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(54) **SENSOR UNIT FOR DIAGNOSTIC MEASUREMENTS**

SENSOREINHEIT FÜR DIAGNOSTISCHE MESSUNGEN

UNITÉ DE CAPTEURS POUR DES MESURES DIAGNOSTIQUES

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- MISJUCHENKO, Igor Leonidovich**
St. Petersburg 197371 (RU)
- GERASIMOV, Oleg Mikhailovich**
Leningradskaya obl.
g. Sertolovo 188650 (RU)
- STRELNIKOV, Aleksandr Sergeevich**
St. Petersburg 196084 (RU)

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

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(56) References cited:
**WO-A1-03/017834 RU-C2- 2 283 025
US-A1- 2004 065 158 US-A1- 2006 116 564
US-A1- 2007 287 923**

(73) Proprietor: **Healbe Corporation
Redwood City, CA 94063 (US)**

(72) Inventors:

- RUBIN, Mikhail Semenovich**
St. Petersburg 191119 (RU)

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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] 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.

[0009] Document WO 03/017834 A1 describes a biological signal sensor for measuring and recording impedance of human body area, pulse wave parameters etc.. This known sensor has four electrodes arranged on a common base, three of which are made as closed circuits, placed one into another, whereas the fourth electrode is placed inside the smallest circuit. The external and central electrodes form a pair of current-feeding elec-

trodes, whereas the electrodes placed between them form a pair of measuring electrodes.

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] The invention is defined in the independent claim 1. Preferred embodiments are set forth in the dependent claims.

[0012] 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.

[0013] 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.

[0014] 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.

[0015] 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.

[0016] In a particular case, said recess in the base is surrounded by a groove, which accommodates the flexible membrane, with the second electrode attached thereto and above said recess. Such positioning of the membrane is technologically more effective since it decreases the transverse dimension of the sensor unit.

[0017] Besides, the membrane can be mounted on the base in a manner that makes the whole sensor unit watertight.

[0018] In one embodiment, an opening for an electric output of the first electrode can be made in the membrane.

[0019] 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.

[0020] Thereat, an opening can be made in the membrane for electric output of the first electrode.

[0021] 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.

[0022] In one embodiment, the flexible membrane is made of a dielectric material.

[0023] The second electrode can be mounted with a gap separating it from the first electrode.

[0024] 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.

[0025] Besides, the central support can be mounted roughly at the center of the piezoelectric element.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] 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

[0027] The sensor unit of the device includes base 1 with recess 8 (see Fig. 3), wherein piezoelectric element 5 of pressure sensor is mounted on flange 9 (Fig. 3); 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 1, or glued to the base 1 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 3, 4 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 2 and electrodes 3, 4 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 17 for mounting static electrode 4. First electrode 3 is mounted opposite recess 8. Second static electrode 4 is glued in groove 17 of membrane 2 around first movable electrode 3. Mounting of the second electrode 4 on a rubber-based material of the membrane 2 provides stability of contact between the second electrode 4 and the skin. Additionally, such an embodiment makes the sensor unit watertight.

[0028] Central support 6 is mounted between first electrode 3 and piezoelectric element 5. Central support 6 has a conical section 19 (Fig. 1 and Fig. 7). The conical section 19 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.

[0029] 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.

[0030] 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

[0031] 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 and configured to be 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 (1) with a recess (8) accommodating a piezoelectric element (5) of the pressure sensor, and a flexible membrane (2) mounted on the base (1) and overlapping the recess (8);
 a first electrode (3) and a second electrode (4) disposed at an outer surface of the flexible membrane (2), the first electrode (3) being positioned opposite of the recess (8) and capable of moving together with the membrane (2), the second electrode (4) being immovable and surrounding the first electrode (3);
 a central support (6) disposed between the first electrode (3) and the piezoelectric element (5); and
 the first electrode (3) and the second electrode (4) being disposed to permit contact with a skin of the body and being coupled to electrical terminals (20,21) of the sensor for measuring impedance.

2. The sensor unit of claim 1, wherein the flexible membrane (2) is hermetically mounted on the base (1).
3. The sensor unit of claim 2, wherein the membrane (2) comprises an opening (13) for an electrical output of the first electrode (3).

4. The sensor unit of claim 1, wherein the first electrode (3) is hermetically attached to the flexible membrane (2).

5. The sensor unit of claim 4, wherein the flexible membrane (2) comprises an opening (13) for an electrical output of the first electrode (3).

6. The sensor unit of claim 4, wherein the flexible membrane (2) comprises an opening (15) for the central support (6).

7. The sensor unit of claim 1, wherein the flexible membrane (2) is made of a dielectric material.

8. The sensor unit of claim 1, wherein the second electrode (4) and the first electrode (3) are separated by a gap.

9. The sensor unit of claim 1, wherein an outer surface of the first electrode (3) is raised above a surface of the second electrode (4) by a range from 0.1 mm to 3 mm.

10. The sensor unit of claim 1, wherein the central support (6) is disposed at a center of the piezoelectric element (5).

Patentansprüche

1. Sensoreinheit für Diagnosemessungen, die konfiguriert ist, um an einem Körper angeordnet zu werden, wobei die Sensoreinheit umfasst:

einen Drucksensor und einen Sensor zum Messen einer Impedanz von Segmenten des Körpers;

wobei die Sensoreinheit eine Basis (1) mit einer Aussparung (8) umfasst, die ein piezoelektrisches Element (5) des Drucksensors aufnimmt, und eine flexible Membran (2), die an der Basis (1) montiert ist und mit der Aussparung (8) überlappt;

eine erste Elektrode (3) und eine zweite Elektrode (4), die an einer Außenfläche der flexiblen Membran (2) angeordnet sind, wobei die erste Elektrode (3) gegenüber der Aussparung (8) positioniert und dazu geeignet ist, sich zusammen mit der Membran (2) zu bewegen, wobei die zweite Elektrode (4) unbeweglich ist und die erste Elektrode (3) umgibt;

einen zentralen Träger (6), der zwischen der ersten Elektrode (3) und dem piezoelektrischen Element (5) angeordnet ist; und

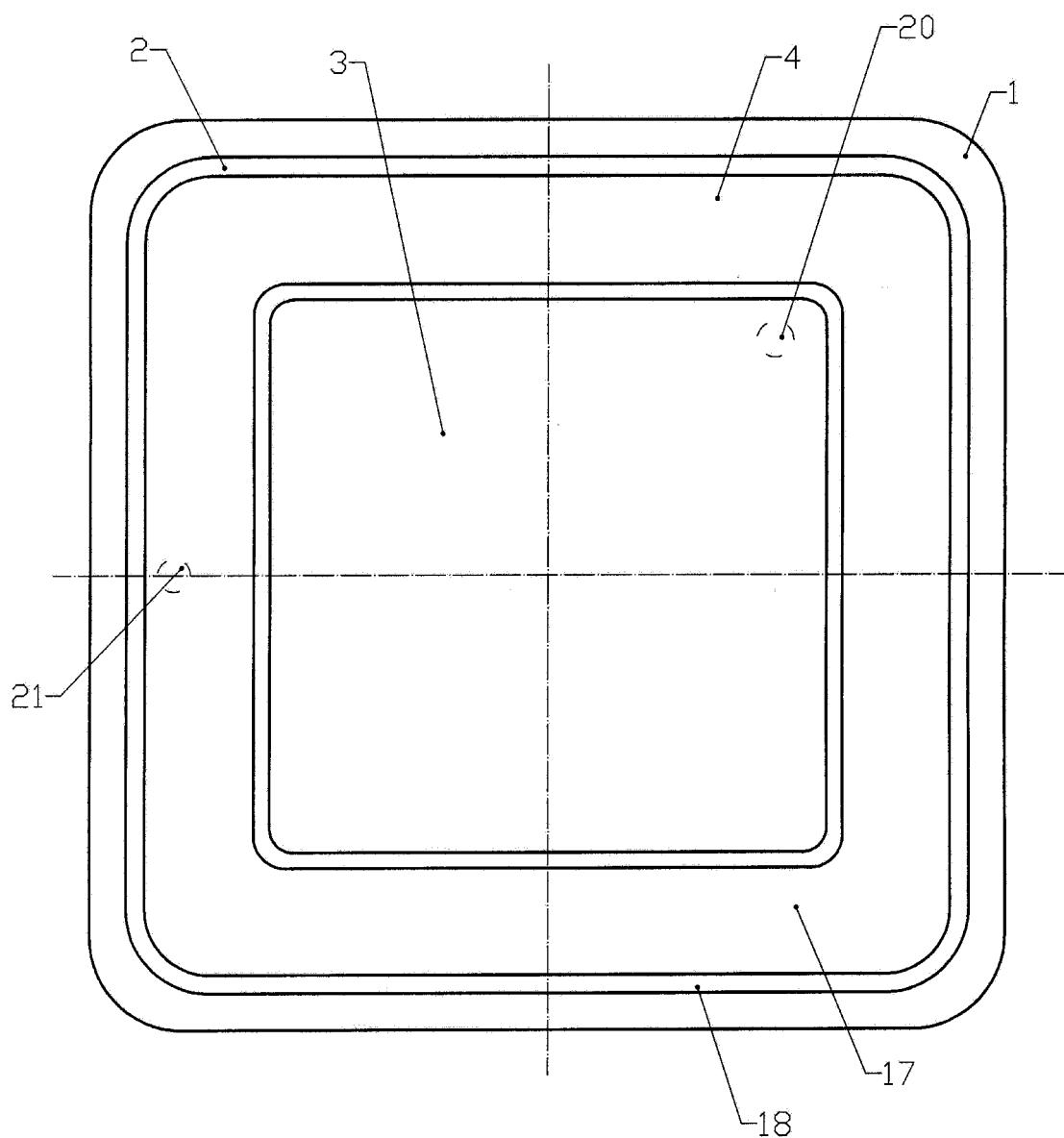
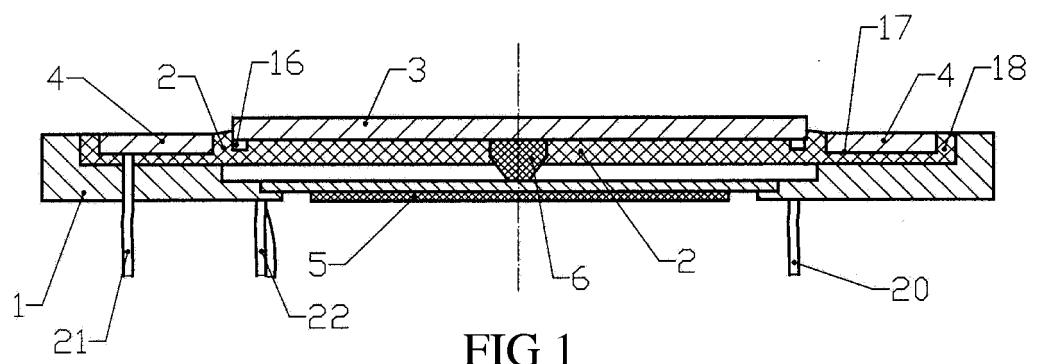
wobei die erste Elektrode (3) und die zweite Elektrode (4) angeordnet sind, um eine Berührung mit einer Haut des Körpers zu ermöglichen,

und zum Messen einer Impedanz an elektrische Anschlüsse (20, 21) des Sensors gekoppelt sind.

2. Sensoreinheit nach Anspruch 1, wobei die flexible Membran (2) hermetisch an der Basis (1) montiert ist. 5
3. Sensoreinheit nach Anspruch 2, wobei die Membran (2) eine Öffnung (13) für einen elektrischen Ausgang der ersten Elektrode (3) umfasst. 10
4. Sensoreinheit nach Anspruch 1, wobei die erste Elektrode (3) hermetisch an der flexiblen Membran (2) angebracht ist. 15
5. Sensoreinheit nach Anspruch 4, wobei die flexible Membran (2) eine Öffnung (13) für einen elektrischen Ausgang der ersten Elektrode (3) umfasst. 20
6. Sensoreinheit nach Anspruch 4, wobei die flexible Membran (2) eine Öffnung (15) für den zentralen Träger (6) umfasst. 25
7. Sensoreinheit nach Anspruch 1, wobei die flexible Membran (2) aus einem dielektrischen Material gefertigt ist. 30
8. Sensoreinheit nach Anspruch 1, wobei die zweite Elektrode (4) und die erste Elektrode (3) durch einen Spalt getrennt sind. 35
9. Sensoreinheit nach Anspruch 1, wobei eine Außenfläche der ersten Elektrode (3) um einen Bereich zwischen 0,1 mm und 3 mm über eine Fläche der zweiten Elektrode (4) angehoben ist. 40
10. Sensoreinheit nach Anspruch 1, wobei der zentrale Träger (6) in einem Zentrum des piezoelektrischen Elements (5) angeordnet ist. 45

Revendications

1. Unité de capteur pour des mesures de diagnostic et configurée pour être disposée sur un corps, l'unité de capteur comprenant :
un capteur de pression et un capteur destiné à mesurer l'impédance de segments du corps ; l'unité de capteur comprend une base (1) avec un évidement (8) accueillant un élément piézoélectrique (5) du capteur de pression, et une membrane flexible (2) montée sur la base (1) et chevauchant l'évidement (8) ; une première électrode (3) et une seconde électrode (4) disposées au niveau d'une surface externe de la membrane flexible (2), la première 55
2. Unité de capteur selon la revendication 1, dans laquelle la membrane flexible (2) est positionnée à l'opposé de l'évidement (8) et capable de se déplacer conjointement avec la membrane (2), la seconde électrode (4) étant immobile et entourant la première électrode (3) ; un support central (6) disposé entre la première électrode (3) et l'élément piézoélectrique (5) ; et la première électrode (3) et la seconde électrode (4) étant disposées pour permettre un contact avec une peau du corps et étant couplées à des bornes électriques (20, 21) du capteur en vue de mesurer l'impédance. 60
3. Unité de capteur selon la revendication 1, dans laquelle la membrane flexible (2) est hermétiquement montée sur la base (1). 65
4. Unité de capteur selon la revendication 2, dans laquelle la membrane (2) comprend une ouverture (13) pour une sortie électrique de la première électrode (3). 70
5. Unité de capteur selon la revendication 1, dans laquelle la première électrode (3) est hermétiquement fixée à la membrane flexible (2). 75
6. Unité de capteur selon la revendication 4, dans laquelle la membrane flexible (2) comprend une ouverture (13) pour une sortie électrique de la première électrode (3). 80
7. Unité de capteur selon la revendication 1, dans laquelle la membrane flexible (2) est constituée d'un matériau diélectrique. 85
8. Unité de capteur selon la revendication 1, dans laquelle la seconde électrode (4) et la première électrode (3) sont séparées par un écartement. 90
9. Unité de capteur selon la revendication 1, dans laquelle une surface externe de la première électrode (3) est soulevée au-dessus d'une surface de la seconde électrode (4) dans une plage de 0,1 mm à 3 mm. 95
10. Unité de capteur selon la revendication 1, dans laquelle le support central (6) est disposé en un centre de l'élément piézoélectrique (5). 100



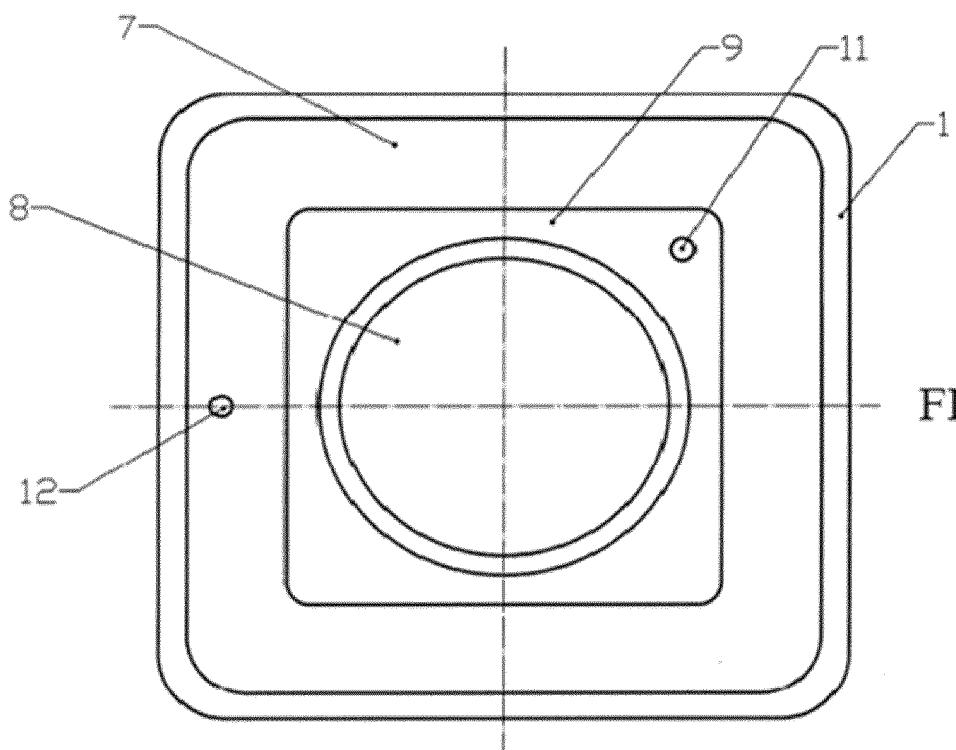


FIG 3

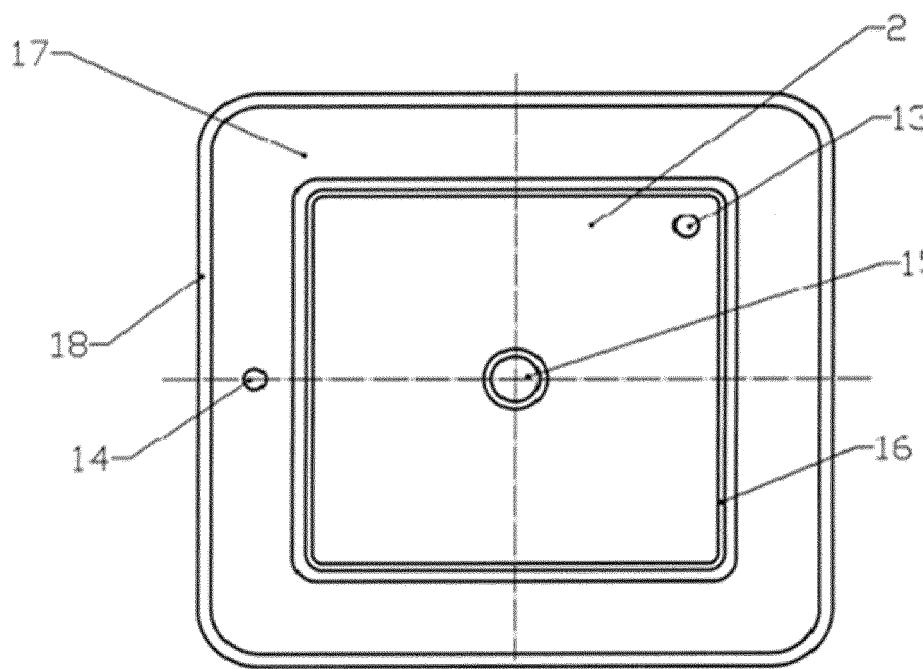


FIG 4

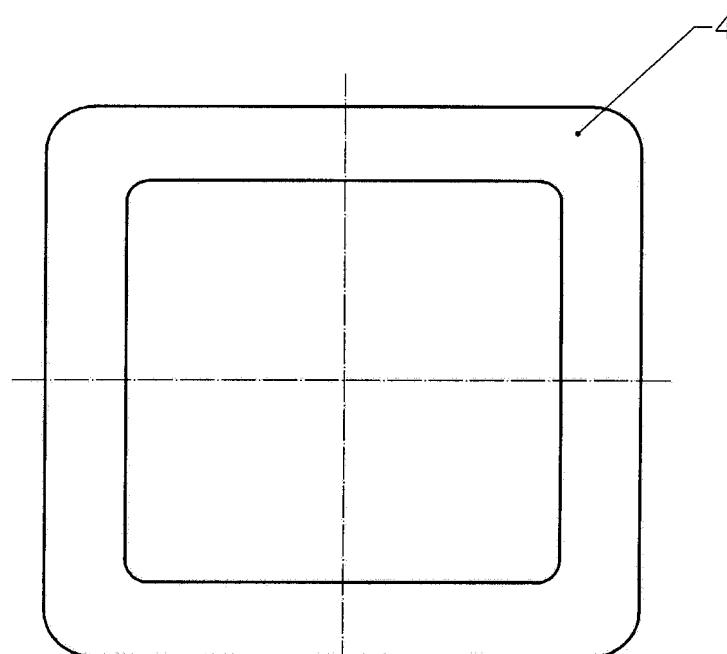


FIG 5

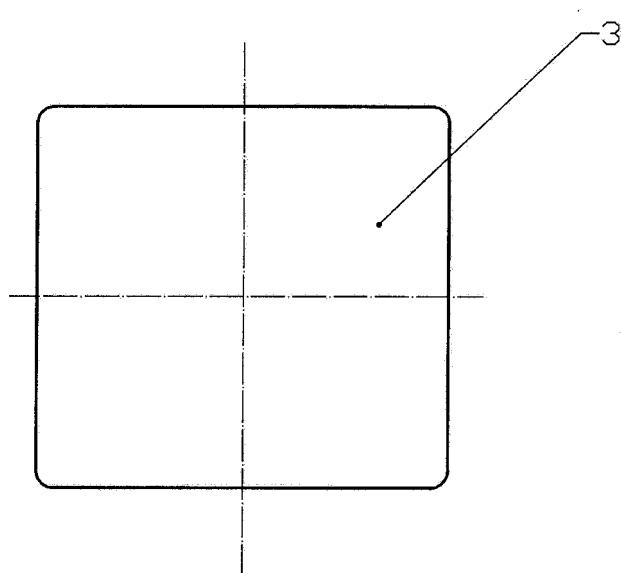


FIG 6

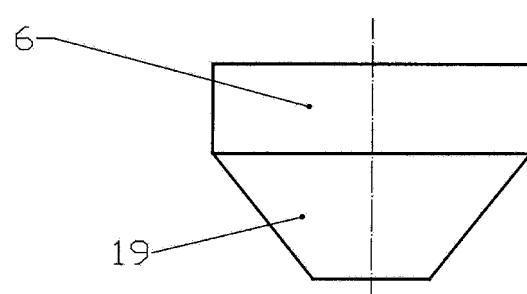


FIG 7

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 2004039254 A [0004]
- US 20070287923 A [0006]
- US 20040065158 A [0007]
- WO 03017834 A1 [0009]