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(71) Applicant (for all designated States except US): **THE GENERAL HOSPITAL CORPORATION** [US/US]; 55 Fruit Street, Boston, MA 02114 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **WARGER, William, C., II** [US/US]; 10 Rogers St., Unit 428, Cambridge, MA 02142 (US). **SCHLACHTER, Simon, C.** [IE/US]; 359 Highland Ave #2, Somerville, MA 02144 (US). **GARDECKI, Joseph** [US/US]; 27 Royal Crest Drive #8, Marlborough, MA 01752 (US). **BOUMA, Brett, E.** [US/US]; 12 Monmouth Street, Quincy, MA 02171 (US). **TEARNEY, Gillermo, J.** [US/US]; 12 Fairmont Street, Cambridge, MA 02139 (US).

(74) Agent: **ABELEV, Gary**; Dorsey & Whitney LLP, 51 West 52nd Street, New York, NY 10019 (US).

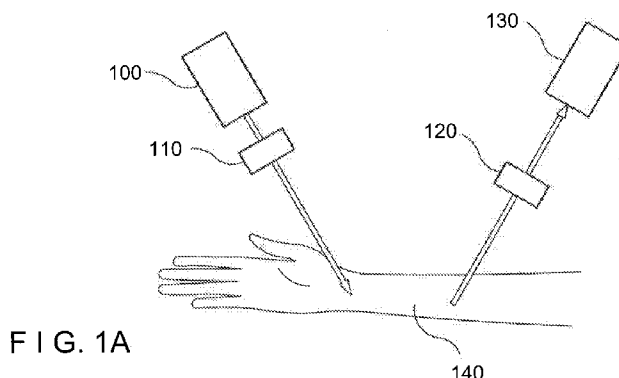
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(54) Title: APPARATUS, SYSTEMS AND METHODS FOR MEASURING BLOOD PRESSURE WITHIN AT LEAST ONE VESSEL



(57) Abstract: Exemplary apparatus and method for obtaining information for at least one structure can be provided. For example, it is possible to forward at least one first electro-magnetic radiation to the at least one structure which is external from the apparatus. At least one second electro-magnetic radiation provided from the at least one structure (which is based on the first electro-magnetic radiation(s)) can be detected. It is also possible to determine at least one characteristic of the structure(s) based on the second electro-magnetic radiation(s), and obtain data relating to a pressure of at least one portion of the structure(s) based on the characteristic(s).



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APPARATUS, SYSTEMS AND METHODS FOR MEASURING BLOOD PRESSURE WITHIN AT LEAST ONE VESSEL

5 CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims priority from U.S. Patent Application Serial No. 61/407,368, filed on October 27, 2010, the entire disclosure of which is incorporated herein by reference.

FIELD OF THE DISCLOSURE

10 [0002] Exemplary embodiments of the present disclosure relates generally to measuring apparatus, systems and methods, and more particularly to apparatus, systems and methods for measuring flow and pressure within at least one vessel using an optical measurement external to the vessel(s).

BACKGROUND INFORMATION

15 [0003] Blood pressure is an important parameter for understanding a range of health conditions, from the acute to the chronic. Currently, a sphygmomanometer cuff and an auscultatory technique have been considered as accurate methods to determine the blood pressure, without resorting to invasive methods. However, the use of the sphygmomanometer cuff likely suffers from several shortcomings. For example,

- 20 • sphygmomanometer cuff generally provides only a non-continuous average blood pressure measurement
- measurement can suffer from several systematic sources of error and/or restricted to relatively healthy individuals
- measurement can likely only be used to ascertain the blood pressure at a limited number of locations on the body

25 [0004] Optical Coherence Tomography (“OCT”), including Fourier Domain OCT, including but not limited to Optical Frequency Domain Imaging (“OFDI”), Swept Source Optical Coherence Tomography (“SS-OCT”), and Spectral-Domain Optical Coherence Tomography (“SD-OCT”) – some of which are described in described in International Patent Application PCT/US2004/029148, filed September 8, 2004 which published as International Patent
30 Publication No. WO 2005/047813 on May 26, 2005, U.S. Patent Application No. 11/266,779,

filed November 2, 2005 which published as U.S. Patent Publication No. 2006/0093276 on May 4, 2006, and U.S. Patent Application No. 10/501,276, filed July 9, 2004 which published as U.S. Patent Publication No. 2005/0018201 on January 27, 2005, and U.S. Patent Publication No. 2002/0122246, published on May 9, 2002), can generally utilize low coherence interferometry and/or optical frequency domain interferometry procedures to measure scattering as a function of depth.

[0005] If the blood pressure could be accurately and reliably measured using an external optical measurement, it would facilitate a high-speed beat-to-beat variation in the blood pressure to be monitored in a large number of locations on the body, e.g., by inexperienced users, in non-clinical settings.

[0006] Previously, other concepts/procedures of utilizing non-invasive optical measurements to estimate the blood pressure within a vessel have been described. Such concepts include Photoplethysmography (see Y.-Z. Yoon and G.-W. Yoon, "Nonconstrained Blood Pressure Measurement by Photoplethysmography," J. Opt. Soc. Korea 10, 91-95 (2006)), laser speckle (see J. Biomed. Opt. 15, 061707 (Nov 22, 2010); doi:10.1117/1.3505008), etc. However, these procedures generally rely on a detection of morphological changes in arteries caused by pressure waves from cardiac output. Thus, these procedures are dependent on hard-to-estimate quantities, such as, e.g., the elasticity of the arterial wall and other physiological factors. These dependencies limit the practicality of such procedures.

[0007] Thus, it may be beneficial to address and/or overcome at least some of the deficiencies of the prior approaches, procedures and/or systems that have been described herein above.

OBJECTS AND SUMMARY OF EXEMPLARY EMBODIMENTS OF DISCLOSURE

[0008] It is therefore one of the objects of the present invention to reduce or address the deficiencies and/or limitations of such prior art approaches, procedures and systems. Thus, exemplary procedure, method, system and apparatus can be provided for measuring flow and pressure within at least one vessel using an optical measurement external to the vessel(s), and which overcome at least some of such deficiencies.

[0009] For example, according to an exemplary embodiment of the present disclosure, it is possible to convert the optical measurement of blood pressure information into derived clinical parameters such as, e.g., systolic pressure, diastolic pressure, pulse pressure, mean arterial pressure, and other metrics known to those having ordinary skill the art. Further, according to one exemplary embodiment of the present disclosure, an exemplary correlation procedure, system and apparatus can be provided that can have, e.g., reduced or minimal location limitations, and can be implemented (e.g., either partially or entirely) via a software arrangement or a software program.

[0010] In a particular exemplary embodiment of the present disclosure, it is possible to utilize an existing OCT (or other optical measurement modality) device, system, method and/or apparatus which can be configured for, e.g., an external measurement of the external, brachial subclavian artery, radial, ulnar or carotid artery to obtain information regarding blood pressure within the artery.

[0011] According to a further exemplary embodiment of the present disclosure, apparatus, system and method for obtaining information for at least one structure can be provided. For example, it is possible (e.g., using at least one first arrangement) to forward at least one first electro-magnetic radiation to the at least one structure which is external from the apparatus. At least one second electro-magnetic radiation provided from the at least one structure (which is based on the first electro-magnetic radiation(s)) can be detected (e.g., using at least one second arrangement). It is also possible (e.g., using at least one third arrangement) to determine at least one characteristic of the structure(s) based on the second electro-magnetic radiation(s), and obtain data relating to a pressure of at least one portion of the structure(s) based on the characteristic(s).

[0012] According to another exemplary embodiment of the present disclosure, the characteristic(s) can include (i) a refractive index of the structure(s), and/or (ii) a change of the refractive index. The third arrangement(s) can be further configured to measure a temperature of the portion(s) and/or obtains the data relating to the pressure using the temperature and the characteristic(s). The structure(s) can include an anatomical structure (e.g., a blood vessel), and the pressure can be provided within the blood vessel. The characteristic(s) can relate to a structure of at least one red blood cell of the portion(s). The

anatomical structure can also include a fascial compartment, and the pressure can be provided within the fascial compartment.

[0013] According to still another exemplary embodiment of the present disclosure, the first arrangement(s) can be further configured to forward at least one third electro-magnetic radiation to a reference, and the second arrangement(s) can be configured to detect the second electro-magnetic radiation(s) provided from the structure(s) and interfered with at least one fourth radiation provided from the reference which is associated with the third electro-magnetic radiation(s). For example, the first and second arrangements can form (i) low coherence interferometric system, (ii) optical frequency domain imaging system, and/or (iii) spectral domain optical coherence tomography system. The first electro-magnetic radiation(s) can include a light radiation. The second electromagnetic radiation(s) can include a plurality of distinct radiation provided from (i) different spatial locations on the structure(s), or (ii) different temporal locations from the structure(s). The characteristic(s) can include a speckle pattern of the structure(s). The characteristic(s) can further include a refractive index that can be determined based on the speckle pattern. The third arrangement(s) can correlate the speckle pattern with further speckle patterns obtained at different wavelengths or times from the portion(s).

[0014] According to yet further exemplary embodiment of the present disclosure the characteristic(s) can include (i) a refractive index of the structure(s), and/or (ii) a change of the refractive index. The second arrangement(s) can detect the electromagnetic radiation based on a wavelength thereof or an angle of remittance from the structure(s) relative to an angle of incidence of the first electromagnetic radiation(s) on the structure(s). The anatomical structure can include (i) an eye, (ii) an ear, (iii) a brain compartment, (iv) a spinal canal, (v) an airway, (vi) a heart cavity, (vii) a gastro-intestinal organ, and/or (viii) a bladder. The characteristic(s) can include (i) a phase of the second electromagnetic radiation(s) relative to the first electromagnetic radiation(s), or (ii) a change of the phase. The characteristic(s) can also include (i) a phase of the electromagnetic radiation(s) relative to the fourth electromagnetic radiation(s), or (ii) a change of the phase.

[0015] According to another exemplary embodiment of the present disclosure, apparatus, system and method can be provided to measure blood pressure within an anatomical structure. For example, it is possible to use at least one first probe arrangement structured to

direct at least one radiation to at least one external portion of the anatomical structure. Further, it is possible to provide at least one second arrangement which is configured to detect the radiation reflected from the anatomical structure. Further, at least one third arrangement can be provided to detect an interference between a first radiation provided from the anatomical structure via the probe arrangement and second a second radiation provided from a reference path as a function of wavelength thereof. In addition, at least one fourth arrangement can be provided which can be configured to determine at least one characteristic of the blood flow as a function of the signal. For example, the fourth arrangement(s) can determine the characteristic(s) as a function of an intensity of the interference and/or as a function of the self-interference (e.g., speckle) pattern generated by first radiation incident on the anatomical structure via the probe arrangement(s).

[0016] The first probe arrangement(s) can include a handheld apparatus. The anatomical structure can comprise an artery, vein, or any location on the skin surface. A wavelength of at least one of the first radiation or the second radiation can vary over time. The second arrangement can include at least one array of detectors, each configured to detect a separate wavelength band of the interference.

[0017] The first probe arrangement(s) can be configured to be immobile during operation of the apparatus. The second and/or third arrangement(s) can determine the characteristic as a function of time and/or determine synchronously with a further physiological measurement. The further physiological measurement can be an EKG, temperature or heart rate. The third arrangement(s) can determine the characteristic before and/or after an administration of a pharmacologic agent.

[0018] These and other objects, features and advantages of the exemplary embodiment of the present disclosure will become apparent upon reading the following detailed description of the exemplary embodiments of the present disclosure, when taken in conjunction with the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Further objects, features and advantages of the present disclosure will become apparent from the following detailed description taken in conjunction with the accompanying figures showing illustrative embodiments of the present disclosure, in which:

[0020] Figure 1A is a block diagram of a first exemplary embodiment of an optical measurement apparatus, system and/or arrangement according to the present disclosure;

[0021] Figure 1B is a block diagram of a second exemplary embodiment of the optical measurement apparatus, system and/or arrangement according to the present disclosure;

5 [0022] Figures 2A-2D are exemplary images, diagrams and graphs indicating a change in the optical characteristics of water and blood at different pressures and temperatures;

[0023] Figure 3 is a block diagram describing exemplary procedures utilized by a method, apparatus, system and/or arrangement according to an exemplary embodiment of the present disclosure to measure pressure from optical and other measurements; and

10 [0024] Figure 4 is are illustration of diagram and graph demonstrating an exemplary minimum resolvable difference in a refractive index that OCT techniques are capable of measuring.

[0025] Throughout the figures, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components or portions of the illustrated
15 embodiments. Moreover, while the subject disclosure will now be described in detail with reference to the figures, it is done so in connection with the illustrative embodiments. It is intended that changes and modifications can be made to the described exemplary embodiments without departing from the true scope and spirit of the subject disclosure as defined by the appended claims.

20 **DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS**

[0026] A block diagram an optical measurement system according to a first exemplary embodiment of the present disclosure is shown in Figure 1A. For example, the exemplary system and/or arrangement can include one or more electro-magnetic radiation sources (e.g., at least one light source) 100 and conditioning optics 110, for delivering at least one first
25 radiation to the sample 140. At least one second radiation, e.g., generated by a reflection of the first radiation(s) can be passed through detection optics 120, and is then incident upon a detection and processing arrangement 130, which can include a processor and a storage medium (e.g., hard drive, CD-ROM, floppy disk, memory stick, combination thereof, etc.).

[0027] Figure 1B shows a block diagram the optical measurement system according to a second exemplary embodiment of the present disclosure. This exemplary system and/or arrangement can include a handheld probe 150 that can include transmission and detection optics 160 for delivering radiation to the anatomical structure 170. The exemplary probe 150 can be coupled to an detection and processing system, apparatus or arrangement 190 which can include a processor and a storage medium (e.g., hard drive, CD-ROM, floppy disk, memory stick, combination thereof, etc) at a proximal end thereof (e.g., via an optical fiber 180).

[0028] Figure 2 illustrates exemplary images, diagrams and graphs indicating a change in the optical characteristics of water and blood at different pressures and temperatures. A summary of relevant optical parameters for blood and water are illustrated at different pressures in Figure 2. For example, as the pressure in arteries and capillaries increases, red blood cells become deformed 200, and thus cause the electromagnetic radiation (e.g., light) to scatter with a different polarization state 210, and in a different direction 220, as shown in a graph 230. In addition, the refractive index of water as shown in a graph 240 can change with a pressure 250 in a linear relationship 260. A complicating factor can be that the refractive index of water can also change with the temperature 170 in a linearly decreasing relationship 180. Data can be taken from R.S. Brock, X.-H. Hu, P. Yang, and J. Lu, "Evaluation of a parallel FDTD code and application to modeling of light scattering by deformed red blood cells," Opt. Express **13**, 5279-5292 (2005) and "Release on the Refractive Index of Ordinary Water Substance as a Function of Wavelength, Temperature and Pressure" International Association for the Properties of Water and Steam, Erlangen, Germany, 1997.

[0029] Figure 3 shows an exemplary flow diagram of an exemplary method and/or procedures for a determination of the pressure from an optical measurement according to an exemplary embodiment of the present disclosure. For example, a plurality of independent initial measurements can be calculated. Such exemplary measurements can include, e.g.,

- An optical measurement using the apparatus of Figure 1 as provided in procedure 300;
- A temperature measurement using standard equipment, e.g., an electronic thermometer as provided in procedure 320

- A heart rate measurement using a conventional equipment, e.g., EKG, pulse oximeter, etc, as shown in procedure 330.

[0030] In the next step 340 of the determination procedure, the optical measurement can be converted to the pressure using the exemplary parameters described herein and shown in Figure 2. Furthermore, the temperature measurement can be used to compensate for errors in the calculation caused by changes in the temperature. The next step 350 in the exemplary determination procedure can utilize the heart rate measurement 330 to increase sensitivity of the measurement by rejecting non-cardiac changes in the signal through the use of, e.g., a lock-in detection mechanism.

[0031] The exemplary optical apparatuses shown in Figures 1A and 1B can be configured to detect extremely small changes in scattering and refractive index. The refractive index changes associated with physiological changes in pressure can be on the order of, e.g., 1×10^{-6} per 50 mmHg. If detecting this change in a vessel having a 1 mm radius, as shown in an illustration 400 of Figure 4, this can lead to a total change in the phase of the light of

$$\theta = \frac{\Delta z \Delta n 2\pi}{\lambda} = \frac{2 \times 1.05e-6 \times 2\pi}{1310e-9} = 5 \text{ mrad.}$$

While this exemplary result may seem to be a small quantity, such exemplary changes that can be measured by OFDI and laser speckle imaging exemplary techniques, systems and/or apparatus, among other optical techniques, systems and/or apparatus. As an example, the phase sensitivity of a typical OFDI system can be given by an illustration 410 of Figure 4. Such phase sensitivity can be dependent on the sample signal 420. An exemplary measured curve 430, as shown in Figure 4, decreases with measured signal until it reaches a plateau defined by the signal intensity provided by a reference measurement. If this exemplary reference measurement (which can be provided by a glass coverslip or similar) is sufficiently high, and the sample signal is better than 45dB, then the exemplary OFDI system can resolve a phase change of less than 5 mrad. These exemplary changes can be linked back to the pressure changes within blood vessels using the exemplary procedures that are shown in the flow diagram shown in Figure 3. The data can be provided from: B. J. Vakoc, S. H. Yun, J. F. de Boer, G. J. Tearney, and B. E. Bouma, "Phase-resolved optical frequency domain imaging" Optics Express 13, 5483 (2005).

[0032] The foregoing merely illustrates the principles of the disclosure. Various modifications and alterations to the described embodiments will be apparent to those skilled

in the art in view of the teachings herein. Indeed, the arrangements, systems and methods according to the exemplary embodiments of the present disclosure can be used with and/or implement any OCT system, OFDI system, SD-OCT system or other imaging systems, and for example with those described in International Patent Application PCT/US2004/029148, filed September 8, 2004 which published as International Patent Publication No. WO 2005/047813 on May 26, 2005, U.S. Patent Application No. 11/266,779, filed November 2, 2005 which published as U.S. Patent Publication No. 2006/0093276 on May 4, 2006, and U.S. Patent Application No. 10/501,276, filed July 9, 2004 which published as U.S. Patent Publication No. 2005/0018201 on January 27, 2005, and U.S. Patent Publication No. 2002/0122246, published on May 9, 2002, the disclosures of which are incorporated by reference herein in their entireties. It will thus be appreciated that those skilled in the art will be able to devise numerous systems, arrangements and methods which, although not explicitly shown or described herein, embody the principles of the disclosure and are thus within the spirit and scope of the present disclosure. In addition, to the extent that the prior art knowledge has not been explicitly incorporated by reference herein above, it is explicitly being incorporated herein in its entirety. Further, the exemplary embodiments described herein can operate together with one another and interchangeably therewith. All publications referenced herein above are incorporated herein by reference in their entireties.

WHAT IS CLAIMED IS:

1. An apparatus for obtaining information for at least one structure, comprising:
 - at least one first arrangement configured to forward at least one first electro-magnetic radiation to the at least one structure which is external from the apparatus;
 - 5 at least one second arrangement configured to detect at least one second electro-magnetic radiation provided from the at least one structure which is based on the at least one first electro-magnetic radiation; and
 - at least one third arrangement configured to (i) determine at least one characteristic of the at least one structure based on the at least one second electro-magnetic radiation, and (ii) obtain data relating to a pressure of at least one portion of the at least one structure based on the at least one characteristic.
2. The apparatus according to claim 1, wherein the at least one characteristic includes at least one of (i) a refractive index of the at least one structure, or (ii) a change of the refractive index.
3. The apparatus according to claim 1, wherein the at least one third arrangement is further configured to measure a temperature of the at least one portion.
4. The apparatus according to claim 3, wherein the at least one third arrangement obtains the data relating to the pressure using the temperature and the at least one characteristic.
5. The apparatus according to claim 1, wherein the at least one structure includes an anatomical structure.
6. The apparatus according to claim 5, wherein the anatomical structure includes a blood vessel.
7. The apparatus according to claim 6, wherein the pressure is provided within the blood vessel.
8. The apparatus according to claim 6, wherein the at least one characteristic relates to a structure of at least one red blood cell of the at least one portion.

9. The apparatus according to claim 5, wherein the anatomical structure includes a fascial compartment.

10. The apparatus according to claim 9, wherein the pressure is provided within the fascial compartment.

11. The apparatus according to claim 1, wherein the at least one first arrangement is further configured to forward at least one third electro-magnetic radiation to a reference, and wherein the at least one second arrangement is configured to detect the at least one second electro-magnetic radiation provided from the at least one structure and interfered with at least one fourth radiation provided from the reference which is associated with the at least one third electro-magnetic radiation.

12. The apparatus according to claim 11, wherein the first and second arrangements form at least one of (i) low coherence interferometric system, (ii) optical frequency domain imaging system, or (iii) spectral domain optical coherence tomography system.

13. The apparatus according to claim 1, wherein the at least one first electro-magnetic radiation is a light radiation.

14. The apparatus according to claim 1, wherein the at least one second electromagnetic radiation is a plurality of distinct radiation provided from (i) different spatial locations on the at least one structure, or (ii) different temporal locations from the at least one structure.

15. The apparatus according to claim 14, wherein the at least one characteristic is a speckle pattern of the at least one portion.

16. The apparatus according to claim 15, wherein the at least one characteristic further includes a refractive index that is determined based on the speckle pattern.

17. The apparatus according to claim 16, wherein the at least one third arrangement correlates the speckle pattern with further speckle patterns obtained at different wavelengths or times from the at least one portion.

18. The apparatus according to claim 1, wherein the at least one characteristic includes at least one of (i) a refractive index of the at least one structure, or (ii) a change of the refractive index.

19. The apparatus according to claim 1, wherein the at least one second arrangement detects the at least one second electromagnetic radiation based on a wavelength thereof or an angle of remittance from the at least one structure relative to an angle of incidence of the at least one first electromagnetic radiation on the at least one structure.

20. The apparatus according to claim 5, wherein the anatomical structure includes at least one of (i) an eye, (ii) an ear, (iii) a brain compartment, (iv) a spinal canal, (v) an airway, (vi) a heart cavity, (vii) a gastro-intestinal organ, or (viii) a bladder.

21. The apparatus according to claim 1, wherein the at least one characteristic includes at least one of (i) a phase of the at least one second electromagnetic radiation relative to the at least one first electromagnetic radiation, or (ii) a change of the phase.

22. The apparatus according to claim 11, wherein the at least one characteristic includes at least one of (i) a phase of the at least one second electromagnetic radiation relative to the at least one fourth electromagnetic radiation, or (ii) a change of the phase.

23. A method for obtaining information for at least one structure which is performed by an apparatus, comprising:

forwarding at least one first electro-magnetic radiation to the at least one structure which is external from the apparatus;

detecting at least one second electro-magnetic radiation provided from the at least one structure which is based on the at least one first electro-magnetic radiation;

determining at least one characteristic of the at least one structure based on the at least one second electro-magnetic radiation; and

obtaining data relating to a pressure of at least one portion of the at least one structure based on the at least one characteristic.

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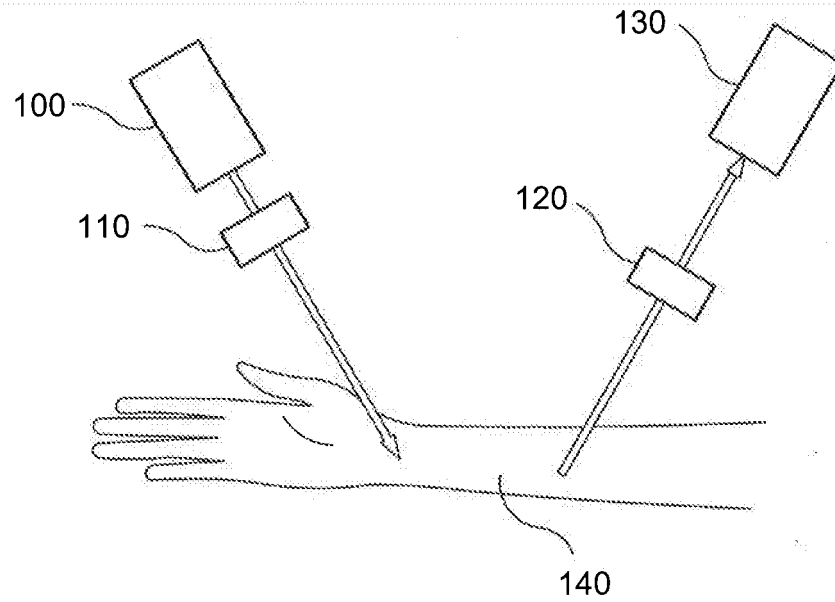


FIG. 1A

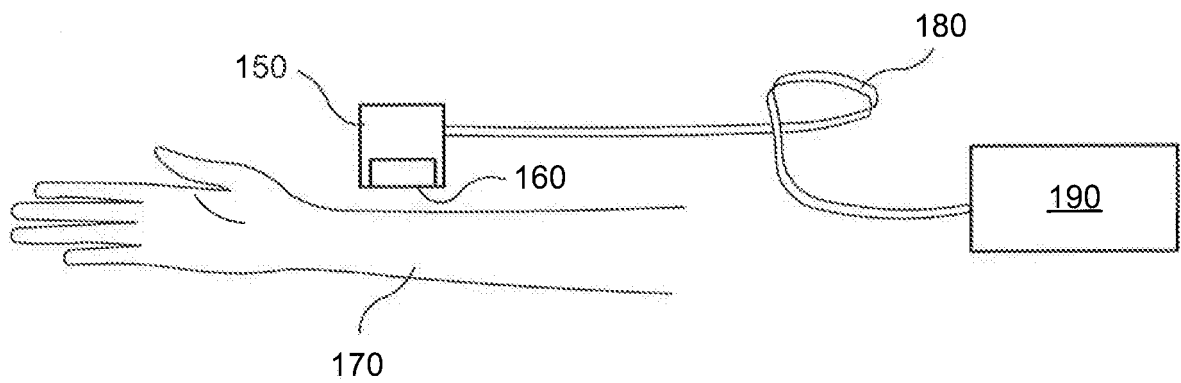


FIG. 1B

2 / 6

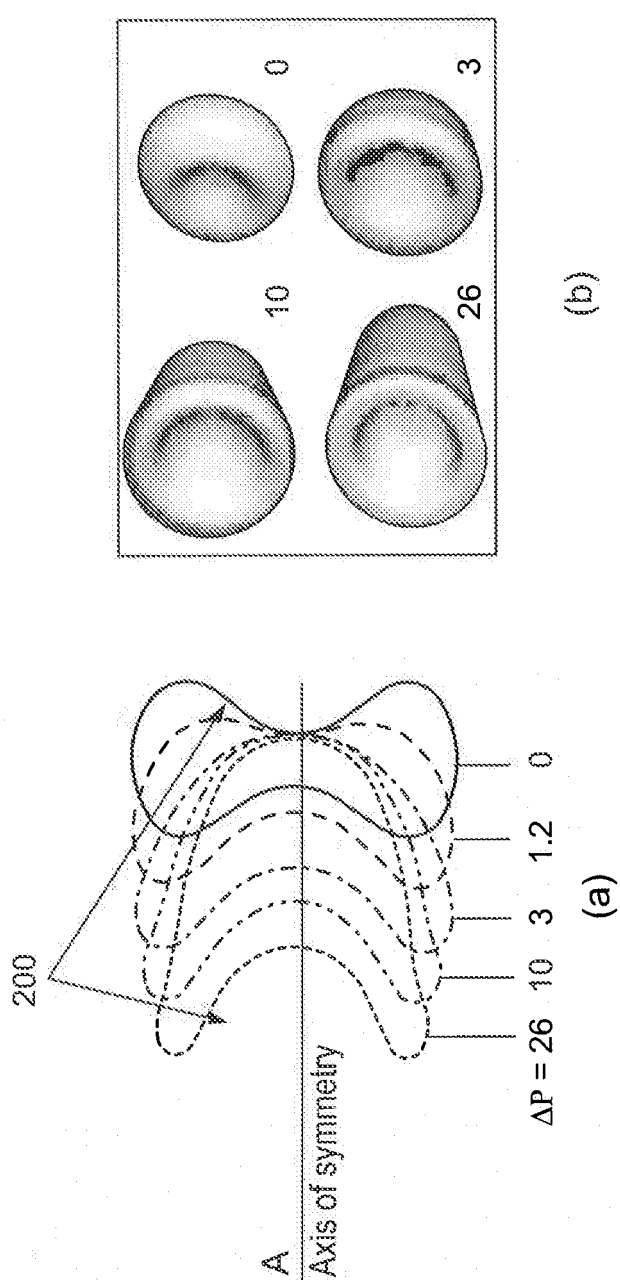


FIG. 2A

3 / 6

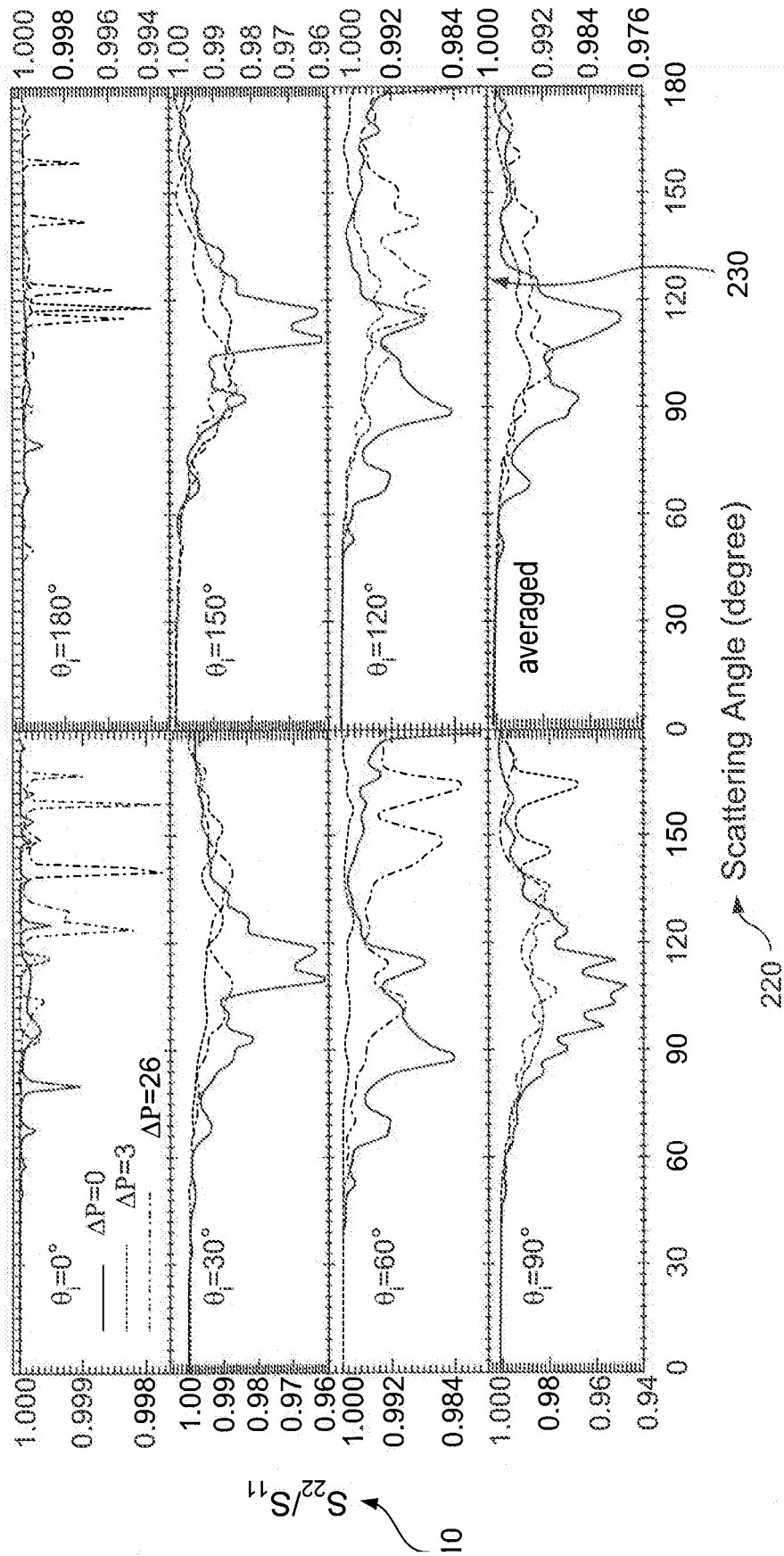


FIG. 2B

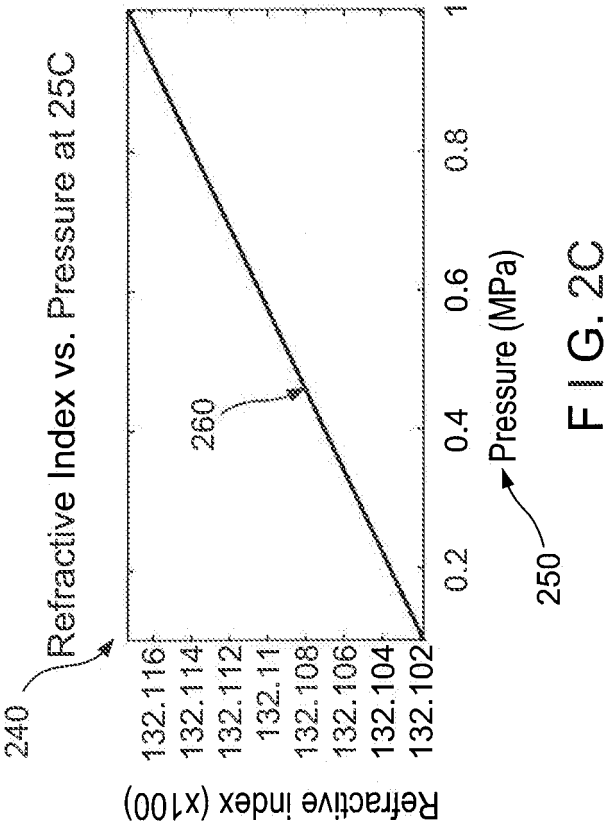


FIG. 2C

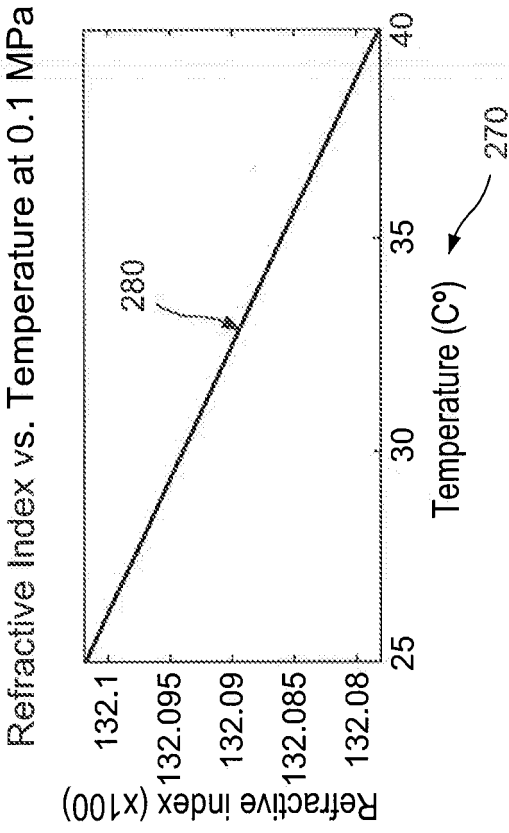


FIG. 2D

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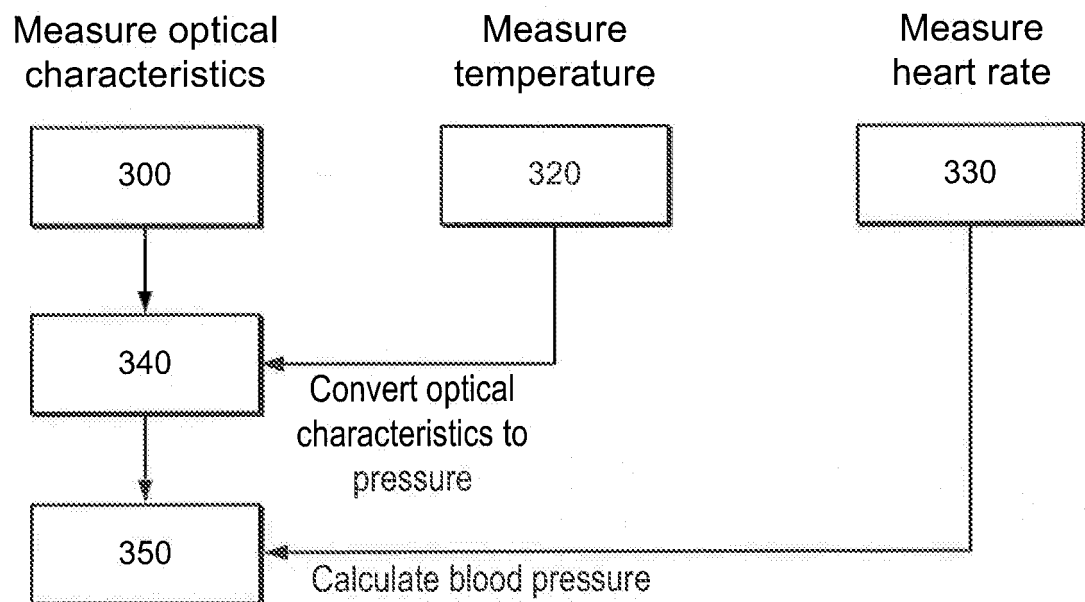


FIG. 3

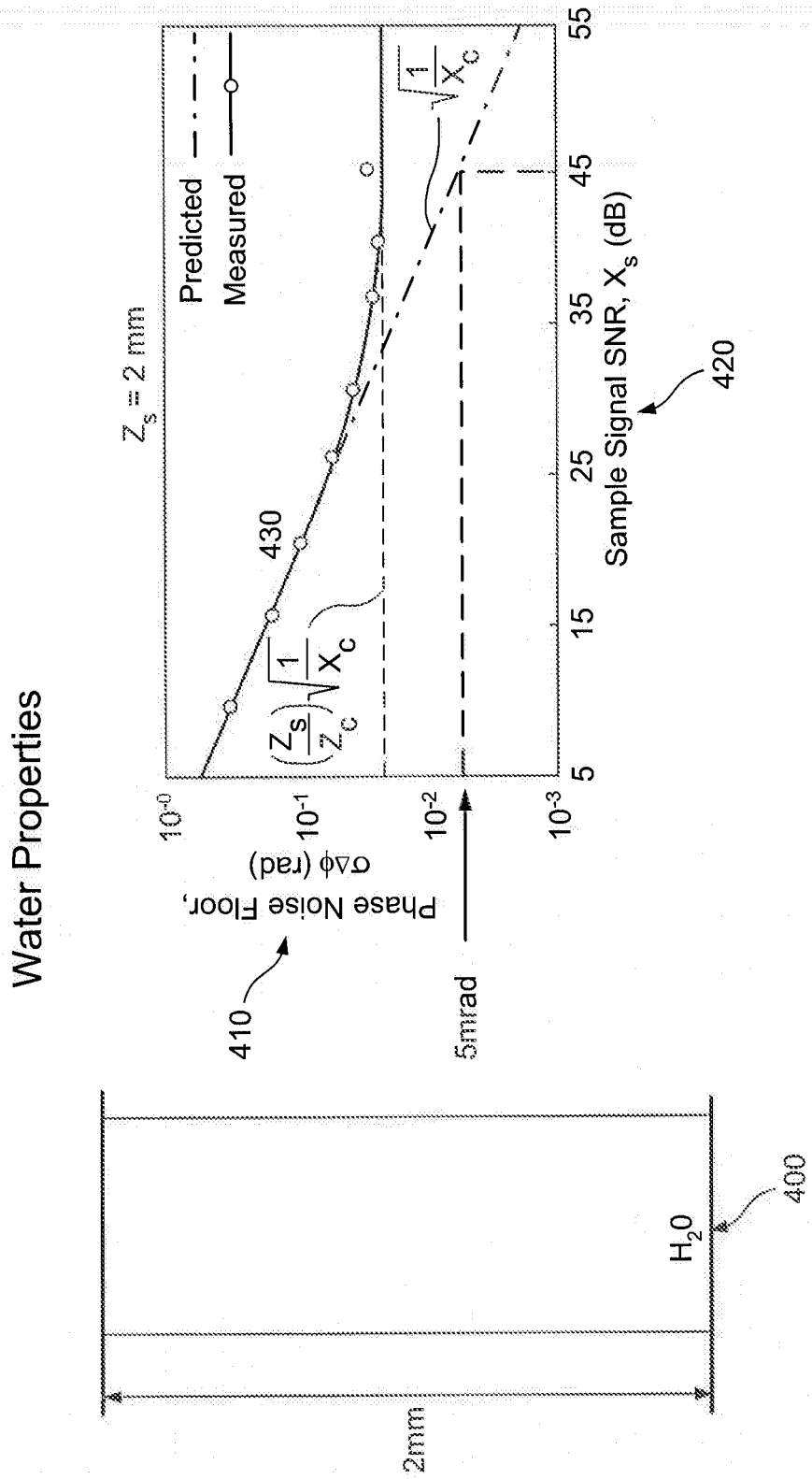


FIG. 4

专利名称(译)	用于测量至少一个容器内的血压的装置，系统和方法		
公开(公告)号	EP2632324A4	公开(公告)日	2015-04-22
申请号	EP2011837061	申请日	2011-10-27
[标]申请(专利权)人(译)	通用医疗公司		
申请(专利权)人(译)	总医院CORPORATION		
当前申请(专利权)人(译)	总医院CORPORATION		
[标]发明人	WARGER WILLIAM C II SCHLACHTER SIMON C GARDECKI JOSEPH BOUMA BRETT E TEARNEY GILLERMO J		
发明人	WARGER, WILLIAM, C., II SCHLACHTER, SIMON, C. GARDECKI, JOSEPH BOUMA, BRETT, E. TEARNEY, GILLERMO, J.		
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优先权	61/407368 2010-10-27 US		
其他公开文献	EP2632324A2		
外部链接	Espacenet		

摘要(译)

可以提供用于获得至少一个结构的信息的示例性装置和方法。例如，可以将至少一个第一电磁辐射转发到设备外部的至少一个结构。可以检测从至少一个结构（基于第一电磁辐射）提供的至少一个第二电磁辐射。还可以基于第二电磁辐射确定结构的至少一个特征，并且基于该特征获得与结构的至少一部分的压力有关的数据。（S）。