US 20150073240A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2015/0073240 A1**

(43) **Pub. Date: Mar. 12, 2015**

Huang et al.

(54) **IMPLANTABLE REAL-TIME OXIMETER TO DETERMINE POTENTIAL STROKES AND POST-TRAUMATIC BRAIN-INJURY COMPLICATIONS**

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(21) Appl. No.: **14/395,494**

(22) PCT Filed: **Mar. 14, 2013**

(86) PCT No.: **PCT/US2013/031236**

§ 371 (c)(1),
(2) Date: **Oct. 19, 2014**

Related U.S. Application Data

(60) Provisional application No. 61/636,299, filed on Apr. 20, 2012.

Publication Classification

(51) **Int. Cl.**

A61B 5/1459	(2006.01)
A61B 5/0205	(2006.01)
A61B 5/00	(2006.01)
A61B 5/1455	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/1459*** (2013.01); ***A61B 5/14552*** (2013.01); ***A61B 5/0205*** (2013.01); ***A61B 5/6876*** (2013.01); ***A61B 5/6884*** (2013.01); ***A61B 5/6885*** (2013.01); *A61B 5/02433* (2013.01)

USPC **600/325**

(57) **ABSTRACT**

A first embodiment of an oximetry probe is attached around a blood vessel near the site of a likely stroke. That will be useful to monitor large and medium size cerebral arteries. Another type of pulse oximeter can be passed within cerebral blood vessels to monitor the oxygenation status of the surrounding cerebral tissues. In that version, the emitter and detector are coplanar and contained in a small area, e.g., 50-12 μm.

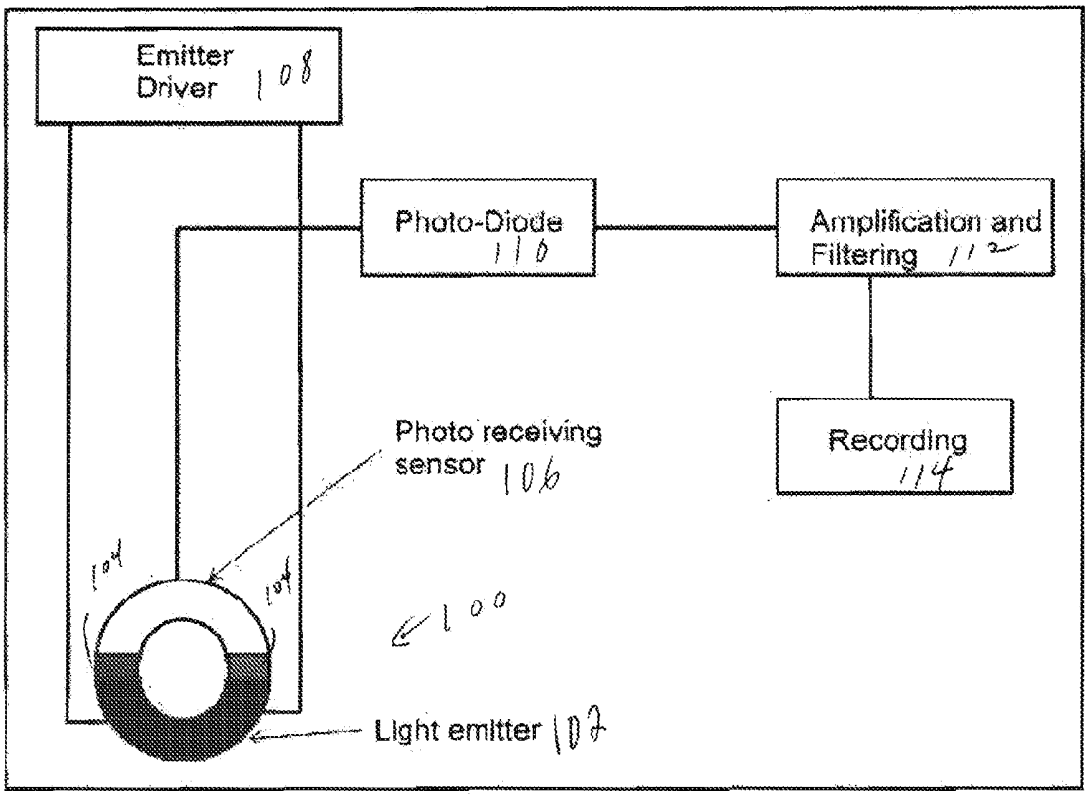


Figure 1

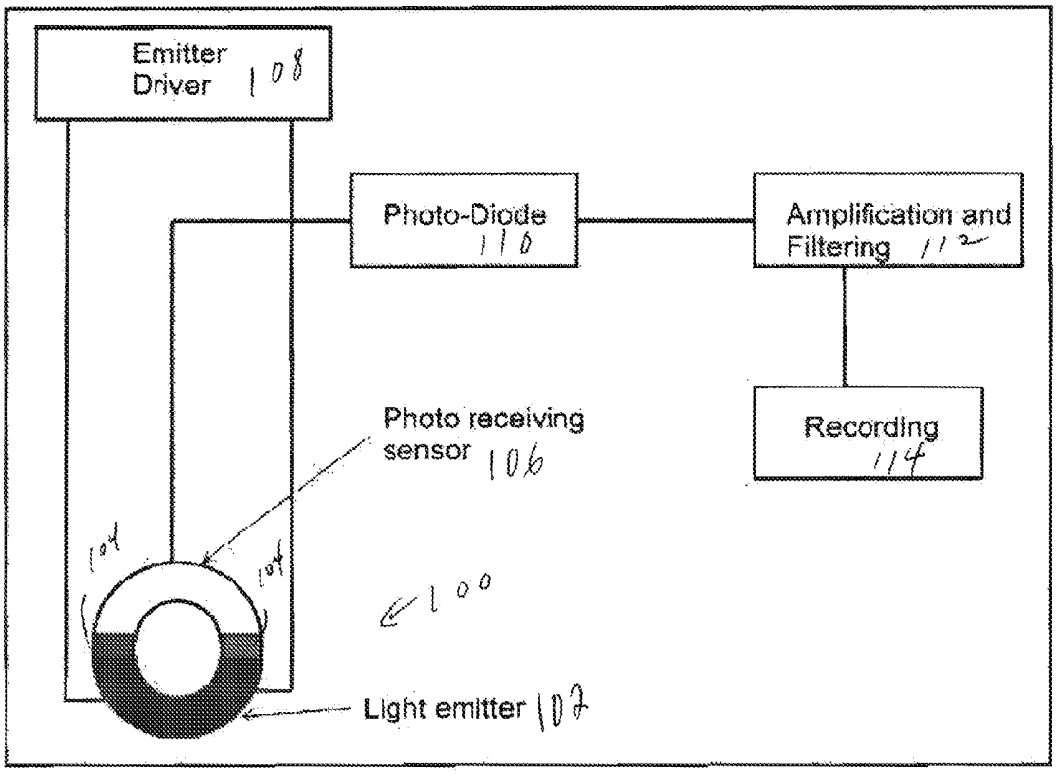
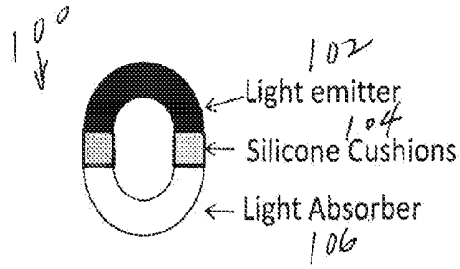
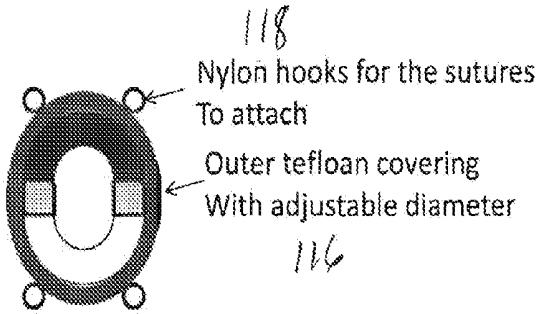


Figure 2A



Coronal section of the sensor

Figure 2B



Coronal section of the sensor with outer covering

Figure 3

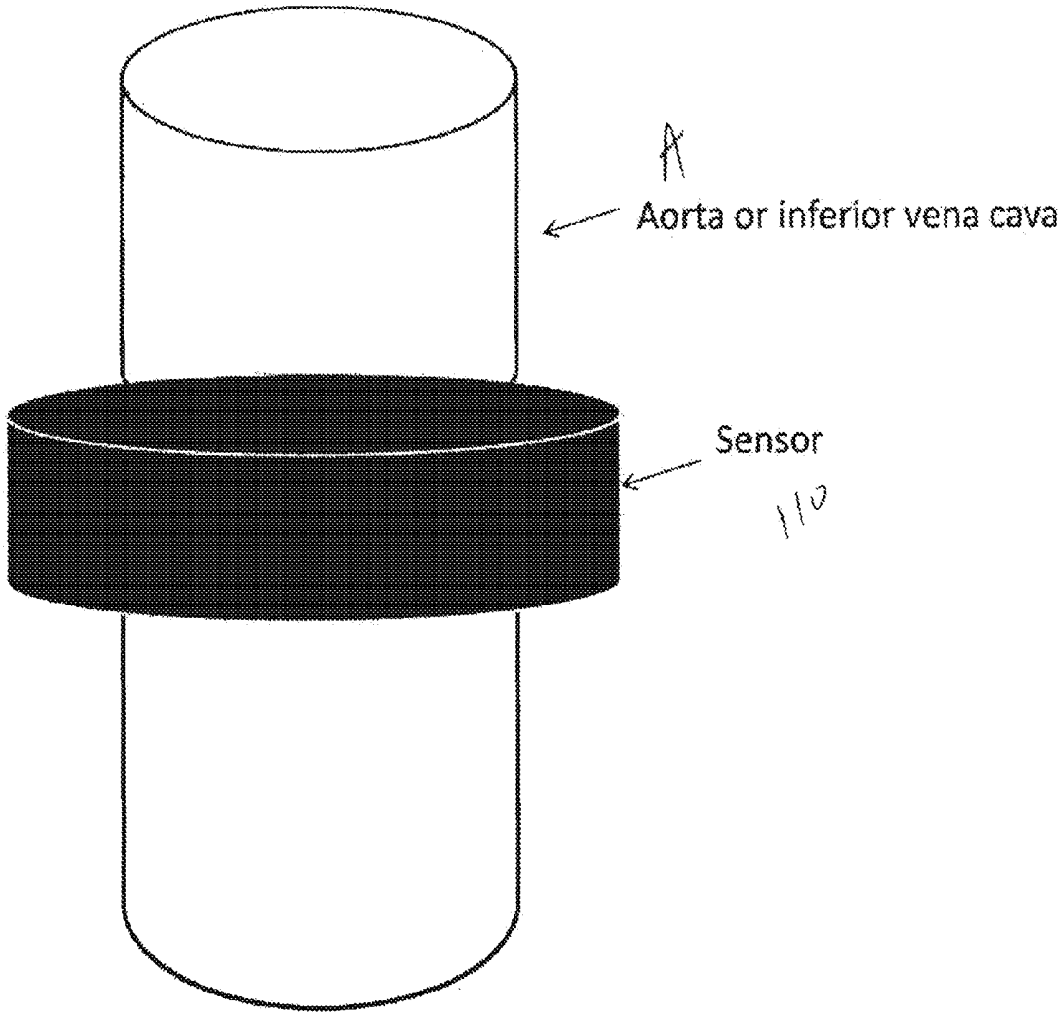


Figure 4

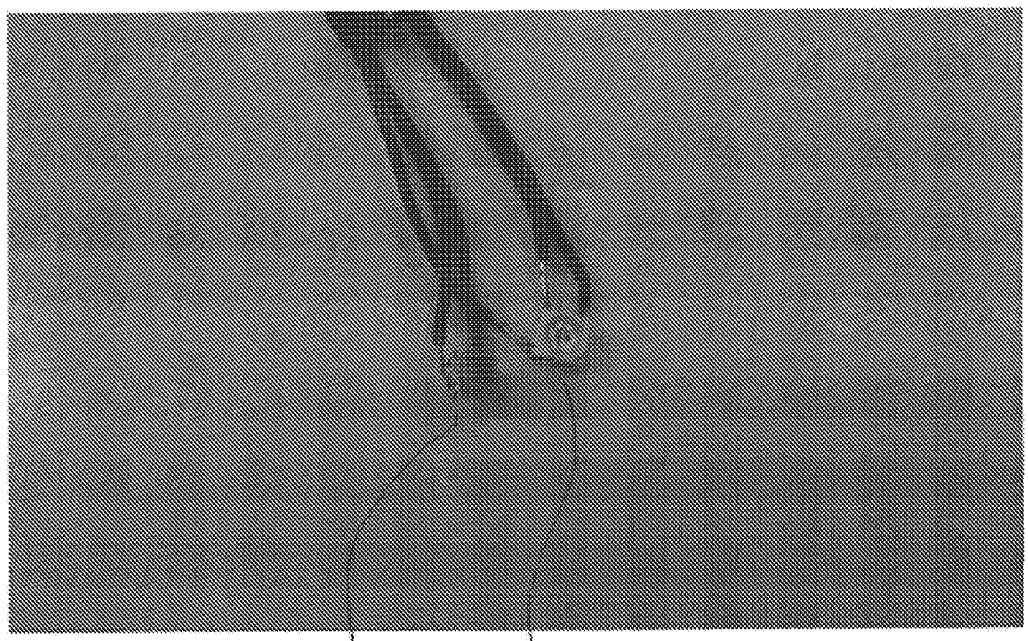


Figure 5

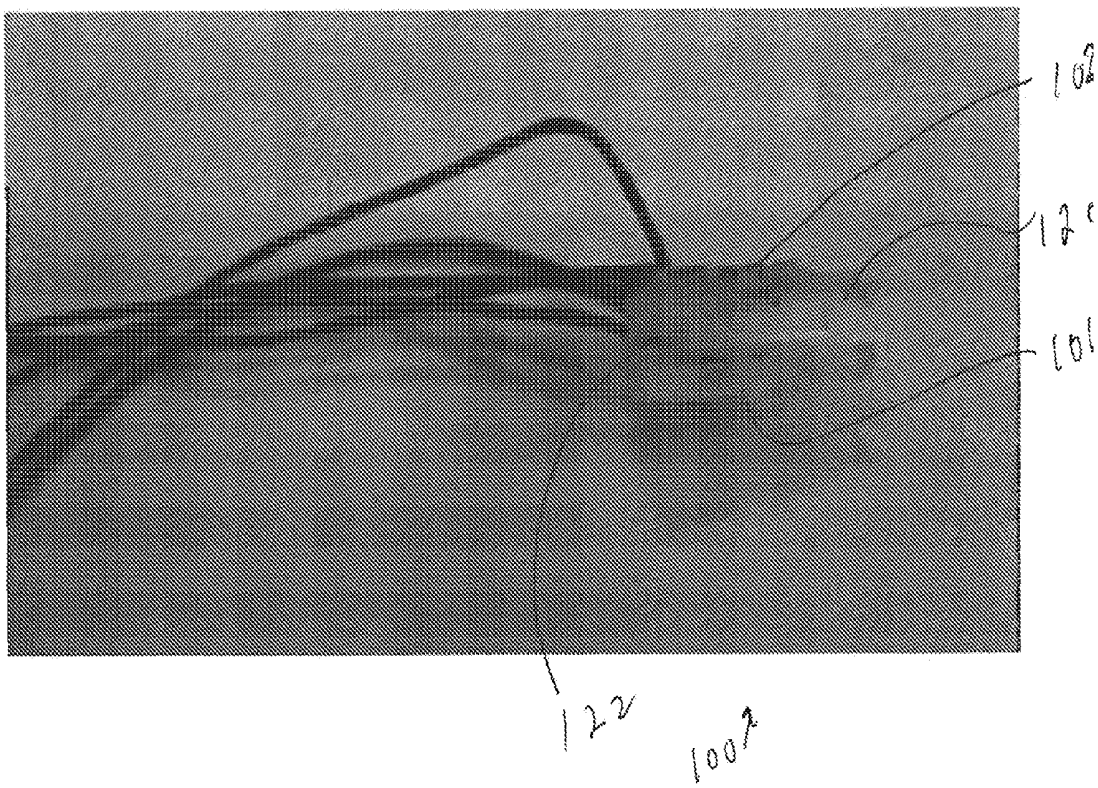


Figure 6

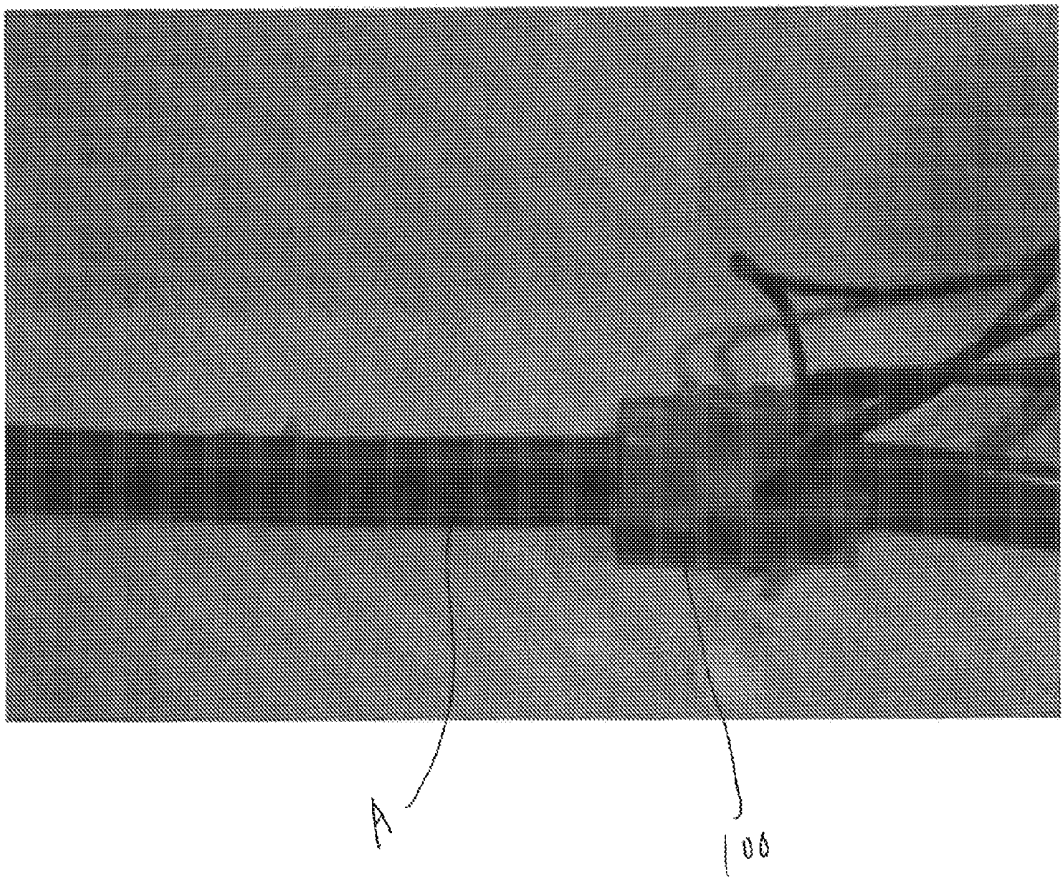


Figure 7A

Figure 7B

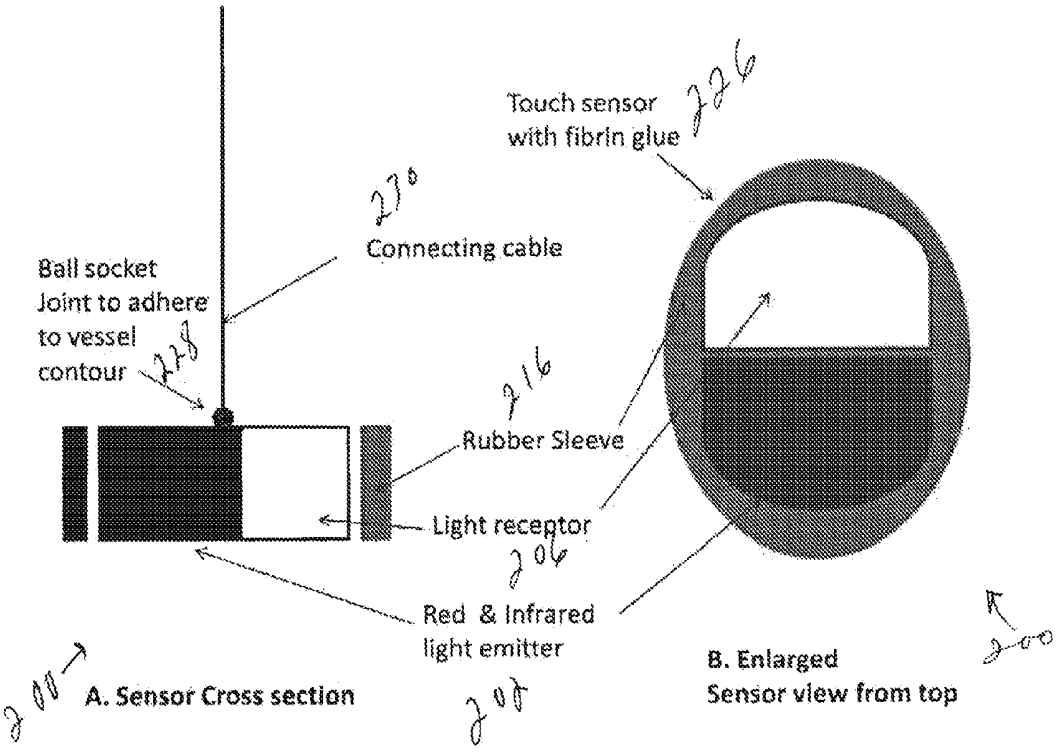


Figure 8

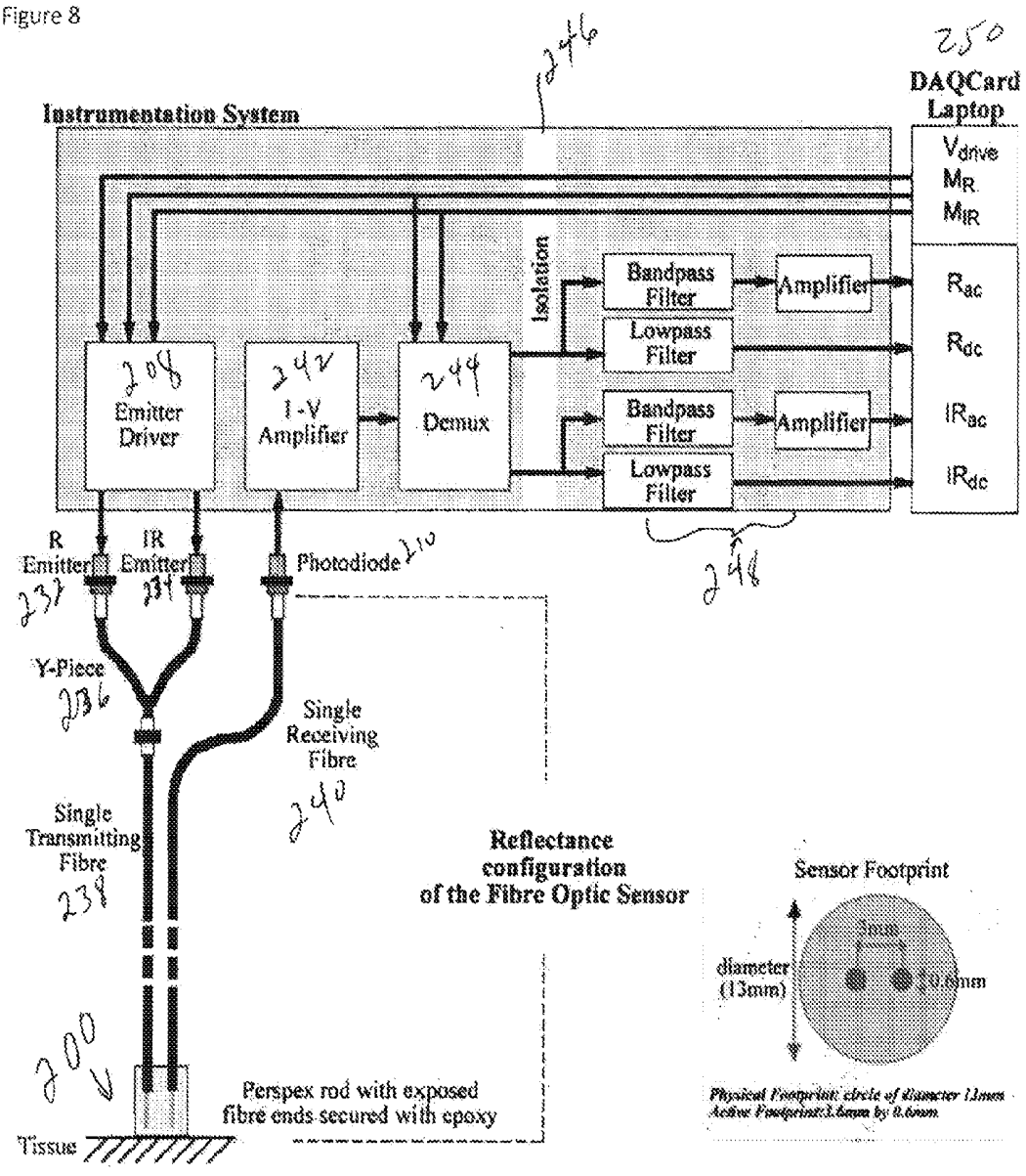

Instrumentation System
246
250
DAQCard Laptop
Vdrive
MR
MIR
Isolation
Bandpass Filter
Amplifier
Lowpass Filter
Bandpass Filter
Amplifier
Lowpass Filter
Rac
Rdc
IRac
IRdc
208
Emitter Driver
242
I-V Amplifier
244
Demux
248
R Emitter
232
IR Emitter
234
Photodiode 210
Y-Piece
236
Single Receiving Fibre
240
Single Transmitting Fibre
238
200
Tissue
Perspex rod with exposed fibre ends secured with epoxy
Reflectance configuration of the Fibre Optic Sensor
Sensor Footprint
diameter (13mm)
5mm
2.6mm
Physical Footprint: circle of diameter 13mm
Active Footprint: 5.6mm by 0.6mm

Figure 9

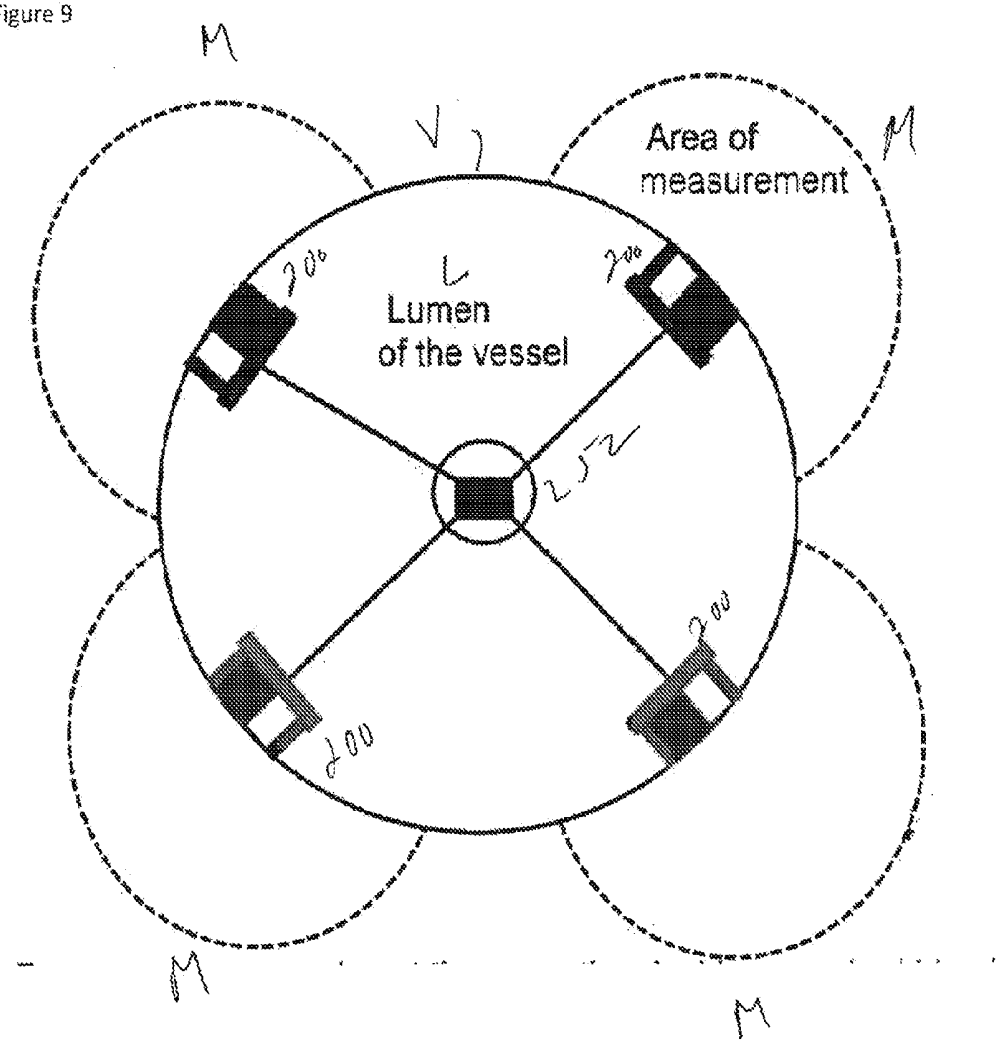
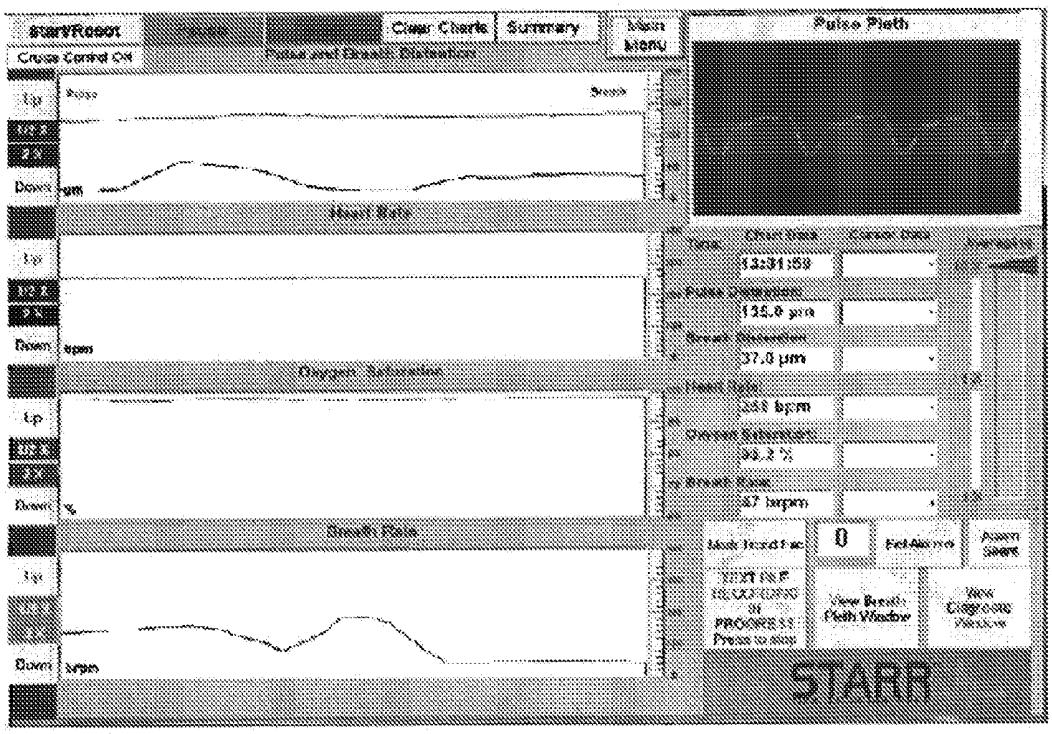


Figure 10


Start/Reset
Clear Charts
Summary
Main Menu
Cruise Control Off
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IMPLANTABLE REAL-TIME OXIMETER TO DETERMINE POTENTIAL STROKES AND POST-TRAUMATIC BRAIN-INJURY COMPLICATIONS

REFERENCE TO RELATED APPLICATION

[0001] The present application claims the benefit of U.S. Provisional Patent Application No. 61/636,299, filed Apr. 20, 2012, whose disclosure is hereby incorporated by reference in its entirety into the present disclosure.

FIELD OF THE INVENTION

[0002] The present invention is directed to a pulse oximeter and more particularly to a pulse oximeter that can be implanted onto a large or medium sized blood vessel in which its occlusion would give rise to a stroke or that can be inserted into a medium or a small cerebral blood vessel non-invasively to measure cerebral tissue oxygenation.

DESCRIPTION OF RELATED ART

[0003] Pulse oximetry is a technique for monitoring the oxygenation of a patient's hemoglobin. A sensor is placed on a thin part of the patient's body, usually a fingertip or earlobe, or in the case of an infant, across a foot. Light of two different wavelengths, typically red and infrared, is passed through or reflected by the patient's blood to a photo detector. The changing absorbance at each of the wavelengths is measured, allowing determination of the absorbances due to the pulsing arterial blood alone, excluding venous blood, skin, bone, muscle, and fat. From the absorbances, the ratio of oxygenated to deoxygenated hemoglobin can be determined.

[0004] Above skin, pulse oximetry has long been used to detect hypoxic situations. Such above skin versions cannot be used on moving patients.

[0005] Available versions cannot be used to measure the oxygenation status of cerebral tissues.

[0006] An implantable pulse oximeter is taught in Reichelt et al, "Development of an Implantable Pulse Oximeter," *Transactions in Biomedical Engineering*, Vol. 55, No. 2, February 2008, pp. 581-588. That article also suggests the use of telemetry to transmit the signal from the detector to an external unit. However, there is no teaching to use the oximeter for stroke or other brain conditions and the oximeter taught therein cannot be miniaturized enough for use on blood vessels near the likely location of a potential stroke. They have not tested the device in vivo.

[0007] Hickey et al., 2011, *Journal of Clinical Monitoring and Computing* (2011) 25:245-255 describes a single plane oximeter.

[0008] In cardiology, there are devices as Holter monitoring to detect rhythm differences. There is no device to monitor cerebral perfusion.

SUMMARY OF THE INVENTION

[0009] It is thus an object of the invention to provide an implantable pulse oximeter for implantation in the blood vessels which can give rise to a stroke (as exemplified by the first preferred embodiment, or Oximeter A) and another (as exemplified by the second preferred embodiment, or Oximeter B) which will have the ability to be passed within a cerebral blood vessel to measure oxygenation of deep brain areas.

[0010] Oximeter A, which will embrace a large rodent vessel, will be developed. That will have a diameter of 1-3 mm. That design will be miniaturized in stages to embrace human carotid or major cerebral arteries or major cerebral artery branches.

[0011] At the same time, oximeter B, a single plane oximeter, in which the light emitter and the acceptor are in the same plane, will also be developed.

[0012] That second device will be used to measure tissue oxygenation levels by measuring capillary oxy/deoxy Hemoglobin levels.

[0013] Oximeter B will be attempted to be miniaturized to a size 125-50 μm. Since oxygen measuring probes as small as 125 μm are known, the target size is deemed to be feasible. The light source and the detector are coplanar, so that the oximeter works by reflection. The oximeter is made of biocompatible materials to avoid immunorejection and will have a design that will allow direct attachment to an inner wall of a blood vessel. The output signal of that will note the oxygenation status of the surrounding brain tissues.

[0014] Signals from both of the above devices can be output to a telemetry unit. That will allow remote detection of the condition of a moving patient.

[0015] The oximeter device A can be implanted to monitor a potential stroke. It can be used for high-risk populations and can be used to determine the need for preemptive treatment.

[0016] The principle involved is the same as that of the present pulse oximeter which is in research/clinical use now. The proposed device will also use the ratio of red and infrared absorption of oxy and deoxy hemoglobin to measure the hemoglobin saturation of oxygen. The present method is non-invasive, and there are no known side effects of that mechanism for the past decades.

[0017] During phase 1 of the project, a semicircular red and infrared light emitter and a semicircular light receptor will be used to make the oximeter A. They will face each other embracing the blood vessel. Considering the biconcave shape of the red blood cell, such an assembly will be able get a better reading.

[0018] The design of Oximeter B is as follows. Infrared and red light sources will be used along with a single light receptor, in which all three will be in the same plane. That sensor will be designed to be passaged through cerebral vessels with or without CT (computer tomography) guidance. The reason for having such an assembly is to measure the oxygen saturation of the hemoglobin in capillaries of adjoining cerebral tissues, none invasive to the cerebral tissues' parse. Our final aim is to build a 50 μm diameter sensor to reach deep brain areas angiographically. We will be using fiber optic light sources and absorption fibers as material. Such an application is described in the manuscript Hickey et al., 2011.

[0019] During phase 3, both devices following phases 1, 2, will be made wireless using telemetry. That will allow patients as well as the hospital to monitor those patients and intervene as soon as the need arises.

[0020] Applications include:

[0021] 1) Monitor patients for complications following traumatic brain injury.

[0022] 2) Post stroke monitoring of the patient to prevent recurrent strokes.

[0023] 3) Diagnose stroke

[0024] 4) Monitor patients with vascular insufficiencies (Transient ischemic attack, carotid stenosis, basilar artery insufficiency, peripheral arterial diseases, mesenteric ischemia, etc),

[0025] 5) Monitor patients with pulmonary insufficiencies (Pulmonary embolism, Asthma, pulmonary edema),

[0026] 6) Monitor patients with cardiac insufficiencies

[0027] 7) Monitoring fetuses and mothers with high risk pregnancies.

[0028] 8) Measurement of intraoperative organ specific blood oxygen saturation

[0029] 9) Presently there aren't any "implantable" pulse oximeters or blood gas measurement devices. Even the external oximeters are unable to measure from moving subjects. That compromises the ability to get a real time recording from moving patients or chronic monitoring patients.

[0030] 10) Identification of ischemic areas of brain. Unlike CT angiography, the present method will not need contrast material.

[0031] 11) Acute, on nidus, monitoring of patients following stroke. That will prevent subsequent strokes.

[0032] During the first phase of our study, we will be developing an implantable pulse oximeter (oximeter A) that can be used to record hemoglobin saturation of oxygen in moving subjects. Such a device will be able to do all of the immediate applications listed under applications (numbers 1-9) above and will be located outside a major blood vessel, embracing it.

[0033] A single plane fiber-optic sensor will be tested and attempted to be miniaturized (Oximeter B). Such an application will be able to reach inner brain areas through an angiocatheter and identify would be ischemic areas. Presently there aren't any devices to measure potential stroke areas or to do intracerebral post stroke monitoring. That will serve functions 8-11. There is an overlap of functions of oximeter A, B. According to the area of measurement either A or B will be selected by the clinician.

[0034] Although implantable on a blood vessel (Oximeter A) or within a blood vessel (Oximeter B), the device will still be non invasive to the cerebral tissues.

[0035] Oximeter B will be useful to identify ischemic deep brain areas. Presently for that purpose, CT perfusion scans are used. A CT perfusion scan finds out the areas of under perfusion. However, areas of under perfusion are not always ischemic due to collateral blood supply. Also, areas which are perfused may still be ischemic due to edema, collected material, etc. Therefore, a CT perfusion scan reading can be inaccurate. Use of contrast material can be harmful for some patients, another shortcoming of CT perfusion scans. Above all, the CT perfusion scan method cannot be used for continuous post stroke measurements.

[0036] Another available option to measure cerebral oxygenation is the "Licox" probe. Due to its size (2-3 mm diameter), that cannot be passed via an interventional radiology route. Also it takes 20 min-2 hrs for the Licox probe to stabilize to give a reading. Therefore, it may not be the ideal solution for an acute stroke patient who has only 2-4 hrs time window for intervention. A Licox probe should be physically located within the brain area which will cause invasion of healthy tissue and more traumas.

[0037] On the other hand, an intravascular pulse oximeter (B) can be sent through the angiographic route to its desired destination. The sensor we are proposing will be devoid of the shortcomings of CT perfusion scan and the Licox probe method. It will still meet the expectations of present stroke treatment regimens.

[0038] Our oximeter B will also have the light emitter as well as the receiver in the same plane.

[0039] Oximeters A and B will be able to monitor the oxygenation status of any organ of the body either during surgery or chronically. Those will also be helpful as diagnostic devices to identify ischemic areas. Therefore, although they are made to monitor stroke, they will be able to be applied to monitor other organs, too.

[0040] The two proposed devices can be implanted either on a blood vessel (oximeter A) or within a blood vessel (oximeter B), to monitor tissue oxygenation levels.

[0041] The probe according to the present invention is preferably autoclavable. The emitter and sensor can be made overlapping to allow adjustment for the size of the blood vessel.

[0042] Monitoring blood oxygenation in the blood vessel, using the probe on top of a vessel, will allow quick diagnosis of an impending stroke. If the blood oxygen levels of a distal artery are low, that favors a proximal obstruction.

[0043] The present invention can be used to measure simultaneous major cerebral artery and vein oxygenation. The difference will be less if there is cerebral swelling (edema, stroke, bleeding). The present method is an alternative method to diagnose complications following traumatic brain injury. Presently, interventions are made in the presence of signs and symptoms only.

[0044] A pulse oximeter (A) is attached to a blood vessel near the site of a likely stroke. That will be useful to monitor large and medium size cerebral arteries. Aim of that is to monitor large areas of cerebral tissues supplied by those arteries. Simultaneous application to an artery and a vein will allow quick diagnosis of cerebral swelling, bleeding, stroke, among many common complications following traumatic brain injury.

[0045] Another type (B) pulse oximeter will be developed which will be able to be passed within cerebral blood vessels to monitor the oxygenation status of the surrounding cerebral tissues. In that version, the emitter and detector are coplanar and contained in a small area, e.g., 50-12 μm. Aim of that is to measure small areas of cerebral tissues located deep within the brain.

[0046] Both applications (A, B) can be useful to monitor any organ in the body either during surgery or chronically.

[0047] The output can be analyzed through suitable software.

[0048] Both versions (A, B) will be converted to send wireless signals in order to allow for chronic monitoring. Presently there is no device to measure cerebral oxygenation, chronically.

BRIEF DESCRIPTION OF THE DRAWINGS

[0049] Preferred embodiments will be set forth in detail with reference to the drawings, in which:

[0050] FIG. **1** is a diagram showing the basic circuitry of the oximeter according to the first preferred embodiment;

[0051] FIGS. **2**A and **2**B are diagrams showing cross-sectional views of the oximeter probe according to the first preferred embodiment;

[0052] FIG. **3** is a diagram showing the manner in which the oximeter probe according to the first preferred embodiment surrounds the blood vessel;

[0053] FIG. **4** is an image showing the emitter and sensor in an un-assembled state;

[0054] FIG. **5** is an image showing the emitter and sensor in an assembled state in a variation of the first preferred embodiment;

[0055] FIG. **6** is an image showing the probe of FIG. **5** attached to a blood vessel;

[0056] FIGS. **7**A and **7**B are diagrams showing the probe according to the second preferred embodiment;

[0057] FIG. **8** is a diagram showing a fiber optic sensor pathway for use with the probe of FIGS. **7**A and **7**B;

[0058] FIG. **9** is a diagram showing four probes according to the second preferred embodiment within a lumen of a blood vessel; and

[0059] FIG. **10** is a screen shot showing measurement.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0060] Preferred embodiments of the invention will now be set forth in detail with reference to the drawings, in which like reference numerals refer to like elements throughout.

[0061] FIGS. **1-6** show the first preferred embodiment, or the oximeter A design.

[0062] FIG. **1** shows the basic circuitry of the extravascular oximeter **100**. The oximeter **100** includes a light emitter **102**, silicone cushions **104**, and a photo receiving sensor **106** configured in a cylindrical shape to surround a vessel (not shown in FIG. **1**). The emitter **102** operates under the control of an emitter driver **108** to emit light at two wavelengths, e.g., in the red and infrared ranges. An output of the photo receiving sensor **106** is made incident via fiber optics onto a photo diode **110**, whose output signal goes to amplification and filtering circuitry **112** and recording circuitry **114**.

[0063] FIGS. **2**A and **2**B show the oximeter A cross section. A waterproof semicircular light emitter **102** and a light sensor **106** will be made. An outer rubber or Teflon covering **116** will embrace both to keep them in place and protect them from moisture. Nylon hooks **118** will receive sutures, which will be used to attach the assembly to the body wall. That sensor will be tested initially while it is embracing the aorta as well as the inferior vena cava of 400-600 g Sprague Dawley rats.

[0064] FIG. **3** shows the sensor **100** wrapped around an aorta or inferior vena cava A.

[0065] FIG. **4** shows the emitter **102** and the sensor **106** in an un-assembled state.

[0066] As shown in FIG. **5**, the emitter **102** and the sensor **106** can be attached to a plastic tube **120**, in which case the silicone cushions **104** are unnecessary. The plastic tube **120** has an opening **122** so that it can be clipped onto a blood vessel A, as shown in FIG. **6**.

[0067] The emitter **102** has the ability to adjust to the light level automatically. Various intensities of light can be used, depending on the environment light intensity.

[0068] FIGS. **7**A-**9** show the design of the oximeter B.

[0069] FIGS. **7**A and **7**B show the second preferred embodiment, namely, the intravascular pulse oximeter (B) **200**. The diameter of the sensor **200** will be 600 μm at the initial stage. At the final stages, the aim is to miniaturize its size to 50 μm. That will be feasible, as there are 125 μm fiber-optic oxygen sensors commercially available in the $100-300 range (http://www.instechlabs.com/Oxygen/fiberoptic/125.php). In that design, the light emitter **202** and the receptor **206** will be in the same plane. A rubber sleeve **216** will encase them both. A touch sensor **226** in the periphery will note the sensor contact with the vessel wall. Biodegradable fibrin glue will be applied to the rubber sleeve, which will allow the sensor to be chronically placed. A ball and socket joint **228** allows the oximeter **200** to adhere to the vessel contour while providing a connection to a connecting cable **230**.

[0070] FIG. **8** shows the basic fiber optic sensor pathway that will be used to record during phase 2 of the project. It was excerpted from Hickey, M et al., Journal of Clinical monitoring and computing (2011) 25:245-255; while it was not originally designed for an oximeter according to the present invention, it can easily be adapted for the oximeter B **200**. An emitter driver **208** controls a red emitter **232** and an infrared emitter **234** to emit red and infrared light, respectively. Their outputs are combined by a Y piece **236** and input via a single transmitting fiber **238** into the oximeter **200**. Light from the sensed area goes through a single receiving fiber **240** into a photodiode **210**, whose output goes to a 1V amplifier **242** and a demux **244**. The above components communicate via isolation **246** with filtering and amplifying circuitry **248** and a computing device **250**. Of course, similar circuitry can be used for the oximeter A **100** of the first preferred embodiment.

[0071] FIG. **9** shows four oximeters (B) **200** in action within a lumen L of a cerebral vessel V. Each sensor **200** will be able to get readings from tissues around the periphery of the blood vessel in an area of measurement M. That will allow isolating the area of ischemia. A few sensors can be arranged to monitor a larger brain area, as shown in the figure.

[0072] The oximeter can be incorporated into a MERCI catheter or a Penumbra catheter to evacuate the thrombus at the same time. A common transmission line **252** can be used. The output of the sensor can be sent to a computing device to analyze the output to achieve any of the above ends. The computing device will be programmed with a suitable algorithm. The device will measure real time oximetry, heart rate, breath rate, breath distension and pulse pressure. Since the sensor and the light emitter is directly attached to a major blood vessel, the measurements will be very accurate and should not have artifacts when getting readings from above skin versions of the oximetry set up presently used in clinical settings.

[0073] The following discussion can apply to either of the preferred embodiments or to any other embodiment.

[0074] FIG. **10** shows a screen shot taken while recording.

[0075] The physiological parameters measured and their scientific basis are as follows. The oximeter provides real-time percent oxygen saturation of functional arterial hemoglobin.

[0076] Real-time cardiac pulse rate is given in bpm (beats per minute).

[0077] A real-time breath rate measurement is updated every few seconds. Note that that parameter is actually derived from respiratory effort, not airflow, and will be present even if the patient is experiencing an obstructive apnea, as long as breathing effort is present. Breath rate is given in breaths per minute or brpm.

[0078] Pulse distention is a measurement of the change in distention of the arterial blood vessels residing between the sensor pads due to a cardiac output pulse. It is a direct measurement of changes in local blood volume that accompany each cardiac pulse. Since the preferred embodiment records from the aorta, the readings are very accurate. For a given vascular compliance, pulse distention can also provide a surrogate for pulse pressure.

[0079] Pulse oximetry measures the oxygen content of arterial blood. The blood is identified as being arterial because of its pulsatile nature. That pulsation is identifiable because it causes a cyclic change in the absorption of light energy from the red and infrared LEDs (Light Emitting Diodes) as it passes through the vessel, due to the presence of changing quantities of blood that occur with every heart beat. Because the blood is arterial, it possesses systemic arterial oxygen content, which is what is measured. Pulse distention is simply a measurement of the change in the effective path length of the light that passes through only the arterial or pulsating blood, and it has true linear distance units of m.

[0080] One could picture that by thinking of placing all of the arterial blood residing in the light path between the sensor pads into a cylinder that has a cross-sectional area equal to the cross-sectional area of the column of the light beam passing from the LEDs to the photodiode. If the cylinder had one inlet and one outlet for the blood to enter and exit, then the level of blood in the cylindrical chamber would rise with each cardiac ejection stroke, and lower during each subsequent cardiac filling phase. The change in height of the blood in that cylinder between ejection and filling, or systole and diastole (Systolic BP-Diastolic BP), would then be measured directly as pulse distention.

[0081] The larger the pulse distention value, the more arterial blood will be available to make oximetry, as well as heart rate and breath rate, measurements.

[0082] Breath distention is a measurement of the change in distention of the arterial blood vessel residing between the sensor pads due to breathing effort. For a given vascular compliance, the breath distention provides a surrogate for intrapleural pressure.

[0083] While two preferred embodiments have been set forth above, those skilled in the art who have reviewed the present disclosure will readily appreciate that other embodiments can be realized within the scope of the invention. For example, recitations of numerical values, specific technologies, and specific materials are illustrative rather than limiting. Therefore, the invention should be construed as limited only by the appended claims.

We claim:

1. An implantable pulse oximetry probe comprising:
an emitter for emitting light;
a detector for detecting the light; and
an attachment for attaching the emitter and the detector around a blood vessel such that the emitter and the detector are on opposite sides of the blood vessel.

2. The probe of claim **1**, wherein the emitter emits the light at at least two wavelengths.

3. The probe of claim **2**, wherein the at least two wavelengths are in the red and infrared ranges.

4. The probe of claim **1**, wherein the probe is configured such that the probe completely surrounds the blood vessel.

5. The probe of claim **4**, further comprising cushions for separating the emitter from the detector.

6. The probe of claim **4**, further comprising a covering around the emitter and the detector.

7. The probe of claim **6**, further comprising a hook attached to the cover for suturing the probe to tissue.

8. The probe of claim **1**, wherein the probe is configured such that the probe partially surrounds the blood vessel.

9. The probe of claim **8**, further comprising a tube to which the emitter and the detector are attached, the tube having an opening for allowing the tube to be clipped onto the blood vessel.

10. The probe of claim **1**, wherein the emitter and the detector are concave.

11. An implantable pulse oximetry probe comprising:
an emitter for emitting light;
a detector for detecting the light; and
an attachment for attaching the emitter and the detector within a lumen of a blood vessel.

12. The probe of claim **11**, wherein the emitter emits the light at at least two wavelengths.

13. The probe of claim **12**, wherein the at least two wavelengths are in the red and infrared ranges.

14. The probe of claim **11**, wherein the attachment is configured to attach the emitter and the detector within the lumen such that the emitter and the detector are coplanar.

15. The probe of claim **11**, wherein the attachment is configured to attach the emitter and the detector to a side of the blood vessel.

16. The probe of claim **15**, wherein the attachment is configured to attach the emitter and the detector to the side of the blood vessel such that the emitter emits the light out of the blood vessel into surrounding tissue and such that the detector detects the light from the surrounding tissue.

17. The probe of claim **15**, wherein the attachment comprises a sleeve for the emitter and the detector.

18. The probe of claim **17**, wherein the attachment further comprises a touch sensor for detecting that the probe is attached to the side of the blood vessel.

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专利名称(译)	可植入的实时血氧计用于确定潜在的中风和创伤后脑损伤的并发症		
公开(公告)号	US20150073240A1	公开(公告)日	2015-03-12
申请号	US14/395494	申请日	2013-03-14
[标]申请(专利权)人(译)	罗彻斯特大学		
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IPC分类号	A61B5/1459 A61B5/0205 A61B5/00 A61B5/1455		
CPC分类号	A61B5/6876 A61B5/6884 A61B5/6885 A61B5/0205 A61B5/1459 A61B5/14552 A61B5/02433 A61B2562/0238		
优先权	61/636299 2012-04-20 US		
其他公开文献	US10004438		
外部链接	Espacenet USPTO		

摘要(译)

血氧测定探针的第一实施方案附着在可能中风部位附近的血管周围。这将有助于监测大中型脑动脉。另一种类型的脉搏血氧计可以在脑血管内通过，以监测周围脑组织的氧合状态。在该版本中，发射器和检测器是共面的并且包含在小区域中，例如50-12μm。