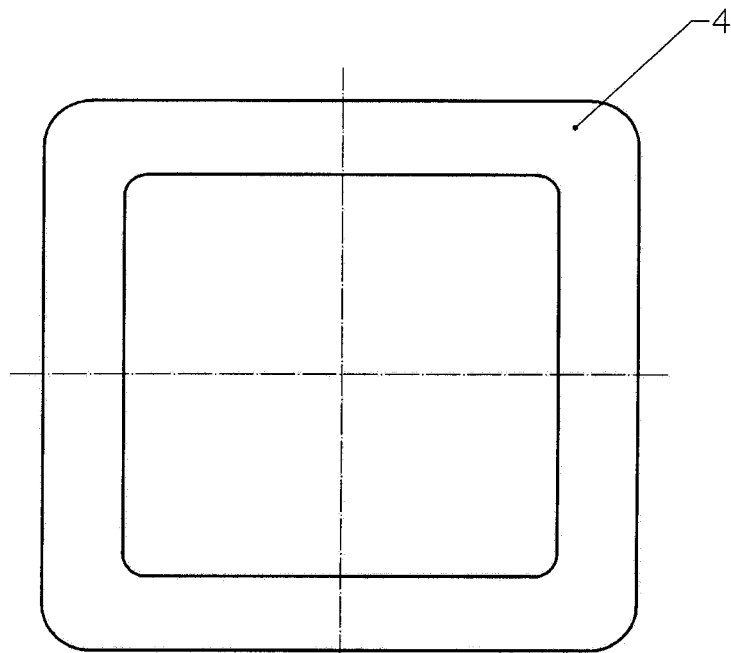
9. The sensor unit of claim 1, wherein the second electrode and the first electrode are separated by a gap.

10. The sensor unit of claim 1, wherein an outer surface of the first electrode is raised above a surface of the second electrode by a range from 0.1 mm to 3 mm.

11. The sensor unit of claim 1, wherein the central support is disposed at a center of the piezoelectric element.







INTERNATIONAL SEARCH REPORT

International application No.
PCT/RU 2016/000269

5	A. CLASSIFICATION OF SUBJECT MATTER		
	A61B5/02 (2006.01) A61B 5/053 (2006.01)		
	According to International Patent Classification (IPC) or to both national classification and IPC		
	B. FIELDS SEARCHED		
10	Minimum documentation searched (classification system followed by classification symbols) A61B 5/00-5/053, G01N 33/483, 27/02		
	Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
15	Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PatSearch, esp@cenet, USPTO, Google		
	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	US 2006/0116564 A1 MARTIN P. MINTCHEV et al. 01.06.2006 abstract, the claims, paragraphs [0007], [0008], [0012], [0026]-[0033], fig. 1-3	1-11
30	A	RU 2283025 C2 (CHINAREV ALEKSANDR ALEKSEEVICH) 10.09.2006	1-11
35			
40	☐ Further documents are listed in the continuation of Box C. ☐ 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 17 August 2016 (17.08.2016)		Date of mailing of the international search report 25 August 2016 (25.08.2016)
55	Name and mailing address of the ISA/ Facsimile No.		Authorized officer Telephone No.

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

- US 2004039254 A [0004]
- US 20070287923 A [0006]
- US 20040065158 A [0007]

专利名称(译)	传感器单元		
公开(公告)号	EP3292816A1	公开(公告)日	2018-03-14
申请号	EP2016789672	申请日	2016-05-04
申请(专利权)人(译)	HEALBE CORPORATION		
当前申请(专利权)人(译)	HEALBE CORPORATION		
[标]发明人	RUBIN MIKHAIL SEMENOVICH MISJUCHENKO IGOR LEONIDOVICH GERASIMOV OLEG MIKHAILOVICH STRELNIKOV ALEKSANDR SERGEEVICH		
发明人	RUBIN, MIKHAIL SEMENOVICH MISJUCHENKO, IGOR LEONIDOVICH GERASIMOV, OLEG MIKHAILOVICH STRELNIKOV, ALEKSANDR SERGEEVICH		
IPC分类号	A61B5/053 A61B5/024 A61B5/00		
CPC分类号	A61B5/02438 A61B5/0531 A61B5/6824 A61B5/02 A61B5/053 A61B5/0205 A61B5/02141 A61B2562/0247 A61B2562/164		
优先权	2015117066 2015-05-06 RU		
其他公开文献	EP3292816A4 EP3292816B1		
外部链接	Espacenet		

摘要(译)

旨在用于同时测量人体组织阻抗和压力的装置的传感器单元，其识别人体血液动力学参数。附接到皮肤表面区段的装置的传感器单元包括具有凹部的基部，压力传感器的压电元件安装在该凹部中。该单元还包括安装在基座上并与所述凹槽重叠的柔性膜。第一和第二电极连接到膜的外表面。第一电极与凹槽相对安装，并且能够与膜一起移动。第二静电极围绕第一电极。中心支撑件安装在第一电极和压电元件之间。连接到所述阻抗测量传感器的电输出，第一和第二电极对准，以允许与皮肤表面接触。这样的实施例使传感器单元的尺寸更小。同时，增加了传感器的操作稳定性和灵敏度。

