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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
04 January 2018 (04.01.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/005298 A1

(51) International Patent Classification:
A61B 5/022 (2006.01) *A61B 5/021* (2006.01)

(21) International Application Number:
PCT/US2017/039103

(22) International Filing Date:
23 June 2017 (23.06.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/354,792 26 June 2016 (26.06.2016) US

(72) Inventors; and
(71) Applicants: **SHIH, Wen-Pin** [CN/CN]; Mechanical Engineering, No. 1, Sec. 4, Roosevelt Rd., Taipei, 10617 (TW). **LEU, Jessica En Shiuan** [US/CN]; 4F., No. 13-3, Aly. 10, Ln. 155, Sec. 2, Guangfu Rd., East Dist., Hsinchu City, 300 (TW).

(72) Inventors: **LIU, Chien-Hao**; Mechanical Engineering, No. 1, Sec. 4, Roosevelt Rd., Taipei, 10617 (TW). **HUANG, Po-Hao**; 2332 Glendenning Ave., Santa Clara, California 95050 (US). **CHEN, Wei-Jie**; 9F.-1, No. 8, Ln. 42, Sec. 2, Yong'an S. Rd., Luzhou Dist., New Taipei City, 24766 (TW). **HU, Shiang**; 3F., No. 25, Ln. 219, Dahushanzhuang St., Neihu Dist., Taipei City, 114 (TW). **CHENG, Chen-Yu**; 1F., No. 185-1, Gongyuan Rd., Linkou Dist., New Taipei City, 244 (TW).

(74) Agent: **HUANG, Jason C.** et al.; Patterson & Sheridan, LLP, 24 Greenway Plaza, Suite 1600, Houston, Texas 77046 (US).

(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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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, KM, ML, MR, NE, SN, TD, TG).

(54) Title: WEARABLE BLOOD-PRESSURE MONITORING DEVICE AND NON-INVASIVE BLOOD-PRESSURE MONITORING METHOD

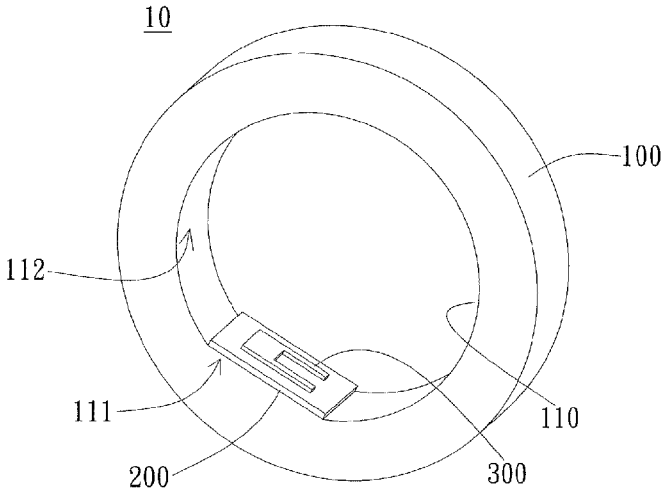

FIG. 2

(57) Abstract: The present invention provides a wearable device for monitoring blood-pressure. Said wearable device comprises a ring body; an elastomer disposed on a monitoring surface at an inner side of the ring body; and a strain gauge disposed on the elastomer at the inner side of the ring body. In said wearable device, the electrical resistance of the strain gauge is indicative of blood-pressure of a wearer.

WO 2018/005298 A1

[Continued on next page]

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))*

WEARABLE BLOOD-PRESSURE MONITORING DEVICE AND NON-INVASIVE BLOOD-PRESSURE MONITORING METHOD

PRIORITY:

[0001] The present application claims benefit and priority from U.S. Provisional Application No. 62/354,792, filed Jun. 26, 2016, which was entitled "A piezoresistive real-time blood pressure sensing device". The entire disclosure of which is hereby incorporated by reference as if fully set forth herein.

FIELD OF INVENTION:

[0002] This invention generally relates to a wearable device and a monitoring method for monitoring blood-pressure. Specifically, the present invention relates to a wearable device and a monitoring method for non-invasive monitoring blood-pressure in real-time.

BACKGROUND:

[0003] Recently, due to the busy lifestyle and the inappropriate diet and eating habits, cardiovascular diseases have become major threats to human beings in modern society. Such cardiovascular diseases might cause acute heart attack and strokes or chronic conditions that long-term affect the patients, and therefore deteriorate the quality of life and increase the risks of mortality in the patients. Thus, prevention of cardiovascular disease is an area of major public health importance.

[0004] Nowadays, a number of drugs or therapeutic strategies have been developed to treat or manipulate the cardiovascular diseases. As a result, predicting short-term and long-term risk of the cardiovascular diseases for people plays an important role in the cardiovascular diseases treatment. To this end, although pathogenesis of different cardiovascular diseases might be distinct from each other, most of them can be monitored and precautionary assessed through specific physical signs. Since most cardiovascular diseases including hypertension diseases and hypotension diseases are significantly related to blood pressures and such monitoring techniques thereof are not well-developed and implemented universal, there is a need to establish or develop a monitoring device or a monitoring method for monitoring blood pressures in households or hospitals in a simpler manner.

[0005] Furthermore, in order to avoid the discomfort of the patients, it is preferred to design and develop a device or a method to efficiently monitor the blood pressures in real-time with a non-invasive manner. Non-invasive blood pressure measuring devices including sphygmomanometers and photoplethysmography have been used in monitoring patient's blood pressures to prevent various cardiovascular diseases or provide doctors with early diagnosis. However, most of them are bulky and heavy which are inconvenient for outdoor applications and long-time monitoring. Therefore, a wearable blood-pressure monitoring device with a light weight and small size or a monitoring method that can be easily operated with a small device is needed in terms of real-time monitoring and portable capability.

SUMMARY OF THE INVENTION:

[0006] TECHNICAL MEANS FOR SOLVING THE PROBLEMS

[0007] To solve the above issues, an embodiment of the present invention provides a wearable device for monitoring blood-pressure. Said wearable device comprises a ring body; an elastomer disposed on a monitoring surface at an inner side of the ring body; and a strain gauge disposed on the elastomer at the inner side of the ring body. In said wearable device, the electrical resistance of the strain gauge is indicative of blood-pressure of a wearer.

[0008] Another embodiment of the present invention provides a monitoring method for non-invasive monitoring blood-pressure. Said monitoring method comprises the steps of measuring a signal representing a deformation of a skin resulted from blood pressure on a subject; and deriving the blood-pressure of the subject from the signal.

[0009] TECHNICAL EFFECTS ACHIEVED BY THE TECHNICAL MEANS

[0010] The wearable device and the monitoring method for monitoring blood-pressure according to the embodiments of the present invention use the signal representing the deformation of the skin to retrieve the blood-pressure. In this way, a change in the blood-pressure can be easily detected in the form of the deformation of the skin and can be transferred into electrical signals to be further processed and revealed. Moreover, according to certain embodiments of the present invention, the strain gauge is applied to detect the deformation of the skin in the wearable device and the monitoring method. In viewing of this, the wearable device including the small strain gauge according to the embodiments of the present invention can be designed to have compact volumes, such that it is suitable for

long-time usage and outdoor activities.

BRIEF DESCRIPTION OF THE DRAWINGS:

[0011] The above and further features, advantages and benefits of the present invention will be apparent upon consideration of the present description taken in conjunction with the accompanying drawings, in which:

[0012] FIG. 1 and FIG. 2 are schematic views of a wearable device according to an embodiment of the present invention.

[0013] FIG. 3 illustrates a schematic section view of a finger according to an embodiment of the present invention.

[0014] FIG. 4 illustrates a schematic section view of a finger wearing the wearable device according to an embodiment of the present invention.

[0015] FIG. 5 illustrates a schematic view of a proposed mechanical model for measuring blood-pressure according to an embodiment of the present invention.

[0016] FIG. 6 illustrates a schematic view of a modified mechanical model for measuring blood-pressure according to an embodiment of the present invention.

[0017] FIG. 7 is a schematic view of a wearable device according to another embodiment of the present invention.

[0018] FIG. 8 illustrates a pressure sensor (FSR400) used in the wearable device shown in FIG. 7.

[0019] FIG. 9 is a schematic view of the circuit of the pressure sensor (FSR400) used in the wearable device according to an embodiment of the present invention.

[0020] FIG. 10A and FIG. 10B are schematic views of wearable devices according to further embodiments of the present invention.

[0021] FIG. 11 and FIG. 12 are schematic views of wearable devices according to first and second modified embodiments of the present invention.

[0022] FIG. 13A and FIG. 13B are schematic views of a wearable device according to a third modified embodiment of the present invention.

[0023] FIG. 14A and FIG. 14B are schematic views of a wearable device according to a fourth modified embodiment of the present invention.

[0024] FIG. 15A and FIG. 15B are schematic views of a wearable device according to a fifth modified embodiment of the present invention.

[0025] FIG. 16A and FIG. 16B are schematic views of an artificial finger according to an embodiment of the present invention.

[0026] FIG. 17 illustrates the force output/voltage curves based on different sensitivity resistor RM; FIG. 18 shows the initial signal monitored by the DBU-120A bridge unit and the signal after being filtered by Matlab; FIG. 19 was the spectrum of the filter signal after Fast Fourier Transform using Matlab; and FIG. 20 is the curve of the output voltage of the FSR400 circuit and the "Normal-Force-Const." using a wearable device and a monitoring method according to an embodiment of the present invention.

[0027] FIG. 21 is the conversion results of the strain signal of FIG. 18 to blood pressure according to an embodiment of the present invention; and FIG. 22 is the comparison curve of the measured blood-pressure obtained according to the embodiment of the present invention and the real applied pressure recorded by the pressure transmitter.

[0028] FIG. 23 is the comparison curve of the measured blood-pressure obtained according to the embodiment of the present invention and the wrist type sphygmomanometer.

DETAILED DESCRIPTION OF THE PRESENT INVENTION:

[0029] The present invention will be described more fully hereinafter with reference to the accompanying drawings, in which exemplary embodiments of the invention are shown. In the drawings, the thickness of layers and regions may be exaggerated or otherwise modified for clarity. The same or similar reference numerals in different drawings represent the same or similar elements. Furthermore, well-known structures, materials, or operations are not shown or described in detail to avoid obscuring aspects of the described devices. As those skilled in the art would realize, the described embodiments may be modified in various different ways, all without departing from the spirit or scope of the present invention. It should be noted that, without conflict, in the embodiment of the present invention and examples of features can be combined with each other. Therefore, it should be appreciated that the embodiments described herein are not intended to be exhaustive of all possible embodiments in accordance with the present disclosure, and that additional embodiments may be conceived based on the subject matter disclosed herein.

[0030] Hereinafter, a wearable device according to an embodiment of the present

invention will be described with reference to FIG. 1 (front view) and FIG. 2 (oblique view).

[0031] According to an embodiment of the present invention, a wearable device 10 for monitoring blood-pressure according to an embodiment of the present invention includes a ring body 100; an elastomer 200 disposed on a monitoring surface 111 at an inner side 110 of the ring body 100; and a strain gauge 300 disposed on the elastomer 200 at the inner side 110 of the ring body 100.

[0032] In said wearable device 10 shown in FIG. 1 and FIG. 2, the ring body 100 may be formed from any rigid materials. For example, the ring body 100 may be made of metal, alloy, plastic, silica, granite, basalt, boron nitride, tungsten carbide, etc., and the present invention is not limited thereto.

[0033] Here, the monitoring surface 111 and a non-monitoring surface 112 may respectively represent continuous surfaces along the inner side 110 of the ring body 100, and in some embodiments of the present invention, the monitoring surface 111 and a non-monitoring surface 112 may have different curvature. Specifically, in a preferred embodiment of the present invention, the monitoring surface 111 is a plate surface or a surface with curvature less than a surface apart from the monitoring surface 111 at the inner side 110 of the ring body 100. That is, in a preferred embodiment of the present invention, the curvature of the monitoring surface 111 is less than the curvature of the non-monitoring surface 112, thereby increasing the contact area and/or the compression of the wearable device 10 on a measured subject matter (for example, skin of a subject) at the monitoring surface 111. However, the present invention is not limited thereto.

[0034] An elastomer 200 softer than the ring body 100 is provided on the monitoring surface 111. That is, the Young's modulus of the elastomer 200 is smaller than the Young's modulus of the ring body 100. In such configuration, stretching of or compression to the monitoring surface 111 would mainly deform the elastomer 200 rather than the ring body 100 itself.

[0035] For example, the elastomer 200 suitable for the wearable device 10 may be Natural rubber, Silicone, Neoprene, Polyurethanes, Polybutadiene, etc. In a preferred embodiment, the elastomer 200 is polydimethylsiloxane (PDMS) with different desired mix ratio. However, the present invention is not limited thereto, and any materials in the prior art or future with elastomeric characteristic compared to the ring body 100 can be used in the present invention as the elastomer 200.

[0036] For placing the elastomer 200, in some embodiments of the present invention, the wearable device 10 shown in FIG. 1 and FIG. 2 further comprises a recess (not shown) formed at the monitoring surface 111. Therefore, the elastomer 200 is securely received in the recess. However, the elastomer 200 can be placed on the monitoring surface 111 in any suitable manner provided that the elastomer 200 is securely positioned on the monitoring surface 111.

[0037] Next, a strain gauge 300 is further disposed on the elastomer 200 at the inner side 110 of the ring body 100 for measuring the surface deformations due to the fluctuations of arteries, which will be further described in detail hereinafter. By this configuration, when wearing the wearable device 10, such as wearing the wearable device 10 on a finger, the strain gauge 300 is disposed between the wear's skin and the elastomer 200, and thus the strain gauge 300 can be used to measure strain between the wear's skin and the elastomer 200. Accordingly, the strain gauge 300 can represent the strain as electrical resistances. Therefore, the electrical resistance of the strain gauge 300 is indicative of blood-pressure of a wearer.

[0038] A suitable range of the gauge factor of the applied strain gauge 300 is from 1.5-200. However, the present invention is not limited thereto, and any value of the gauge factor possible to detect the deformation of the skin due to the blood-pressure can be used in the present invention.

[0039] In a preferred embodiment of the present invention, the stain gauge 300 is a semi-conductor type strain gauge, such as KSN-2-120-E3-16 produced by KYOWA, which has a high gauge factor of 100. However, the present invention is not limited thereto, and any type of the strain gauge can be used in the present invention provided it can reflect the deformation of the skin resulted from blood pressure. Moreover, in further embodiments of the present invention, the strain gauge 300 can be replaced with any specific device used to reflect the deformation of the skin resulted from blood pressure.

[0040] In an embodiment of the present invention, for obtaining significant differences of the electrical resistance due to the deformation of the skin, the strain gauge 300 is elongated along the perimeter of the ring body 100, as shown in FIG. 2. However, the present invention is not limited thereto, and the configuration direction of the strain gauge 300 disposed on the elastomer 200 can be any form based on the type of the strain gauge and the magnitude of the measured strain it is capable to present.

[0041] Next, a monitoring method for non-invasive monitoring blood-pressure will be

explained in detail with reference to FIG. 3 to FIG. 5.

[0042] In FIG. 3, a schematic section view of a finger 12 is shown. In FIG. 4, a schematic section view of a finger 12' wearing the wearable device 10' is shown. Specifically, in the wearable device 10', a recess 105 is further formed in the monitoring surface 111 and the elastomer 200 is received in the recess 105.

[0043] Referring to FIG. 3, a simplified schematic view of a finger 12 shows that the finger 12 comprises skin 15, subcutaneous tissue 25, bone 35, muscle 45 and two arteries (a digital artery and a radial artery) 55. Here, the arrow 14 indicates the finger pulp.

[0044] As described above, when wearing a wearable device 10' in accordance with one embodiment of the present invention on the finger 12, one of the arteries 55 of the finger 12' wearing the wearable device 10' is faced with the monitoring surface 111 of the wearable device 10', and the skin 15 of the finger 12' is pressed by the monitoring surface 111 of the wearable device 10' at a position corresponding to an artery 55.

[0045] Here, the gap d between the non-monitoring surface 112 and the finger 12' is exaggerated for clarity, and in certain embodiments of the present invention, at least a part of the gap d between the non-monitoring surface 112 and the finger 12' is zero. That is, at least a part of the non-monitoring surface 112 may substantially contact the skin 15 under less compression compared to the monitoring surface 111.

[0046] Further referring to FIG. 5, a proposed mechanical model 16 representing an enlarged view of the part B of finger 12' is shown. In detail, in an embodiment of the present invention, the step of measuring the signal is performed on a finger of the subject since the artery of the finger is much closer to the skin. However, the finger 12' is proposed as an example taken in conjunction with the above stated wearable device 10', and all other configurations complied with the proposed mechanical model 16 should all fall within the scope of the present invention as defined in the claims.

[0047] To achieve a more accurate blood-pressure, the step of measuring the signal is preferentially performed on a position of the skin 15 corresponding to an artery 55. As shown in FIG. 5, the part B of FIG. 4 comprises the artery 55, the subcutaneous tissue 25, the skin 15, the strain gauge 300, the elastomer 200 and the ring body 100. In said proposed mechanical model 16, the artery 55 represents the subject artery 3000 to be measured, the subcutaneous tissue 25 and the skin 15 collectively represents the intermediate module 2000,

and the strain gauge 300, the elastomer 200 and the ring body 100 collectively represents the deformation detect sensor 1000.

[0048] Accordingly, in view of the proposed mechanical model 16, in an embodiment of the present invention, a monitoring method for non-invasive monitoring blood-pressure comprises the steps of: measuring a signal representing a deformation of the intermediate module 2000 resulted from the blood pressure of the subject artery 3000 to be measured on a subject (such as a patient or a person in need) by the deformation detect sensor 1000; and deriving the blood-pressure of the subject from the signal. In an embodiment of the present invention, the blood-pressure is positively correlated with the deformation of the skin.

[0049] Specifically, according to an embodiment of the present invention shown in FIG. 4, based on the proposed mechanical model 16 of FIG. 5, the fluctuations of the artery 55 (the subject artery 3000) can transfer through the subcutaneous tissue 25 and the skin 15 (the intermediate module 2000) and cause deformations on the skin 15 (deformations on the surfaces of the intermediate module 2000). Since the deformation detect sensor 1000 substantially measure the deformation by the strain gauge 300 provided on the elastomer 200 in such embodiments, referring to FIG. 6, the blood pressures can be derived from the following hypothesis functions.

[0050] In detail, the subcutaneous tissue and the skin (the intermediate module, referred as the skin tissue hereafter) can be modeled as a spring-mass-damper system where the damper is exploited to analogize the viscoelastic behavior of the skin tissue. Assuming that the artery is the only source of force and the blood pressure is a periodic wave, blood flow can be represented as a sinusoidal wave $F = \beta \sin \omega t$ where β is the concentrated force transmitted by the wall of the blood artery. The governing equations are expressed as:

$$M\ddot{x}_M = -k_s x_M + k_t(x_m - x_M) + \mu(\dot{x}_m - \dot{x}_M) \qquad \text{equation (1)}$$

$$m\ddot{x}_m = F - k_t(x_m - x_M) - \mu(\dot{x}_m - \dot{x}_M) \qquad \text{equation (2)}$$

where M represents the mass of the skin tissue. k_s is the effective spring constant of the strain gauge and the elastomer used in the measurement, which is measured using a load cell (M. Ghaz. (2-11, Jan). Structure and Function of the Skin. [Online]. Available: http://skin-conditions.knoji.com/structure-and -function-of -the-skin) and k_t indicates the skin tissue's spring constant. μ represents the damping coefficient of the skin tissue, m represents the mass of the artery wall. θ represents degree to which strain deviated from plane strain, r represents

the radius in a circle with the same curvature as the strain gauge. Based on equations (1) and (2), the strain ε_θ in θ direction can expressed as:

$$\varepsilon_\theta = \frac{1}{E}\left[\frac{1}{2\sin\theta \cdot A_\theta} - \nu\frac{1}{r \cdot w \cdot 2\sin\theta}\right] \cdot k_s[Im(X_M e^{i\omega t})] \quad \text{equation (3)}$$

Equation (3) can be used in conversion from strain ε_θ to the force F on the artery wall, further on converse to blood pressure by dividing the area of which the strain gauge project on to the blood artery. Table 1 shows the Dimensional parameters exploited in the mechanical model (reported by T. Birch, "Continuous Non-Invasive Blood-Pressure Measurements" [online]. Available: http://www.maths-in-medicine.org/uk/2007/blood-pressure/report.pdf).

Table 1

Parameter	Symbol	Typical Value
Lower mass	m	1
Upper mass	M	2
Damping Coefficient	μ	1
Tissue's spring constant	k_t	10

[0051] According to the embodiment of FIG. 6, in said monitoring method stated in FIG. 5, the signal representing the deformation is electrical resistance change of the strain gauge, and the step of measuring the signal comprises using the strain gauge to detect the deformation of the skin. To this end, in said monitoring method, a step of disposing the strain gauge between the skin and the elastomer before the step of measuring the signal is performed.

[0052] Hereinafter, a wearable device 20 of another embodiment of the present invention will be further described with reference to FIG.7 to FIG. 9.

[0053] Referring to FIG. 7, the difference between the wearable device 20 and the wearable device 10 is that the wearable device 20 further comprises a pressure sensor 400 disposed with the strain gauge 300. The pressure sensor 400 is used to detect a default

pressure to calibrate the measured blood-pressure.

[0054] In detail, to compensate the different pre-normal force (that is, the contact pressure/the default pressure) of which the strain gauge 300 presses on to the skin due to differences of finger radius or slight displacement of the strain gauge 300 to where the artery produced the largest displacement on the skin, a pressure sensor 400 was placed closely beside the strain gauge 300. That is, a pressure sensor 400 is further disposed on the inner side 110 of the ring body 10 for determining the contact pressure between the ring body 100 and a wearer's skin.

[0055] In one embodiment of the present invention, for example, a commercially available force sensing resistor FSR400 shown in FIG. 8 was placed closely beside the strain gauge 300 as the pressure sensor 400. In viewing of this, the circuit of the FSR400 was shown in FIG. 9, where V_{out} was the output of the circuit and v+ was the excitation voltage. A sensitivity resistor was in series with the FSR400. The output voltage of the circuit differed when different normal force was applied to it and was used to calibrate the micro strain signal in the wearable device. However, the force sensing resistor FSR400 is shown and described as an example, and any other devices that can measure and reflect the pre-normal force (that is, the contact pressure/the default pressure) can be used as the pressure sensor 400, and the present invention is not limited thereto.

[0056] According to the embodiment of the present invention shown in FIG. 7 to FIG. 9, The step of deriving the blood-pressure further comprises calibrating the blood-pressure with a default pressure detected by a pressure sensor 400 disposed with the strain gauge 300. Specifically, the governing equations employed in the monitoring method in such embodiment can be modified and expressed as follows.

equations (4)

$$\Delta R = GF \times R \times \frac{1}{E}\left[\frac{1}{2\sin\theta \cdot A_\theta} - \nu\frac{1}{r \cdot w \cdot 2\sin\theta}\right] \cdot k_4[\mathrm{Im}(\frac{\beta(i\omega\mu + k_3)}{(i\omega\mu + k_3)\left[k_4 - (M+m)\omega^2\right] - m\omega^2(k_4 - M\omega^2)} e^{i\omega t})]$$

[0057] In equation 4, β is the amplitude of the sine wave indicating the force on the artery wall, ω is the frequency of the sine wave, m and M represent the effective mass of the artery wall and the skin tissue respectively, k_3 is the effective spring constant of the skin tissue, k_4 is the effective spring constant of the pressure sensor and the elastomer, μ is the damping constant of a system between an artery and the strain gauge (the skin tissue), A

represents a surface area of the pressure sensor under applied the force from the skin, E and ν are the Young's modulus and the Poisson ratio of material of the pressure sensor respectively, GF indicates the gauge factor which is relative to the magnification of signals obtained from the pressure sensor, R represents the electrical resistance of the strain gauge, θ represents degree to which strain deviated from plane strain, r represents the radius in a circle with the same curvature as the strain gauge, i is the mathematical imaginary unit, Im presents the action of taking the imaginary part, t is the variable time domain, and ω is the variable in frequency domain defined as in Fourier transform.

[0058] However, the above statement is only illustrated as examples, and the governing equations employed in the monitoring method for non-invasive monitoring blood-pressure can be modified and expressed based on modified wearable devices and the applied situations accordingly. For example, in some embodiments, the step of measuring the signal in the monitoring method further comprises using a calibration strain gauge without the elastomer to calibrate electrical resistance variations of the strain gauge due to temperature variations, and the governing equations employed in the monitoring method will be calibrated and adjusted accordingly.

[0059] For calculating, calibrating, processing or revealing, according to an embodiment of the present invention, the wearable device may further comprise a processing unit 500, wherein the strain gauge 300 is communicated with the processing unit 500 for calculating the blood-pressure from the signal. For example, a chip or a small processing device employed as the processing unit 500 may be mounted at the ring body 100 in the wearable device 30 as shown in FIG. 10A, or a smartphone or other processing devices employed as the processing unit 500 is separated from the ring body 100 and communicated to the strain gauge 300 via the wire 350 or via a wireless manner in the wearable device 40 as shown in FIG. 10B. The wire 350 can be one, two, or more lines, and the depicted line indicating the wire 350 in FIG. 10B is only illustrated as a schematic view. Further, provided that the processing unit 500 can be used to perform the calculating, calibrating, processing or revealing functions, the arrangement and the type of the processing unit 500 is not limited thereto.

[0060] Hereinafter, several wearable devices of different modified embodiments of the present invention will be illustrated with reference to FIG. 11 to FIG. 15B.

[0061] As shown in FIG. 11, a wearable device 50 of a first modified embodiment of

the present invention is revealed in a front view, in which the inner side 110 of the ring body 100 consists of two monitoring surfaces 111 and 113 and at least a non-monitoring surface 112. In such embodiment, the wearable device 50 can simultaneously monitoring two different arteries at the same time, such as a digital artery and a radial artery correspondingly opposite to each other with respect to the nail bone (as shown in FIG. 3 or FIG. 4). Accordingly, the blood-pressure can be more accurately calculated by calibrating the measured deformation with two monitoring surfaces 111 and 113.

[0062] Moreover, in a wearable device 60 of a second modified embodiment of the present invention, the above stated calibration strain gauge 300' in the monitoring method can be mounted on one of the monitoring surfaces 111 and 113 without the elastomer provided. For example, in calibration monitoring surface 113, only calibration strain gauge 300' is disposed on the calibration monitoring surface 113 without the elastomer provided, such that the monitoring surface 111 and the calibration monitoring surface 113 are respectively and symmetrically disposed on the ring body 100. Such configuration can calibrate electrical resistance variations of the strain gauge 300 due to temperature variations through the calibration strain gauge while measuring. Therefore, it can decrease the accuracy deficiency of the wearable device 60 due to the temperature variations.

[0063] In all embodiments in the specification, the monitoring surfaces can be substantially disposed to correspond to a quarter round of the ring body. Thus, when wearing the wearable device, the monitoring surfaces can cover the skin corresponding to the arteries while pressing the skin at appropriate compression for the measuring. However, the present invention is not limited thereto.

[0064] Since the arteries are located on both sides of the nail bone in the finger at lower side (near the finger pulp), in a preferred embodiment, the two monitoring surfaces can be designed to correspond to the two quadrants of the lower half of the ring body. However, the present invention is not limited thereto.

[0065] Next, according to a third modified embodiment of the present invention shown in FIG. 13A (front view) and FIG. 13B (oblique view), a wearable device 70 will be described.

[0066] Here, for the sake of convenience, the following embodiments will be presented to have two monitoring surfaces. However, the present invention is not limited thereto, and all the embodiments disclosed in the specification may have one, two or more

monitoring surfaces

[0067] Referring to FIG. 13A and FIG. 13B, the difference between the wearable device 70 and the wearable device 50 shown in FIG. 11 is that the ring body 100 of the wearable device 70 further comprises a first semi-circular portion 130 and a second semi-circular portion 140 connected together. The first semi-circular portion 130 and the second semi-circular portion 140 correspond to two lateral parts of the ring body 100. In such embodiments, the monitoring surface may be substantially disposed along a part of the first semi-circular portion, a part of the second semi-circular portion, or both. In a preferred embodiment, the monitoring surfaces 111 and 113 are respectively and symmetrically provided on a part of the first semi-circular portion 130 and a part of the second semi-circular portion 140.

[0068] In said wearable device 70, the first semi-circular portion 130 and the second semi-circular portion 140 are connected with each other at a first joint 135 and a second joint 135'. That is, the first semi-circular portion 130 and the second semi-circular portion 140 are connected to each other at both ends. However, the first semi-circular portion 130 and the second semi-circular portion 140 can be connected to each other only at one end, and the present invention is not limited thereto.

[0069] According to the third embodiment of the present invention, the tightness and/or angle of the wearable device 70 are adjustable with the configuration including the first semi-circular portion 130 and the second semi-circular portion 140, such that a suitable compression can be achieved while measuring the blood-pressure. In addition, such configuration also provides certain degree of freedom for the wearer to adjust the wearable device on the finger, so as to improve the fitness and comfortableness of the wearable device on the wearer.

[0070] In a preferred embodiment, the first semi-circular portion 130 and the second semi-circular portion 140 are detachably connected. Thus, the convenience of the wearable device for the wearer to be used, put on or taken off is further increased.

[0071] Further, a fourth modified embodiment of the present invention will be described with reference to FIG. 14A (front view) and FIG. 14B (oblique view).

[0072] Referring to FIG. 14A and FIG. 14B, the difference between the wearable device 80 and the wearable device 70 shown in FIG. 13A and FIG. 13B is that the wearable

device 80 is designed as a clipper-form. In detail, in the wearable device 80, the first semi-circular portion 130 and the second semi-circular portion 140 are substantially two half clipper bodies of a clipper, and the wearable device 80 further comprises two operating handles 132 and 142 used to operate the clipper. That is, when pressing the operating handles 132 and 142 respectively along the directions 131 and 141 next to the first joint 135, the first semi-circular portion 130 and the second semi-circular portion 140 can be transformed into an exerted state from the original release state and can be separated from each other at the second joint 135'. Therefore, when a force is exerted on the operating handles 132 and 142, the wearable device 80 in a clipper-form can be open, and an enlarged opening 155 can be obtained so as to let the finger passes therethrough. In such manners, it is easier to put the wearable device 80 on the finger, and the tightness and/or angle of the wearable device 80 can be adjusted in a simpler way.

[0073] Any clipper form suitable for performing the above functions can be applied in the wearable device 80. For example, a metal rod can be inserted through the two hinges 145 of the first semi-circular portion 130 and the second semi-circular portion 140 at the first joint 135 with a torque spring. The torque spring applies the necessary force to make the wearable device closely tightened around the finger, enabling wearers to take on/off by pressing operating handles 132 and 142. However, the present invention is not limited thereto.

[0074] Although in FIG. 14A and FIG. 14B, the first semi-circular portion 130 and the second semi-circular portion 140 are not contact with each other at the second joint 135' at a release state, the first semi-circular portion 130 and the second semi-circular portion 140 can be contact with each other at the second joint 135' at a release state in certain embodiments of the present invention.

[0075] Next, a fifth modified embodiment of the present invention will be described with reference to FIG. 15A (front view) and FIG. 15B (oblique view).

[0076] Referring to FIG. 15A and FIG. 15B, the difference between the wearable device 90 and the wearable device 80 shown in FIG. 14A and FIG. 14B is that the non-monitoring surface 112 of the wearable device 90 contains lumpy sections 165. Here, only parts related to the lumpy sections 165 will be depicted and explained in detail, other configurations that are the same or similar like those in the wearable device 80 will be omitted for the sake of brevity and convenience.

[0077] In detail, in the wearable device 90, the non-monitoring surface 112 is provided with several sections having different heights. Therefore, a lumpy surface (uneven surface) is formed on the non-monitoring surface 112. Accordingly, when wearing the wearable device 90 on the finger, the wearable device 90 can be more surely fixed on the finger by the friction force exerted between the lumpy surface and the finger. Thus, the steady and the fitness of the wearable device 90 can be improved, such that the measured blood-pressure is more reliable.

[0078] As the person having ordinary skill in the art would know, the lumpy surface can be employed in all the other embodiments disclosed herein, and the specific form of the lumpy surface can be adjusted as desired for the stated function or other functions (such as desired appearance). Therefore, the present invention is not limited to the above-described examples. Further, apart from the various embodiments shown above, the wearable device of the present invention may be provided with various mechanical mechanisms or designs as desired.

[0079] For different user/wearer with different finger sizes, the size of the ring-monitoring wearable device can be designed into several sizes to be chosen. However, the present invention is not limited thereto, and in some embodiment of the present invention, the wearable device is adjustable by changing the inner radius to create suitable size for each individual in any suitable manner.

[0080] Hereinafter, an example of a blood-pressure measuring effect of the wearable device 90 is described in detail.

[0081] In detail, to validate the measuring effect of the wearable device and the monitoring method according to the embodiments of the present invention, an artificial finger is applied in the following test example. The design of the artificial finger simplified as a long tube is shown in FIG. 16A and 16B. Specifically, FIG. 16A illustrates a schematic view of the artificial finger 150, and FIG. 16B illustrates a section view of the artificial finger 150 taken along the line Z-Z' in FIG. 16A.

[0082] The applicants use acrylic tube filled with PDMS with the ratio of 35: 1 as the artificial skin 15' and the artificial subcutaneous tissue 25' (Diameter: 16 mm), use acrylic rods as the artificial bone 35' (Diameter: 5 mm), and use a metallic tube as the artificial artery 55' (Diameter: 1 mm) placed inside the acrylic tube and under the inner surface with a distance of 3 mm.

[0083] A table of the Young's Modulus of different mixing ratios of base and silicon curing agent were listed in Table 2 as follows (F. De Paoli, "Measuring Polydimethylsiloxane (PDMS) Mechanical Properties Using Flat Nanoindentation Focusing on Obtaining Full Contact", M.S. thesis, Dept. Mech. Eng.,Univ. South Florida, Florida, 2015). Here, Young's modulus of PDMS 33:1 is 0.56 MPa which is very close to the Young's modulus of the skin. However, the materials used as the elastomer can be determined by the applied finger structure properties in different embodiments, and the present invention is not limited thereto.

Table 2 Average stiffness for different cross-linking degree samples

Cross-linking degree	E_{ave} (MPa)
PDMS 5:1	3.59±0.11
PDMS 7:1	2.91±0.036
PDMS 10:1	2.61±0.021
PDMS 16.7:1	1.21±0.069
PDMS 25:1	0.98±0.037
PDMS 33:1	0.56±0.021

[0084] The Young's modulus of 33:1 mixing ratio resembled closely to that of the human skin (M. Ghaz.(2-11,Jan). Structure and Function of the Skin. [Online]. Available: http://skin-conditions.knoji.com/structure-and -function-of -the-skin). Supposedly, the softer the substrate of which the strain gauge lays on, the higher the signal of the strain gauge. Considering the time that the strain gauge recovered from its deformation. The softer the PDMS, the more time it needed to recover from deformation. Therefore, by choosing a Young's modulus closer of that of the human skin, it is preferentially to ensure that the strain gauge is capable of being recovered from its deformation, presumably as the same pace at which the skin recovered from its deformation due to the blood pulse.

[0085] In said example, a PDMS was fabricated and placed at the recesses of the ring body. In addition, the data sheet of the strain gauge used in the embodiment of the present invention is shown in Table 3.

Table 3 Datasheet of the strain gauge

Type	Gauge resistance	Gauge Factor
KSN-2-120-E3-16	113.9 Ω	-105 ± 3%

[0086] Since the strain gauge received a preload force when the wearable device was placed on the finger, the gain and the sensor sensitivity needed to be carefully adjusted to assure accuracy (Y Luo, S Niu, J Cordero, H Deng and Y Shen, "Bioinspired non-invasive radial pulse sensors: from biomimetic design, system calibration, to clinic application ", Robotics and Biomimetics, vol. 1, No. 1). Therefore, a Wheatstone half bridge circuit was employed using DBU-120A bridge unit produced by KYOWA. The data sheet of the DBU-120A was shown in Table 4 as follows.

Table 4 Data sheet of DBU-120A

Characteristics	Limits
Applicable gauge resistance	120 Ω to 1k Ω
Bridge excitation	0.5V,2V,5V
A-D conversions	16 bits
Sampling frequency	1hz to 20khz
Low pass filter cut-off frequency	10, 30, 100, 300 Hz and Flat

[0087] The recesses in the monitoring surfaces were placed with the strain gauge and PDMS. One side of the strain gauge was used for heart beat displacement strain detection, while the other acted as a calibration strain gauge (dummy gauge, without PDMS) which compensated the error cause by temperature. The wires of the strain gauge were connected to DBU-120A bridge unit according to its half bridge configuration.

[0088] In said example, a water pump is employed to create pressure waves which is analogous to the blood-pressure. The pumping rate can be adjusted by changing the applied voltages. Hence, by using function generator, different periodic waveforms can be generated to analogize different blood-pressure waves.

[0089] To monitor the true blood pressure, a traditional sphygmomanometer is used

to compare the measured value. While the sphygmomanometer monitor time might differ from that of the wearable device of the embodiment of the present invention, it is assumed that the individual's blood pressure changed slightly in the time gap. The DBU-120A bridge unit was set to half bridge with an excitation voltage of 2 volts, and low pass filter frequency of 10hz. By setting the calibration factor of the DBU-120A according to the strain gauge factor, the output signal was set as micro strain. The signal was then transmitted to Matlab and filtered by its band-pass filter function, with a band-pass frequency between 0.5Hz and 4Hz and a filter order of 2. The excitation voltage 5v of the FSR circuit and the amplifier power was supplied by a power supply. The sensitivity resistor RM was chosen to be 15kΩ while the output voltage was recorded by a digital multi-meter. The output voltage of the FSR circuit was then use to calibrate the micro strain signal and the true blood pressure by MATLAB. A suitable curve and function of the output voltage and 'Normal-Force-Const.' by applying the Least Square Method can be found.

[0090] The "Normal-Force-Const." was a calibration factor of which it can be multiplied to the micro strain signal of the DBU-120A bridge unit. The converted micro strain signal was then converse to the blood pressure by the equations mentioned earlier via MATLAB. In viewing of the foregoing, according to an embodiment of the present invention, the experiment result and the corresponding data are shown in FIGS. 17-21.

[0091] Specifically, FIG. 17 shows the force output/voltage curves based on different sensitivity resistor RM; FIG. 18 shows the initial signal monitored by the DBU-120A bridge unit and the signal after being filtered by Matlab; and FIG. 19 was the spectrum of the filter signal after Fast Fourier Transform using Matlab. The frequency where the highest peak lied clearly indicated that the signal was concentrated at a frequency around 1Hz, which was the average frequency of the human heart rate. The second highest pitch illustrated the Dicrotic notch of the typical blood pressure wave form.

[0092] Here, FIG. 20 is the curve of the output voltage of the FSR400 circuit and the "Normal-Force-Const." The R^2 of the calibrated curve was 0.9276. The conversion of the strain signal of FIG. 18 to blood pressure was illustrated in FIG. 21. Herein, the applied model is performed based on equation (3) depicted above. However, the present invention is not limited thereto, and any other model such as equations (4) fall within the scope of the present invention as set forth in the claims can be applied in the present invention. Accordingly, the blood-pressure can be retrieved from the result in the example described

above (FIG. 21). Referring to FIG. 22, the measured blood-pressure obtained according to the embodiment of the present invention is substantially complied with the applied pressure recorded by the pressure transmitter.

[0093] Further, according to another test example of the present invention, said wearable device and said monitoring method is put on a real human finger directly for vitro-test. The contestant's blood pressure was monitored and confirmed by a wrist type sphygmomanometer (OMRON HEM-603, commercially available). The result of measure blood-pressure of the wearable device and the wrist type sphygmomanometer are respectively shown in FIG. 23. As shown in FIG. 23, the wearable device according to the embodiment of the present invention achieves a similar result as the wrist type sphygmomanometer (OMRON HEM-603, commercially available). On average, the systolic blood pressure was 119 mmHg, whereas the diastolic blood pressure was 73 mmHg which was very close to the measured results according to the embodiment of the present invention.

[0094] As shown above, based on the normal blood-pressure patterns in humans, in the case of the systolic blood pressure, since a larger pressure is exerted on the artery wall, the deformation of the skin is larger. Therefore, the detected electrical resistance of the strain gauge and the measured blood-pressure is larger. Conversely, in the case of the diastolic blood pressure, since a smaller pressure is exerted on the artery wall, the deformation of the skin is smaller. Therefore, the detected electrical resistance of the strain gauge and the measured blood-pressure is smaller.

[0095] In practical use, while wearing the wearable device and measuring the blood-pressure thereby, the monitoring surfaces are preferentially placed at the lower section of the wearable device at the location of the artery besides the nail bone lays in an embodiment of the present invention. Therefore, the deformations of the skin due to blood pulse struck directly upon the strain gauge producing the maximum strain and signal. In a preferred embodiment, a more accurate measured blood-pressure can be retrieved if the wearer maintains relax.

[0096] As described above, according to the embodiments of the present invention, a strain-gauge and pressure sensor are mounted on the inner surfaces of the wearable devices which can calculate the blood pressures based on the surface deformations due to the variations of finger arteries. Accordingly, the wearable devices and the monitoring methods according to the embodiments of the present invention are expected to be beneficial for real-

time monitoring of patients and bio-medical applications.

[0097] Further, the wearable device has light-weight and compact volumes, and is comfortable for human beings to wear. Thus, the wearable device is suitable for long-time wearing and accordingly long-term blood-pressure monitoring.

[0098] In addition, since the arteries at finger are close to the skin surface, such ring-shaped wearable device can measure the blood-pressure easier. Also, by measuring the blood-pressure directly on the skin surface close to the arteries in a form of deformation of the surface, the accuracy of the measured blood-pressure can be increased. In certain embodiments of the present invention, the signal representing the deformation of the surface can be directly represented as the electrical resistance, thus simplifying the following signal processing procedures in the electronic device since it is already an electrical signal form.

[0099] Although the present invention has been described with reference to the preferred embodiments thereof, it will be understood that the invention is not limited to the details thereof. Various changes and modifications in accordance with the appropriate technical solutions and technical concepts of the present invention should belong to the invention as claimed. Therefore, all such substitutions and modifications are intended to be embraced within the scope of the invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A wearable device for monitoring blood-pressure, comprising:

a ring body ;

an elastomer disposed on a monitoring surface at an inner side of the ring body; and

a strain gauge disposed on the elastomer at the inner side of the ring body,

wherein:

electrical resistance of the strain gauge is indicative of blood-pressure of a wearer.

2. The wearable device of claim 1, wherein the ring body further comprises a first semi-circular portion and a second semi-circular portion connected together, wherein the first semi-circular portion and the second semi-circular portion correspond to two lateral parts of the ring body.

3. The wearable device of claim 2, wherein the first semi-circular portion and the second semi-circular portion are connected to each other at one end or at both ends.

4. The wearable device of claim 2, wherein the first semi-circular portion and the second semi-circular portion are detachably connected.

5. The wearable device of claim 2, wherein the monitoring surface is substantially disposed along a part of the first semi-circular portion, a part of the second semi-circular portion, or both.

6. The wearable device of claim 1, further comprising a calibration monitoring surface,

wherein the monitoring surface and the calibration monitoring surface are respectively and symmetrically disposed on the ring body, and a calibration strain gauge is disposed on the calibration monitoring surface without the elastomer, and

wherein electrical resistance variations of the strain gauge due to temperature variations is

calibrated through the calibration strain gauge.

7. The wearable device of claim 1, wherein the monitoring surface is substantially disposed to correspond to a quarter round of the ring body.

8. The wearable device of claim 1, wherein the monitoring surface is a plate surface or a surface with curvature less than a surface apart from the monitoring surface at the inner side of the ring body.

9. The wearable device of claim 1, further comprising a recess formed at the monitoring surface, wherein the elastomer is received in the recess.

10. The wearable device of claim 1, further comprising a processing unit, wherein the strain gauge is communicated with the processing unit for calculating the blood-pressure from the electrical resistance.

11. The wearable device of claim 10, wherein the processing unit is mounted at the ring body or is separated from the ring body.

12. The wearable device of claim 1, further comprising a pressure sensor disposed on the inner side of the ring body for determining the contact pressure between the ring body and a wearer's skin.

13. The wearable device of claim 1, further comprising a pressure sensor disposed with the strain gauge, wherein the pressure sensor is used to detect a default pressure to calibrate the measured blood-pressure.

14. The wearable device of claim 1, wherein the gauge factor of the strain gauge is ranged

from 1.5-200.

15. The wearable device of claim 1, wherein the strain gauge is elongated along the perimeter of the ring body.

16. The wearable device of claim 1, wherein the Young's modulus of the elastomer is smaller than the Young's modulus of the ring body.

17. The wearable device of claim 1, wherein the inner side of the ring body consists of two monitoring surfaces and at least a non-monitoring surface.

18. A monitoring method for non-invasive monitoring blood-pressure, comprising the steps of:

measuring a signal representing a deformation of a skin resulted from blood pressure on a subject; and

deriving the blood-pressure of the subject from the signal.

19. The monitoring method of claim 18, wherein the signal is electrical resistance detected by a strain gauge, and the step of measuring the signal comprises using the strain gauge to detect the deformation of the skin.

20. The monitoring method of claim 19, further comprising a step of disposing the strain gauge between the skin and an elastomer before the step of measuring the signal.

21. The monitoring method of claim 20, wherein the step of deriving the blood-pressure comprises calibrating the blood-pressure with a default pressure detected by a pressure sensor disposed with the strain gauge.

22. The monitoring method of claim 20, wherein the step of measuring the signal further

comprises using a calibration strain gauge without the elastomer to calibrate electrical resistance variations of the strain gauge due to temperature variations.

23. The monitoring method of claim 18, wherein the step of measuring the signal is performed on a finger of the subject.

24. The monitoring method of claim 18, wherein the step of measuring the signal is performed on a position of the skin corresponding to an artery.

25. The monitoring method of claim 18, wherein the blood-pressure is positively correlated with the deformation of the skin.

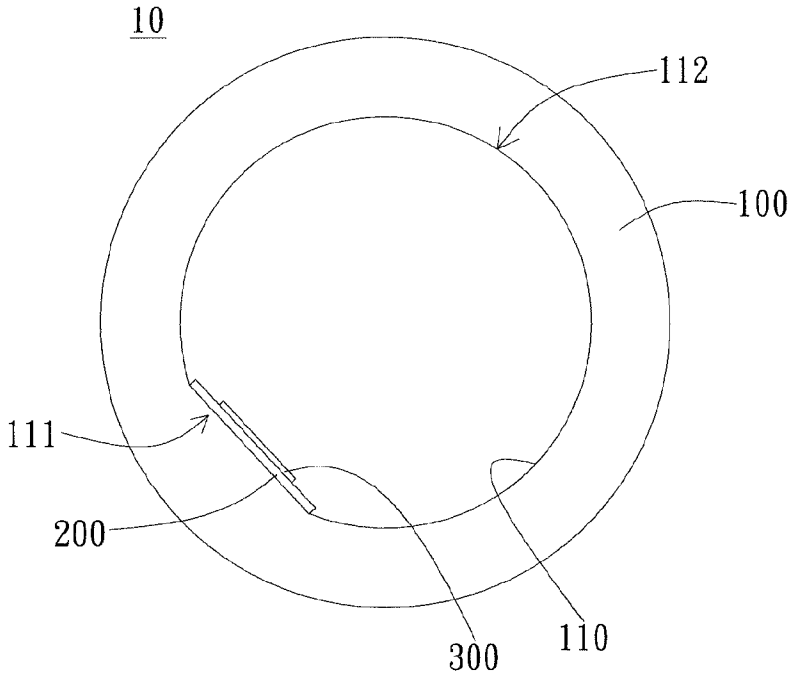

FIG. 1

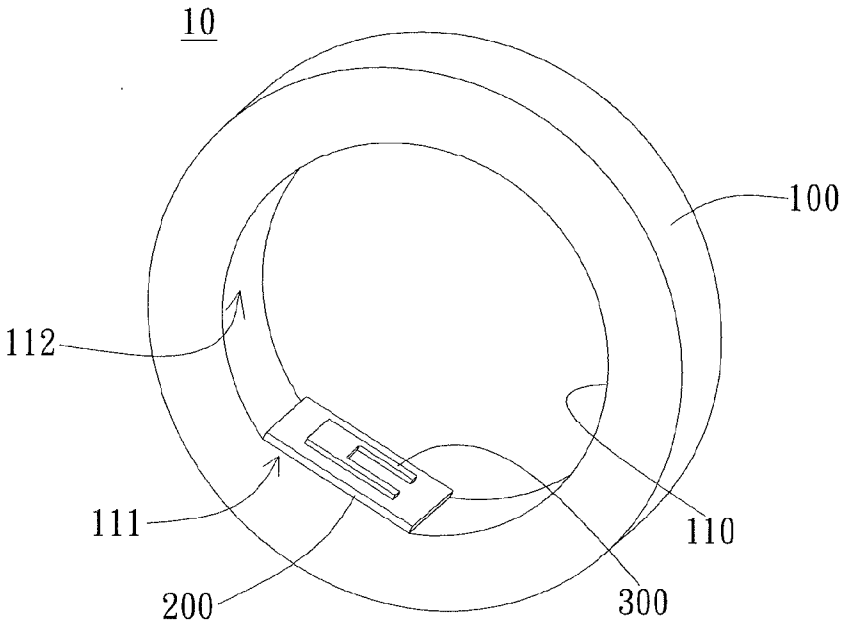

FIG. 2

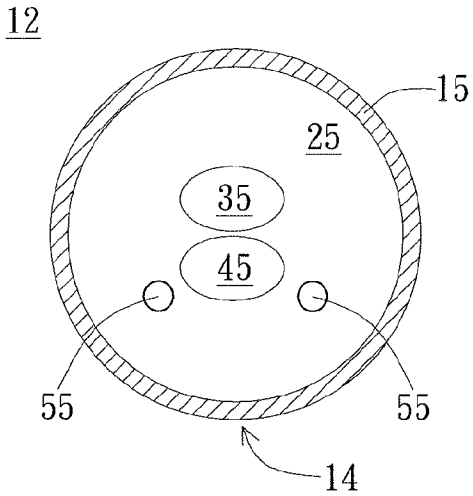

FIG. 3

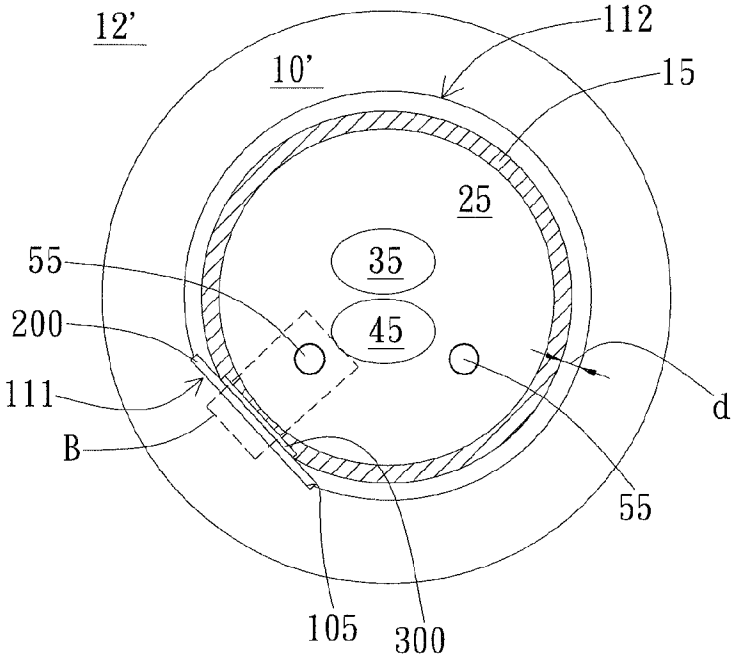

FIG. 4

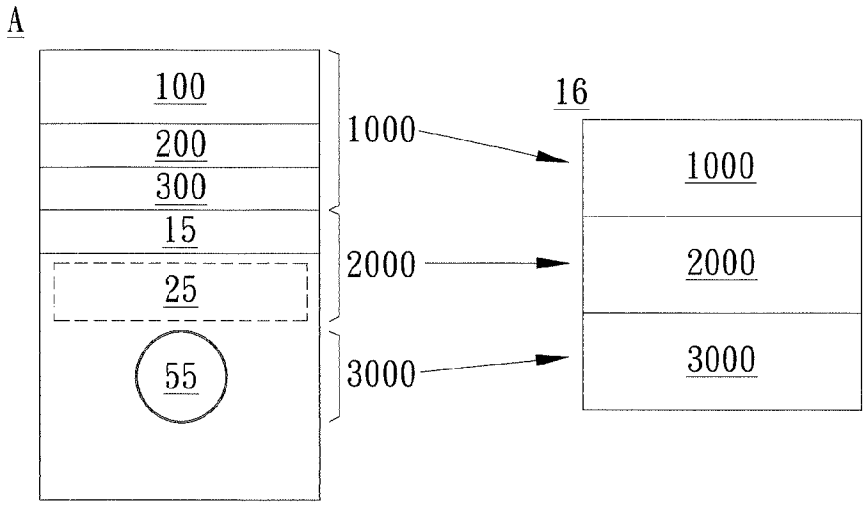
A
100
200
300
15
25
55
1000
2000
3000
16
1000
2000
3000

FIG. 5

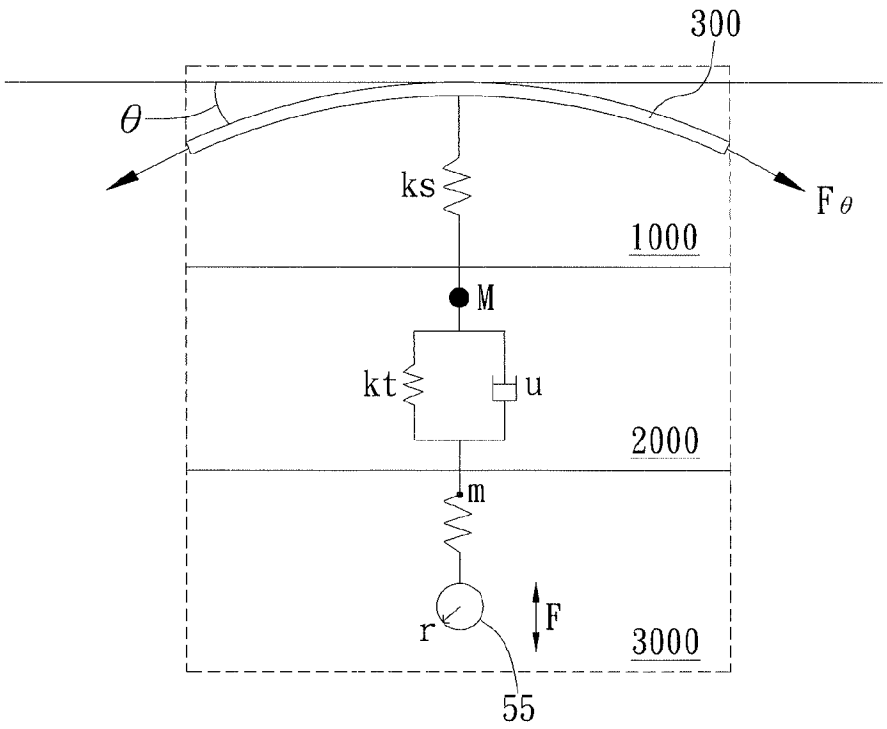
300
θ
ks
Fθ
1000
M
kt
u
2000
m
r
F
3000
55

FIG. 6

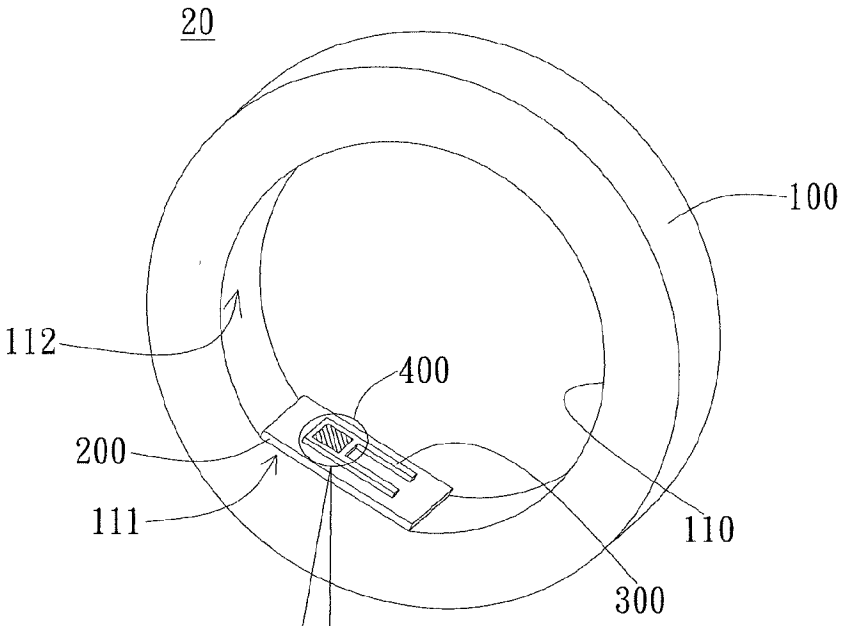

FIG. 7

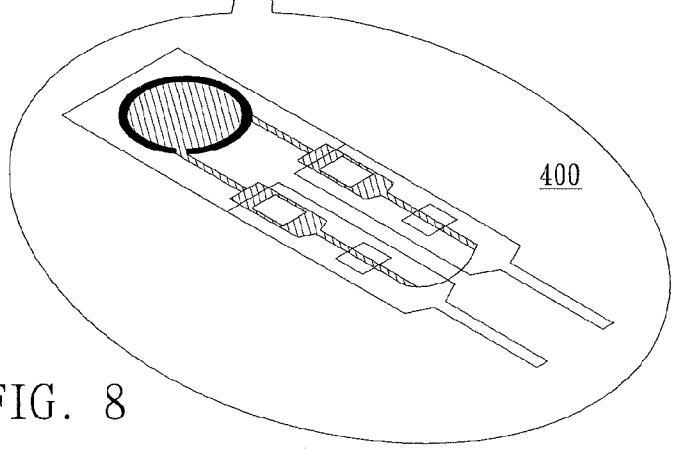

FIG. 8

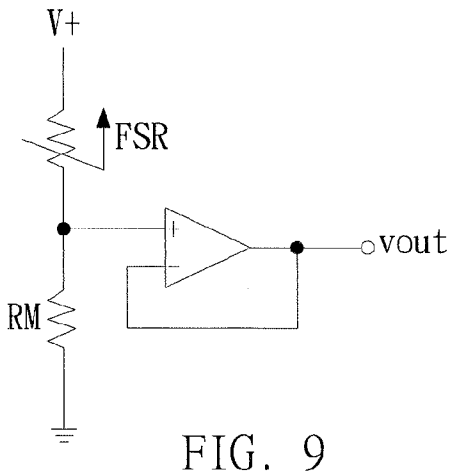

FIG. 9

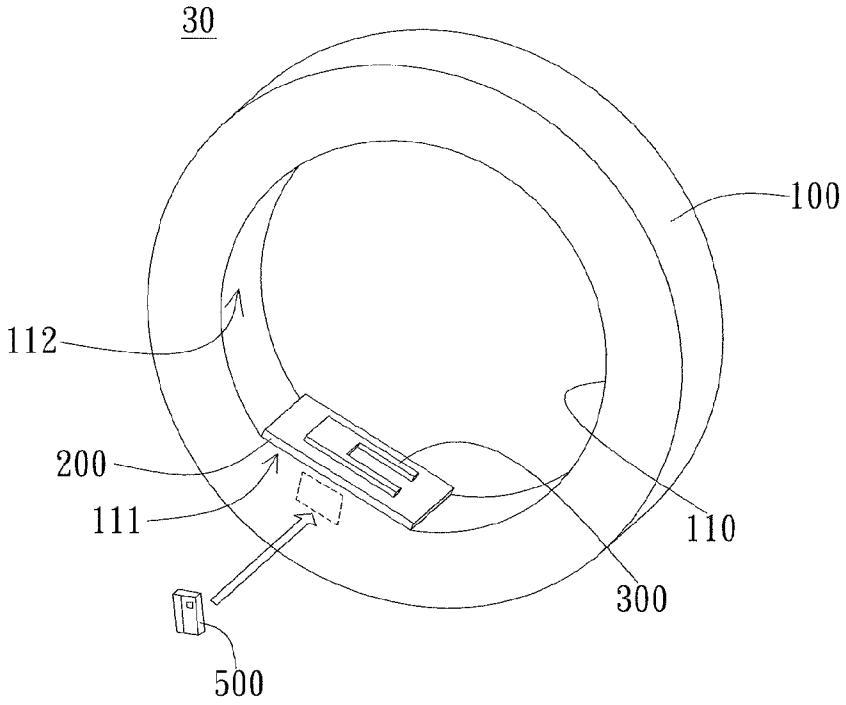

FIG. 10A

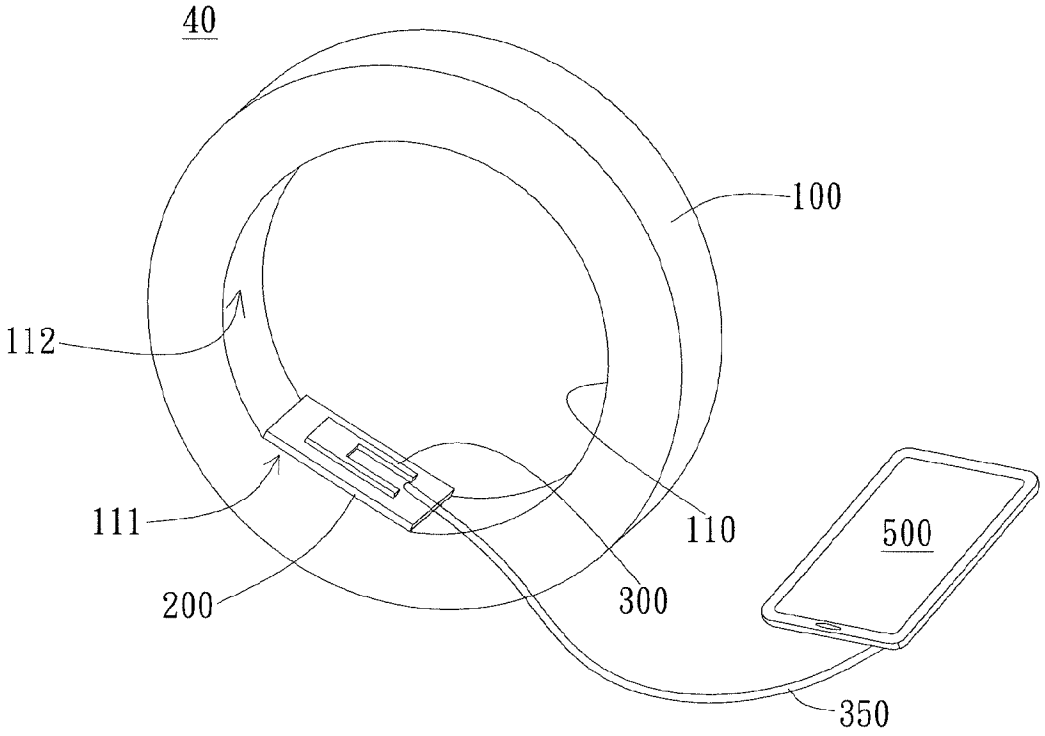

FIG. 10B

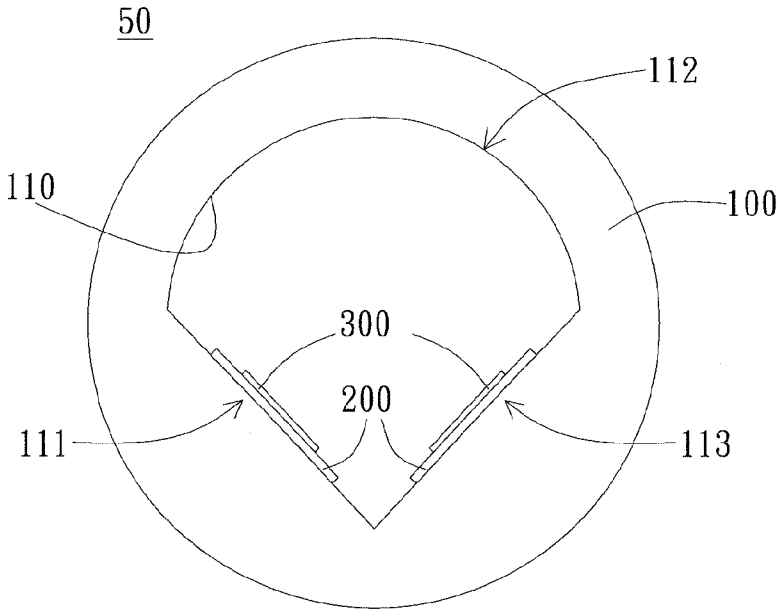

FIG. 11

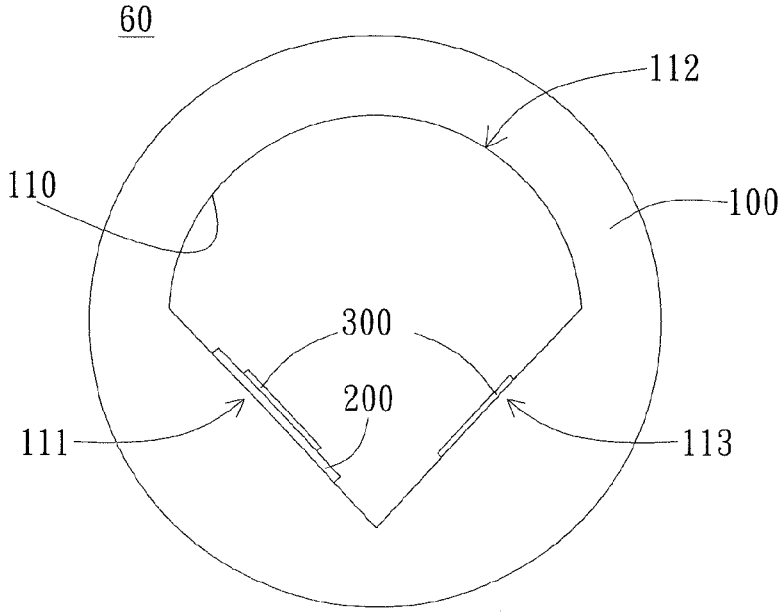

FIG. 12

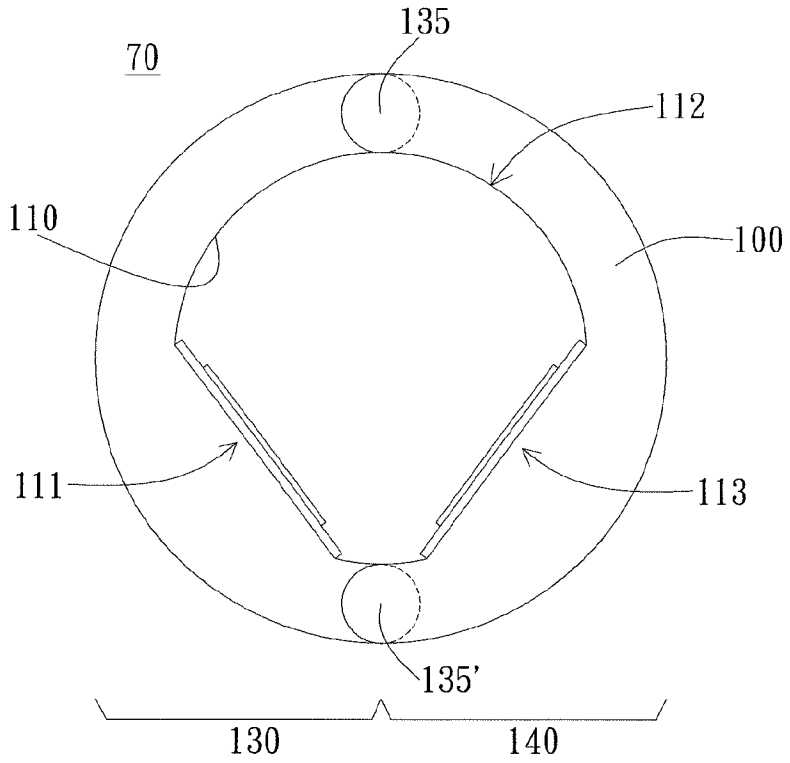

FIG. 13A

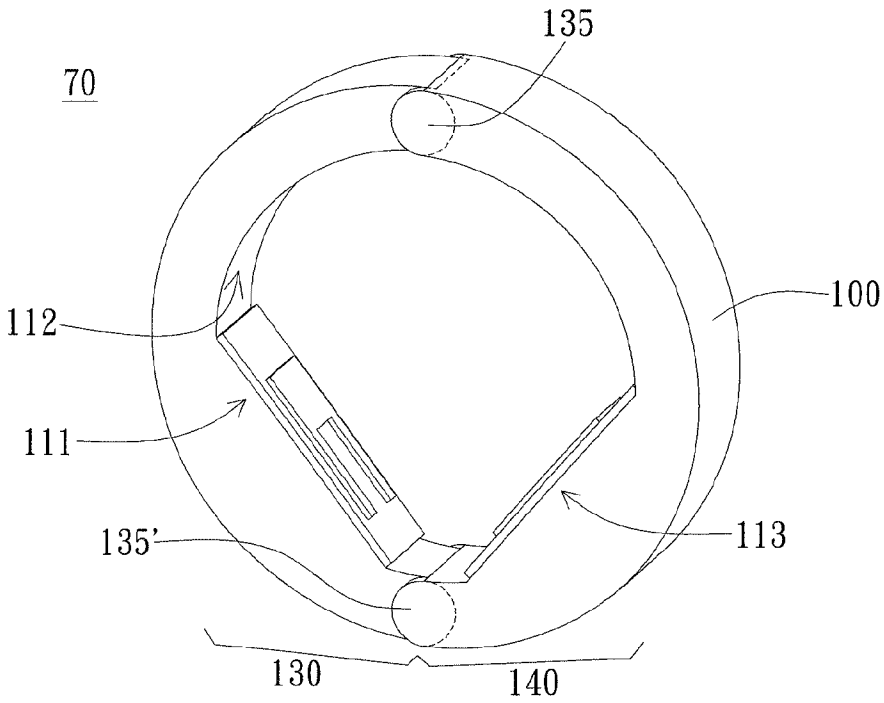

FIG. 13B

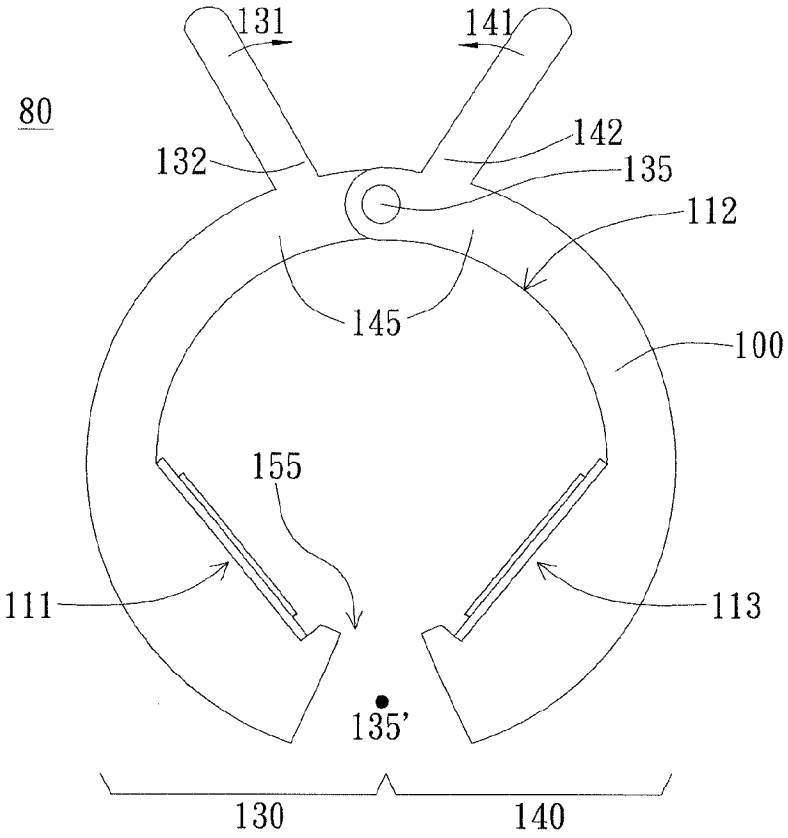

FIG. 14A

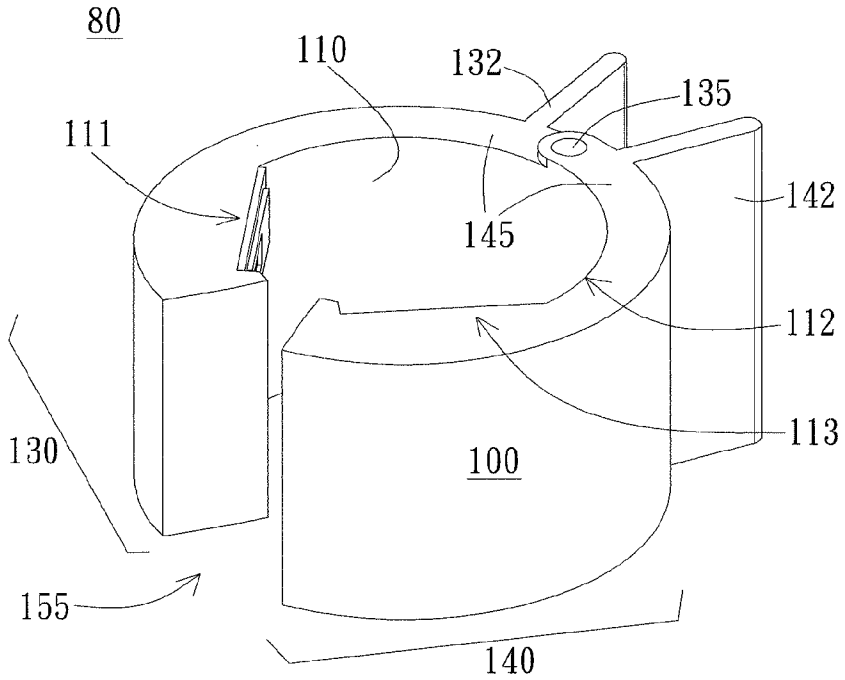

FIG. 14B

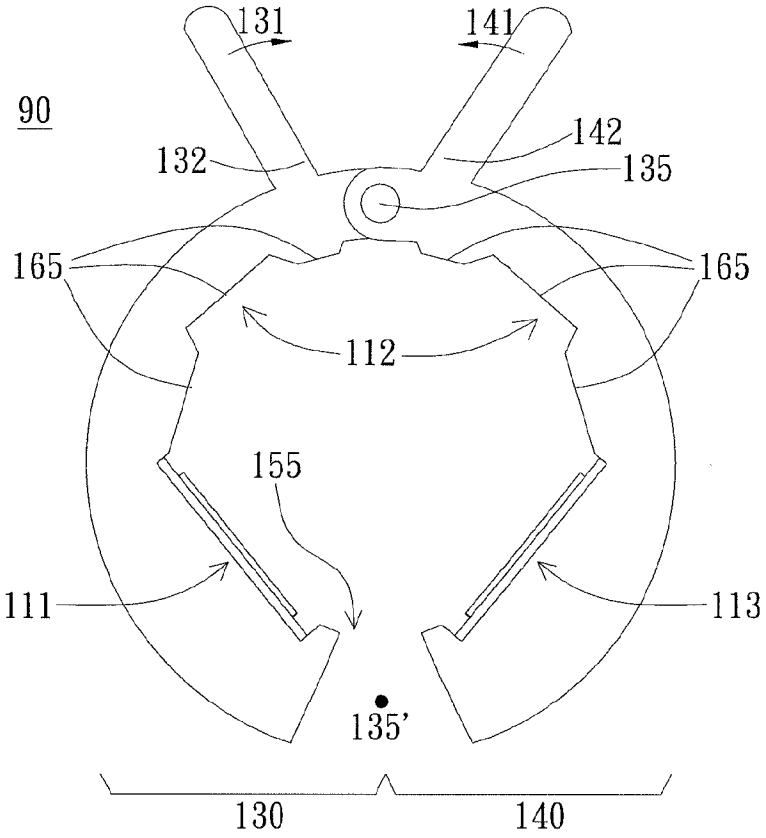

FIG. 15A

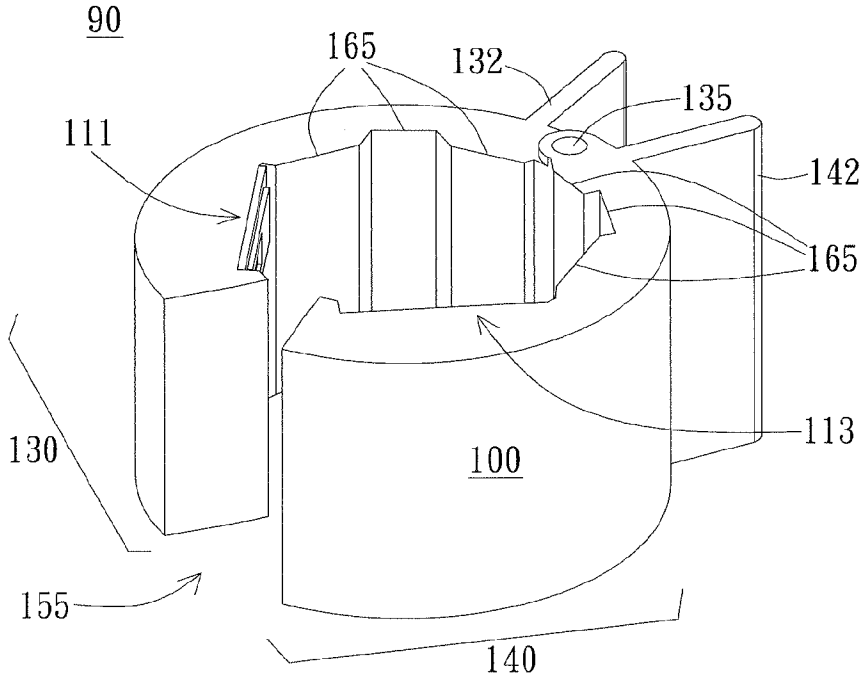

FIG. 15B

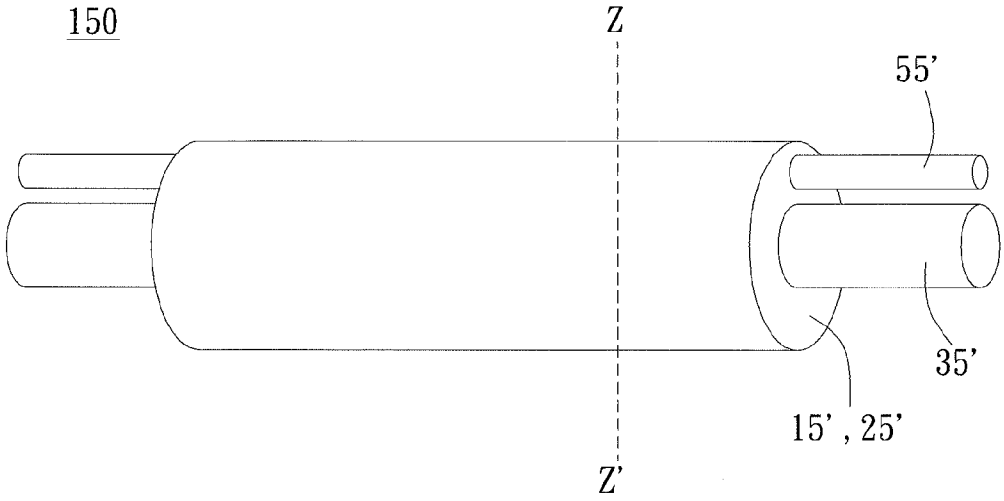

FIG. 16A

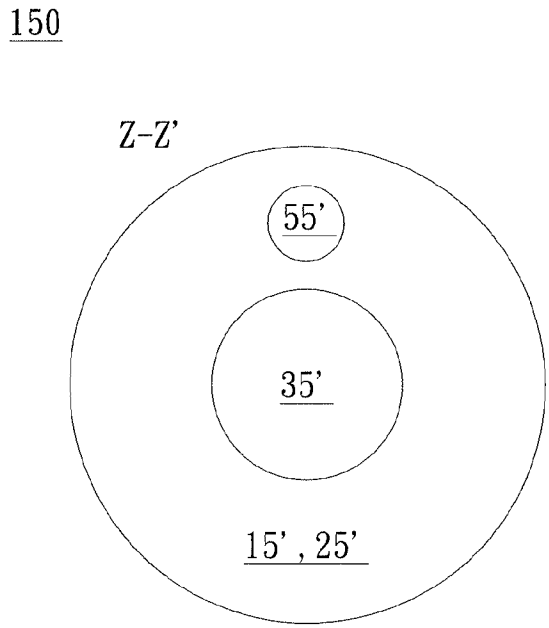

FIG. 16B

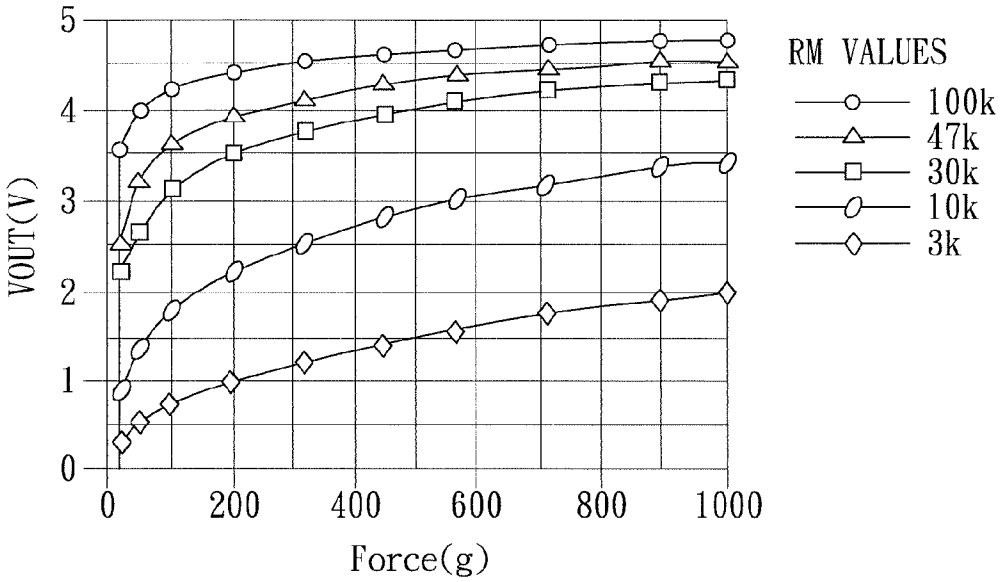
VOUT(V)
Force(g)
RM VALUES
100k
47k
30k
10k
3k

FIG. 17

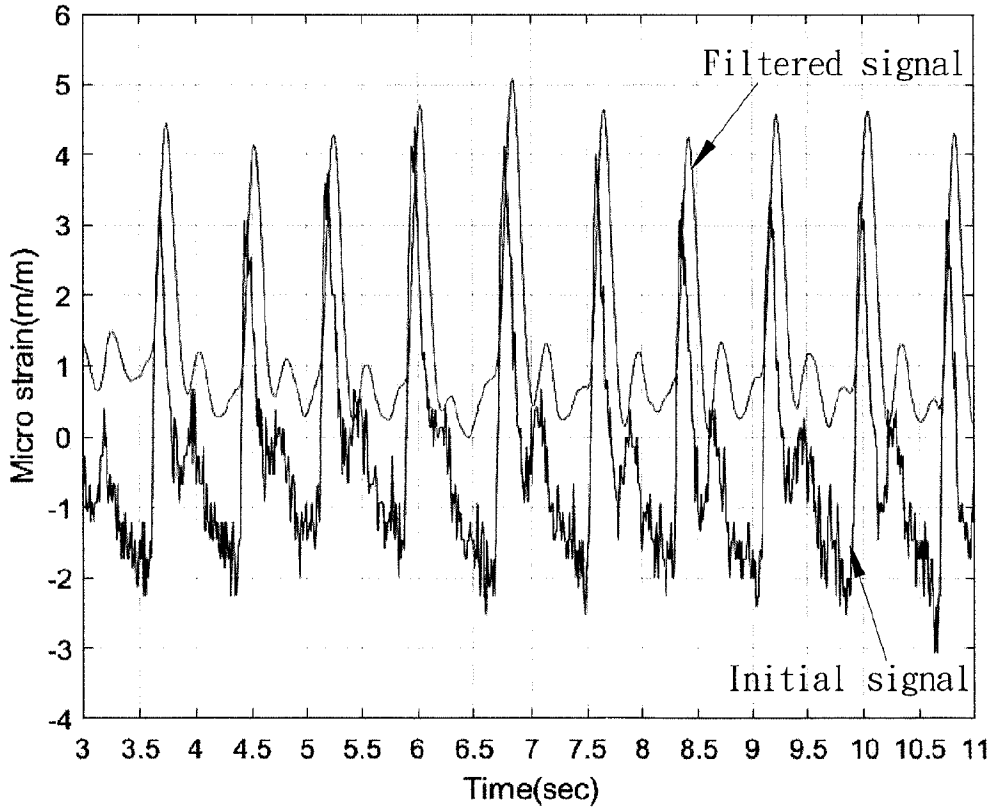
Micro strain(m/m)
Time(sec)
Filtered signal
Initial signal

FIG. 18

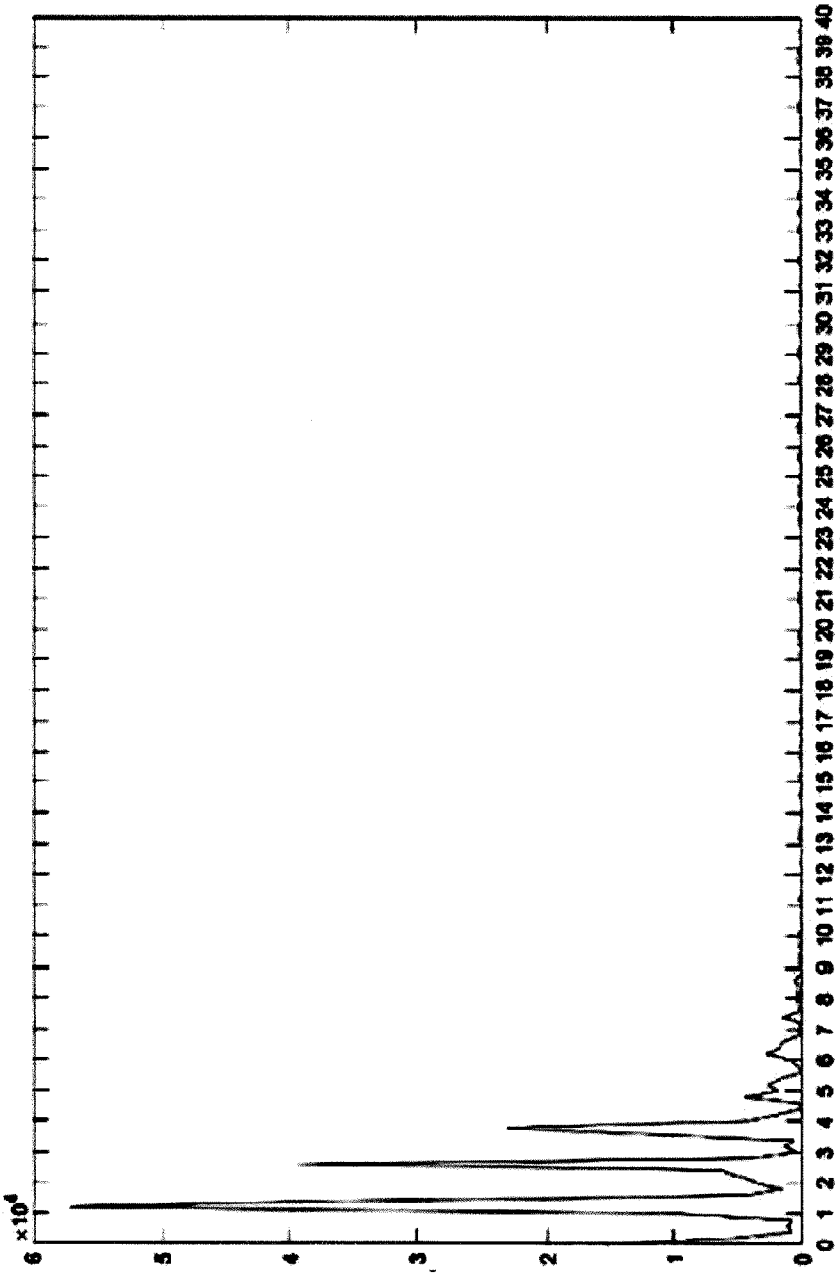
Frequency(Hz)
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40
x10^4
0 1 2 3 4 5 6
FET Amplitude

FIG. 19

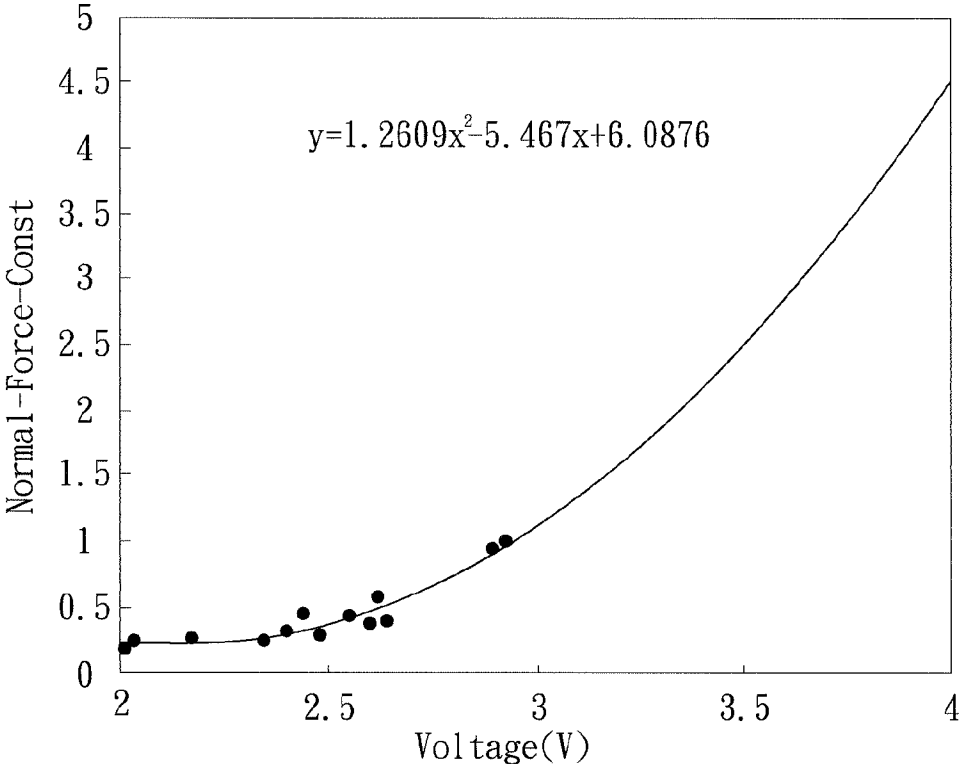
y=1.2609x²-5.467x+6.0876
Normal-Force-Const
Voltage(V)
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
2
2.5
3
3.5
4

FIG. 20

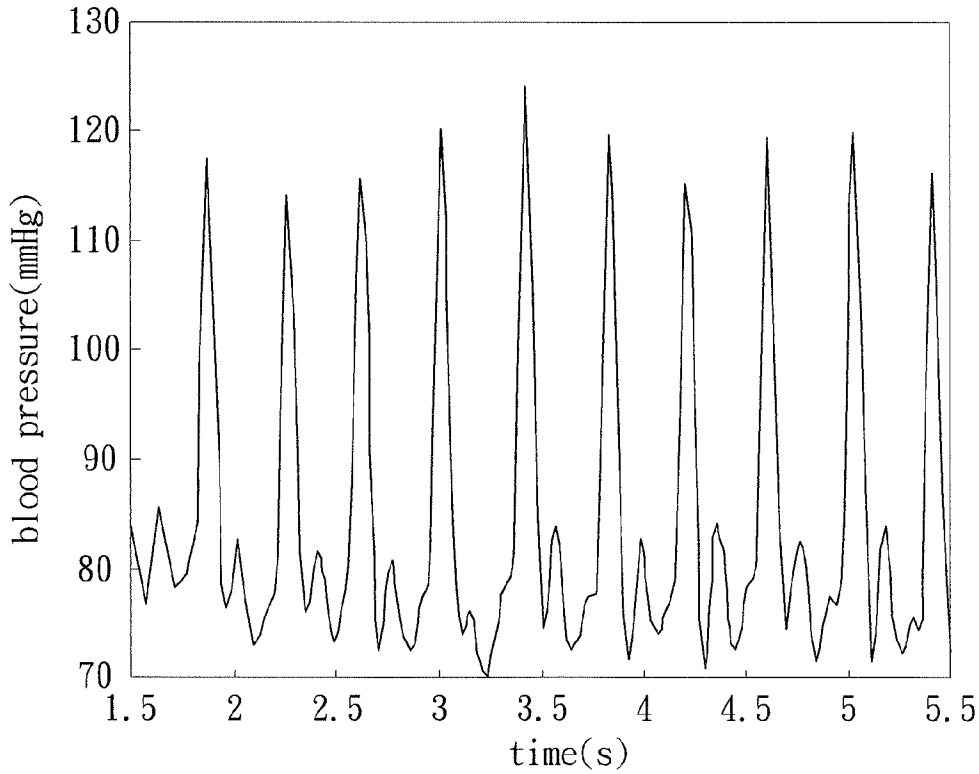
blood pressure(mmHg)
time(s)
130
120
110
100
90
80
70
1.5
2
2.5
3
3.5
4
4.5
5
5.5

FIG. 21

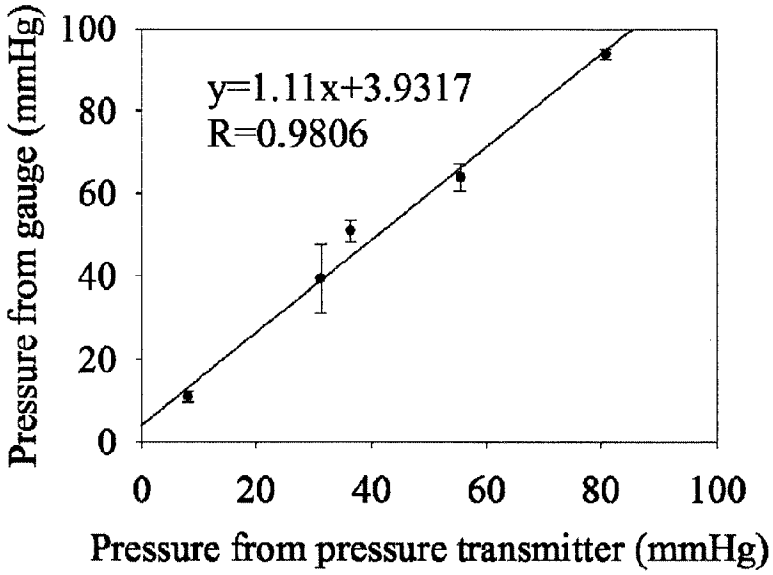
y=1.11x+3.9317
R=0.9806
Pressure from gauge (mmHg)
Pressure from pressure transmitter (mmHg)
0
20
40
60
80
100

FIG. 22

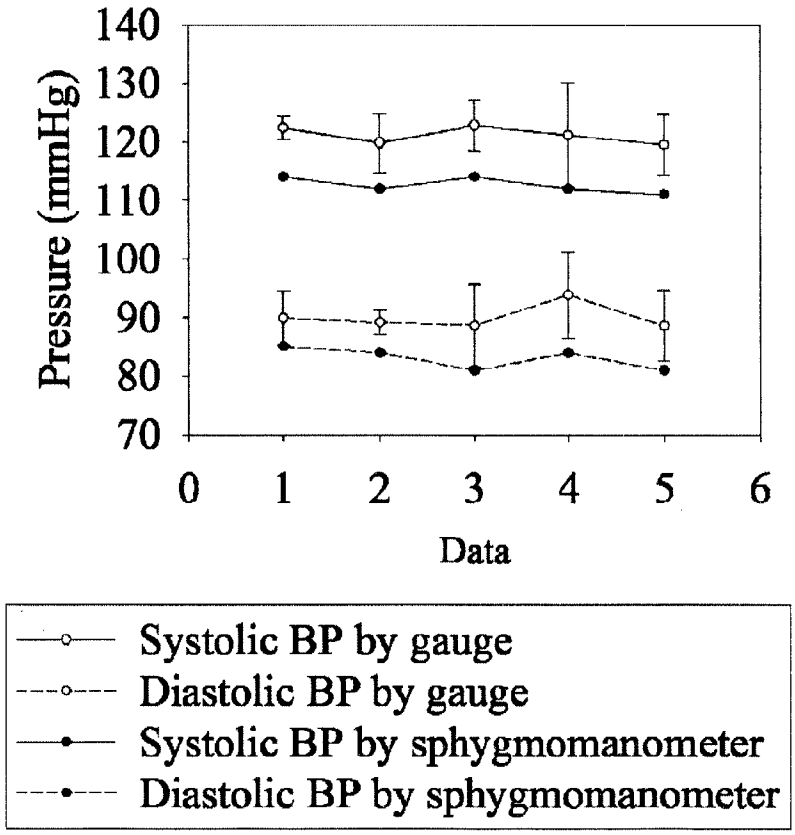
Pressure (mmHg)
Data
140
130
120
110
100
90
80
70
0
1
2
3
4
5
6
Systolic BP by gauge
Diastolic BP by gauge
Systolic BP by sphygmomanometer
Diastolic BP by sphygmomanometer

FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/39103

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/022, A61B 5/021 (2017.01)
CPC - A61B 5/022, A61B 5/021, A61B 5/6824, A61B 5/681, A61B 5/6831, A61B 2562/0261

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)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- A	WO 2015/193045 A1 (STBL MEDICAL RESEARCH AG et al.), 23 December 2015 (23.12.2015), entire document, especially Fig. 1-2 and 5-9; pg. 17, ln 10 to pg. 28, ln 14; pg. 30, ln 10-17	1-5 and 7-17 ---------- 6
A	US 2014/0288438 A1 (Fitbit, Inc.), 25 September 2014 (25.09.2014), entire document	1-17
A	WO 2015/070343 A1 (THE UNIVERSITY OF WESTERN ONTARIO), 21 May 2015 (21.05.2015), entire document	1-17
A	US 4,993,422 A (Hon et al.), 19 February 1991 (19.02.1991), entire document	1-17
A	US 2016/0150362 A1 (Webandz, Inc.), 26 May 2016 (26.05.2016), entire document	1-17
A	US 6,360,615 B1 (Smela), 26 March 2002 (26.03.2002), entire document	1-17
A	US 7,547,282 B2 (Lo et al.), 16 June 2009 (16.06.2009), entire document	1-17

☐ Further documents are listed in the continuation of Box C. ☐ 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 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

Date of the actual completion of the international search	Date of mailing of the international search report
09 October 2017	30 OCT 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/39103

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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
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:

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:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-17, directed to a wearable device for monitoring blood pressure.

Group II: Claims 18-25 directed to a monitoring method for non-invasive monitoring blood-pressure.

-*-Continued in Supplemental Box-*-

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 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.:
1-17

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.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/39103

-*- Box III - Observations where Unity of Invention is Lacking -*-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a ring body; an elastomer disposed on a monitoring surface at an inner side of the ring body; and a strain gauge disposed on the elastomer at the inner side of the ring body, wherein: electrical resistance of the strain gauge is indicative of blood-pressure of a wearer, not required by the claims of Group II.

The invention of Group II includes the special technical feature of measuring a signal representing a deformation of a skin resulted from blood pressure on a subject; and deriving the blood-pressure of the subject from the signal, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of monitoring blood pressure. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2015/0335282 A1 (Lee), which discloses a wearable blood pressure monitor (wrist watch style blood pressure monitor 1, Fig. 1-2; para [0046]) for measuring and monitoring blood pressure over time (taking measurements of blood pressure regularly at the same time every day in order to determine a pattern, para [0053] and [0055]-[0056]).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.