(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 387 943 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
12.02.2014 Bulletin 2014/07

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***A61B 17/29*** *(2006.01)*

(21) Application number: **11250528.4**

(22) Date of filing: **16.05.2011**

(54) Optical sensors for intraoperative procedures

Optische Sensoren für intraoperative Verfahren

Capteurs optiques pour procédures peropératoires

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

(30) Priority: **17.05.2010 US 345414 P**
21.04.2011 US 201113091519

(43) Date of publication of application:
23.11.2011 Bulletin 2011/47

(73) Proprietor: **Covidien LP**
Mansfield, MA 02048 (US)

(72) Inventors:
- **Banerjee, Saumya**
  Hamden, CT 06514 (US)
- **Sargeant, Timothy**
  Guilford, CT 06437 (US)
- **Stopek, Joshua**
  Guilford
  CT 06437 (US)

(74) Representative: **Soames, Candida Jane et al**
Maschio & Soames LLP
20 Carlton Crescent
Southampton, SO15 2ET (GB)

(56) References cited:
US-A- 5 807 261 **US-A- 6 134 458**
US-A1- 2005 033 556 **US-A1- 2008 221 409**
US-A1- 2009 137 876 **US-A1- 2010 087 782**

EP 2 387 943 B1

Description

Technical Field

[0001] The present disclosure relates to devices and methods of using devices to monitor conditions within a body cavity, and more particularly to optical sensors and methods of using optical sensors during a surgical procedure to monitor the physical condition of the surgical site.

Background of Related Art

[0002] During or after a surgical procedure, the physical conditions of the surgical site might need to be monitored. The early detection of complications during or after a surgical procedure may facilitate a timely therapeutic response prior to the onset of irreversible damage. For example, the presence of certain particulates or contaminants may complicate a procedure. In addition, the lack of sufficient vascularization at the tissue site may disrupt adequate oxygen circulation to the tissue. A lack of oxygen circulation to the tissue may endanger the function and survival of tissue.

[0003] Various devices and methods to monitor the conditions of a surgical site have been employed. For example, a photopelythysmograph (PPG) is a device that optically measures the amount of blood in a part of the body. For example, the PPG measures the amount of light passing through a patient's finger by placing a light source on one side of the finger and a light sensitive resistor on the other side. By monitoring the variations in resistance of the light sensitive resistor, the PPG can optically capture the pulsation and oxygen saturation of the arterial blood flow.

[0004] The accuracy of the data collected, using such devices and methods, is limited by the configuration of the sensors used and the placement of the sensors in relation to the surgical site. Disturbances, including a patient's motion and ambient lighting, may distort the measurements collected by the sensors.

[0005] US2009/137876, US6134458, US5807261 and US2005/033556 disclose intra-operative sensor devices with features in common with the preamble of the independent claims.

SUMMARY

[0006] The present disclosure describes an optical sensor for intra-operative procedures and methods for using the optical sensor.

[0007] According to the invention there is an intra-operative sensor as recited in the independent claim.

[0008] In one aspect, an intra-operative sensor device for detecting tissue or body parameters includes a sensor including one or more light emitting sources and one or more photo-detectors, wherein an optical isolator ring is placed around either the one or more light emitting sources or the one or more photo-detectors.

[0009] The sensor may include light emitting sources and photo-detectors that are arranged in different configurations. In a first configuration, the one or more light emitting sources is placed within the optical isolator ring, and the one or more photo-detectors radially surround the optical isolator ring and the one or more light emitting sources that are placed within the optical isolator ring. In a second configuration, the one or more photo-detectors is placed within the optical isolator ring, and the one or more light emitting sources radially surround the optical isolator ring and the one or more photo-detectors that are placed within the optical isolator ring.

[0010] The intra-operative sensor device is operatively coupled to a member which is adapted and configured to transition between a furled state and an unfurled state. In one embodiment, the member is an inflatable sleeve and a hose may be operatively coupled to the inflatable sleeve to provide inflation fluid. In the unfurled state, the inflatable sleeve may be inserted into an incision and placed adjacent a tissue. By reducing the pressure in the inflatable sleeve, the inflatable sleeve will transition to the furled state and may be wrapped around the adjacent tissue.

[0011] These and other embodiments of the present disclosure will be described in greater detail with reference to the appended figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] By way of description only, embodiments of the disclosure will be described with reference to the accompanying drawings, in which:

Fig. 1 illustrates an intra-operative sensor including a first configuration of light sources and photo-detectors in accordance with an embodiment of the present disclosure;
Fig. 2 illustrates an intra-operative sensor including a second configuration of light sources and photo-detectors in accordance with another embodiment of the present disclosure;
Figure 2A illustrates another embodiment of the sensor arrangement of the present disclosure;
Fig. 3 is a top view of an intra-operative sensor device shown in a first state in accordance with an embodiment of the present disclosure; and
Fig. 3A is a side view of the intra-operative sensor device of Fig. 3 shown in a second state.

DETAILED DESCRIPTION

[0013] Particular embodiments of the present disclosure will be described herein with reference to the accompanying drawings. As shown in the drawings and as described throughout the following descriptions, and is traditional when referring to the relative positioning on an object, the term "proximal" refers to the end of the apparatus that is closer to the user and the term "distal" refers to the end of the apparatus that is further from the user. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail.

[0014] The intra-operative sensors described herein function by collecting reflected and/or backscattered light of varying wavelengths and processing the information collected to identify the physiological condition of the tissue being operated upon or the conditions within the body cavity, including, but not limited to, clearance and/or absorption of, for example, specific particulates, oxygen saturation, or contaminants. The intra-operative sensors can also identify leaks. The sensors could also identify lack of vascularization at the tissue site. For example, the application of the intra-operative sensors disclosed herein can range from checking for gastrointestinal leaks, where vascularization at the site of anastomosis is critical to healing, to checking oxygen saturation in burn victims to determine any compromise in the healing process.

[0015] Depending upon the particular application, an intra-operative sensor may include a particular configuration of photo-detectors and light emitting sources. A first and a second embodiment of an intra-operative sensor 10, 20 include different configurations of photo-detectors 6 and light emitting sources 4 and will now be described with reference to Figs. 1 and 2.

[0016] The first embodiment of an intra-operative sensor 10, as shown in Fig. 1, includes a photo-detector 6 around which multiple light emitting sources 4 are placed (more than one photo-detector could also be provided). The light emitting sources 4 may be placed radially around the one or more photo-detectors 6. In the embodiment shown, the light emitting sources 4 substantially encircle the photo detector(s) 6. In addition, the light emitting sources 4 may be spaced equidistantly apart from one another. Other spacings are also contemplated. The light emitting sources 4 may include, but are not limited to, light emitting diodes (LED's).

[0017] An optical isolator ring 2 may be placed around the one or more photo-detectors 6. In this manner, the ring 2 is between the detector(s) 6 and light emitting sources 4. The optical isolator ring 2 inhibits direct interference from light emitting sources or from ambient light, i.e., the ambient light of the operating room. By reducing the interference from light sources other than the light emitting sources 4, the accuracy of measurements collected by the photo-detectors 6 may be enhanced.

[0018] In a second embodiment of Fig. 2, intra-operative sensor 20 includes a configuration of photo-detectors 16 and light emitting sources 14, in which multiple photo-detectors 16 are placed radially around one or more light emitting sources 14. The photo-detectors 16 may be placed radially around the one or more light emitting sources 14. In the embodiment shown, the photo-detectors 16 substantially encircle the light emitting sources 14. In addition, the photo-detectors 16 may be placed equidistantly from one another, although other spacings are also contemplated. The placement of multiple photo-detectors 16 around light emitting sources 14 facilitates an accurate spot-check measurement of the tissue. An optical isolator ring 12 may be placed around the one or more light emitting sources 14. In this manner, ring 12 is between light emitting sources 14 and detector(s) 16, and as described above, this placement of the optical isolator ring 12 inhibits unwanted interference from light sources other than light emitting sources 14.

[0019] The light emitting sources 4, 14 may be matched to a particular wavelength and may also be modulated to allow for selective signal detection. Moreover, the intra-operative sensors may include a plurality of light emitting sources 4, 14, in which the light emitting sources are configured and adapted to radiate a plurality of wavelengths into a tissue site. The photo-detectors 6, 16 are configured to receive the light radiated by the light emitting sources after absorption of the light by the substance, e.g., tissue or blood, through which the light was radiated. In addition, the photo-detector 6, 16 may provide a constant feedback to provide information about the substance, such as a tissue or fluid through which the light from the light emitting source 4, 14 traveled.

[0020] The intra-operative sensors 10, 20 described herein function by collecting reflected and/or backscattered light of varying wavelengths. A processing unit interprets the data collected to identify the physiological condition of the tissue being operated upon or the conditions within the body cavity, including, but not limited to, clearance and/or absorption of, for example, specific particulates, oxygen saturation, or contaminants.

[0021] The intra-operative sensors 10, 20 can also identify leaks and lack of vascularization at the tissue site. For example, the application of the intra-operative sensors disclosed herein can include checking for gastrointestinal leaks, where vascularization at the site of anastomosis is critical to healing. It can also include checking oxygen saturation in burn victims to determine any compromise in the healing process.

[0022] In the Fig. 1 embodiment, the photo-detector is placed in the center with multiple light sources surrounding it. In this way, calculations of an average over a specific area are performed. That is, an average measurement of the tissue surface area covered by the light-emitting source is calculated. In the embodiment of Figure 2, with the light source in the center encircled by photo-detectors, detailed spot check measurements of tissue are provided.

[0023] Intra-operative sensors 10, 20 may be employed as stand alone instruments or may be operatively coupled to a surgical instrument, such as, device for open surgery or an arthroscopic or laparoscopic device, e.g., a grasper. In addition, the intra-operative sensors 10, 20 may be operatively coupled to any device that passes through small incisions or through a port placed within an incision during a minimally invasive surgical procedure.

[0024] In the alternate embodiment of Figure 2A, a flexible patch 50 has a mesh-like structure 56 which is made of an optical isolator that prevents contamination of the received signal from ambient or refracted light from adjacent emitters. As shown schematically, photo-detectors are designated by reference numeral 52 and light emitting sources are designated by reference numeral 54, separated by mesh 56. As with the other embodiments, this arrangement will display parameter such as oxygenation, CO/CO2 levels and/or contaminant presence. The intra operative sensor of Figure 2A can be used as a stand alone instrument or operatively coupled to a surgical instrument.

[0025] Examples of devices incorporating intra-operative sensors, e.g., intra-operative sensors 10, 20, will now be described with reference to Figs. 3-3A. The intra-operative sensor device 100 generally includes an inflatable sleeve 108 on which one or more light emitting sources 104 and one or more photo-detectors 106 are mounted. An optical isolator ring 102 may be placed around either the one or more light emitting sources 104 or the one or more photo-detectors 106, and in the illustrated embodiment of Fig. 3, the optical isolator ring 102 is placed around the photo detectors 106.

[0026] The inflatable sleeve 108 is configured and adapted to transition between a furled state (Fig. 3A) and an unfurled state (Fig. 3). To facilitate this transition, a hose or conduit 111 may be operably coupled to the inflatable sleeve 108 to provide inflation fluid. The inflatable sleeve 108 may have a generally rectangular shape and may be biased to transition to one of the furled and unfurled states in the absence of pressure provided to the inflatable sleeve 108 in the form of inflation fluid. For example, in the absence of inflation pressure, the inflatable sleeve 108 may transition to the furled, i.e., rolled, state (Fig. 3A). It is to be understood, that the inflatable sleeve 108 may define other geometric shapes or configurations. For example, inflatable sleeve 108 may have a triangular, diamond, circular, or non-symmetrical shape. One skilled in the art may envision other configurations for the inflatable sleeve 108. The sleeve 108 provides an increased surface area to enable provision of a larger number of sensors. It can also provide measurements over different areas of tissue due to its size (length/width) and can provide real time information on the tissue surface area. Providing plots of saturation or other parameters is also contemplated.

[0027] The intra-operative sensor device 100 may be wrapped around tissue. As the intra-operative sensor device 100 is inflated, it unrolls and extends to the unfurled state (Fig. 3). In the unfurled state, the intra-operative sensor device 100 may be placed adjacent a tissue. As the inflation pressure is lessened, the intra-operative sensor device 100 will transition back to the furled or rolled state, and will become wrapped around the tissue upon which the intra-operative sensor device 100 was placed. It is to be understood that the inflation of the inflatable sleeve 108 may be accomplished by using a gas or a liquid.

[0028] In other embodiments, instead of an inflatable sleeve 108, a flexible pad is utilized which contains the sensor which is configured and adapted to transition between furled and unfurled states through mechanical and/or electro-mechanical means. The pad can be rolled up and inserted through a cannula, then unrolled by a grasper. It can then be removed by pulling it back through a cannula with a grasper.

[0029] In one application, the sensor can be wrapped around anastomosed tissue to take a measurement of the entire staple line of the anastomosis.

[0030] It will be understood by those skilled in the art that various modifications and changes in form and detail may be made herein without departing from the scope of the claims.

Claims

1. An intra-operative sensor device (100) for detecting tissue or body parameters comprising a sensor including one or more light emitting sources (104) and one or more photo-detectors (106), wherein an optical isolator ring (102) is placed around either the one or more light emitting sources (104) or the one or more photo-detectors (106), said device being **characterized in that** it further comprises a member (108) in which the sensor is operatively mounted, the member movable between a furled state and an unfurled state.

2. The intra-operative sensor device of claim 1, wherein the one or more light emitting sources (104) is placed within the optical isolator ring (102), and the one or more photo-detectors (106) radially surround the optical isolator ring (102) and the one or more light emitting sources (104) that are placed within the optical isolator ring (102).

3. The intra-operative sensor device of claim 1, wherein the one or more photo-detectors (106) is placed within the optical isolator ring (102), and the one or more light emitting sources (104) surround the optical isolator ring (102) and the one or more photo-detectors (106) that are placed within the optical isolator ring (102).

4. The intra-operative sensor device of claim 1, wherein the member includes an inflatable sleeve (108), wherein injection of inflation fluid moves the member to the furled state.

5. The intra-operative sensor device of claim 4, wherein the member is biased to the furled state.

6. The intra-operative sensor device of claims 1, 4 or 5, wherein the member is adapted and configured to be wrapped around tissue.

Patentansprüche

1. Intraoperative Sensorvorrichtung (100) zum Erkennen von Gewebe- oder Körperparametern, umfassend einen Sensor, der eine oder mehrere Leuchtquellen (104) und einen oder mehrere Photodetektoren (106) umfasst, wobei ein Optokopplerring (102) entweder um die eine oder die mehreren Leuchtquellen (104) oder um den einen oder die mehreren Photodetektoren (106) herum angeordnet ist, wobei die Vorrichtung **dadurch gekennzeichnet ist, dass** sie ferner ein Element (108) umfasst, in das der Sensor betriebsfähig eingebaut ist, wobei das Element zwischen einem eingerollten Zustand und einem ausgerollten Zustand bewegbar ist.

2. Intraoperative Sensorvorrichtung nach Anspruch 1, wobei die eine oder die mehreren Leuchtquellen (104) in dem Optokopplerring (102) angeordnet ist bzw. sind, und der eine oder die mehreren Photodetektoren (106) radial den Optokopplerring (102) und die eine oder die mehreren Leuchtquellen (104), die in dem Optokopplerring (102) angeordnet ist bzw. sind, umgibt bzw. umgeben.

3. Intraoperative Sensorvorrichtung nach Anspruch 1, wobei der eine oder die mehreren Photodetektoren (106) in dem Optokopplerring (102) angeordnet ist bzw. sind, und die eine oder die mehreren Leuchtquellen (104) den Optokopplerring (102) und den einen oder die mehreren Photodetektoren (106), der bzw. die in dem Optokopplerring (102) angeordnet ist bzw. sind, umgibt bzw. umgeben.

4. Intraoperative Sensorvorrichtung nach Anspruch 1, wobei das Element eine aufblasbare Muffe (108) umfasst, wobei die Injektion von Aufblasfluid das Element in den eingerollten Zustand bewegt.

5. Intraoperative Sensorvorrichtung nach Anspruch 4, wobei das Element in den eingerollten Zustand vorgespannt ist.

6. Intraoperative Vorrichtung nach Anspruch 1, 4 oder 5, wobei das Element geeignet und konfiguriert ist, um um Gewebe herum gewickelt zu werden.

Revendications

1. Dispositif capteur peropératoire (100) pour détecter des paramètres tissulaires ou corporels, comprenant un capteur comportant une ou des sources électroluminescentes (104) et un ou des photodétecteurs (106), dans lequel un anneau isolateur optique (102) est placé autour de la ou des sources électroluminescentes (104) ou du un ou des photodétecteurs (106), ledit dispositif étant **caractérisé en ce qu'**il comprend en outre un élément (108) dans lequel le capteur est monté en service, l'élément étant mobile entre un état enroulé et un état déroulé.

2. Dispositif capteur peropératoire selon la revendication 1, dans lequel la ou les sources électroluminescentes (104) est ou sont placées dans l'anneau isolateur optique (102) et le ou les photodétecteurs (106) entoure(nt) radialement l'anneau isolateur optique (102) et la ou les sources électroluminescentes (104) qui est ou sont placées dans l'anneau isolateur optique (102).

3. Dispositif capteur peropératoire selon la revendication 1, dans lequel le ou les photodétecteurs (106) est ou sont placés dans l'anneau isolateur optique (102) et la ou les sources électroluminescentes (104) entoure(nt) l'anneau isolateur optique (102) et le ou les photodétecteurs (106) qui est ou sont placés dans l'anneau isolateur optique (102).

4. Dispositif capteur peropératoire selon la revendication 1, dans lequel l'élément comprend un manchon gonflable (108), dans lequel l'injection d'un fluide de gonflage déplace l'élément à l'état enroulé.

5. Dispositif capteur peropératoire selon la revendication 4, dans lequel l'élément est pressé à l'état enroulé.

6. Dispositif capteur peropératoire selon les revendications 1, 4 ou 5, dans lequel l'élément est adapté et configuré pour s'enrouler autour d'un tissu.

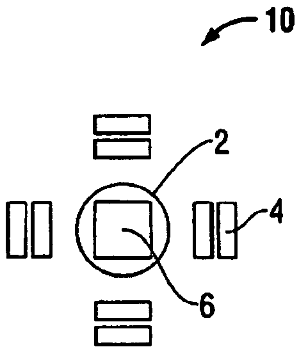

FIG. 1

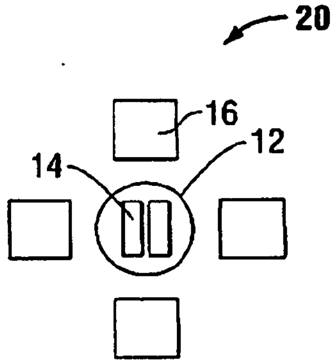

FIG. 2

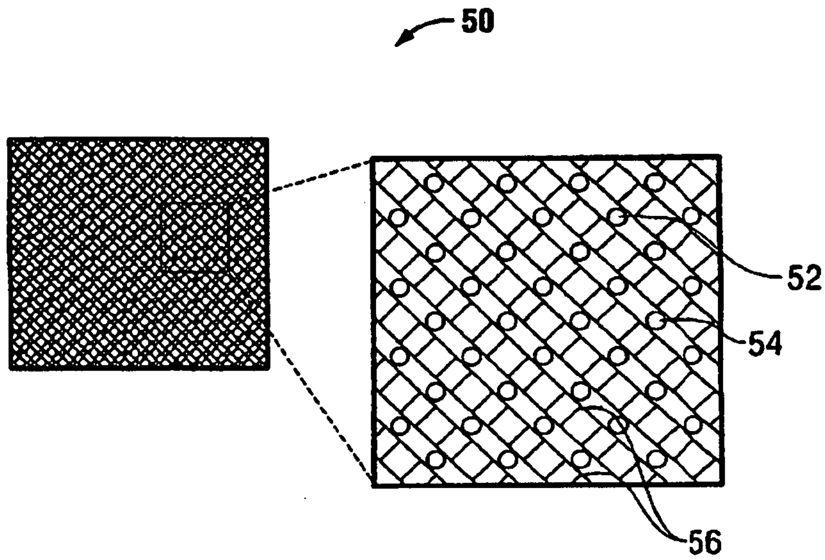

FIG. 2A

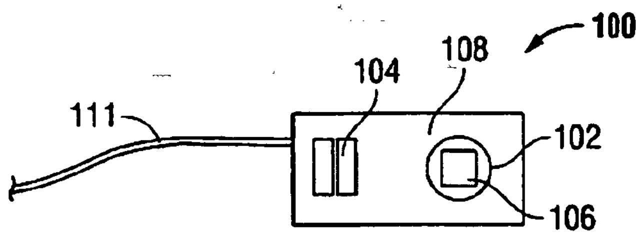

FIG. 3

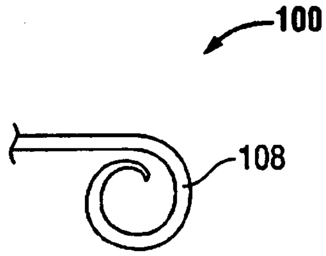

FIG. 3A

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 2009137876 A **[0005]**
- US 6134458 A **[0005]**
- US 5807261 A **[0005]**
- US 2005033556 A **[0005]**

专利名称(译)	用于术中手术的光学传感器		
公开(公告)号	[EP2387943B1](#)	公开(公告)日	2014-02-12
申请号	EP2011250528	申请日	2011-05-16
[标]申请(专利权)人(译)	柯惠有限合伙公司		
申请(专利权)人(译)	泰科医疗集团LP		
当前申请(专利权)人(译)	COVIDIEN LP		
[标]发明人	BANERJEE SAUMYA SARGEANT TIMOTHY STOPEK JOSHUA		
发明人	BANERJEE, SAUMYA SARGEANT, TIMOTHY STOPEK, JOSHUA		
IPC分类号	A61B5/00 A61B17/29		
CPC分类号	A61B5/0059 A61B5/0084 A61B5/14552 A61B5/6833 A61B5/6846 A61B5/6876 A61B5/6884 A61B17/07207 A61B17/1155 A61B17/29 A61B90/06 A61B2017/00057 A61B2017/00544 A61B2017/2927 A61B2090/309 A61B2562/164		
优先权	61/345414 2010-05-17 US 13/091519 2011-04-21 US		
其他公开文献	EP2387943A2 EP2387943A3		
外部链接	[Espacenet](#)		

摘要(译)

用于检测组织或身体参数的术中传感器装置包括一个或多个发光源和一个或多个光电检测器。光学隔离器环可以放置在一个或多个发光源周围或者围绕一个或多个光电检测器。术中传感器装置可以是独立装置或可以可操作地耦合到手术器械中，例如腹腔镜装置。

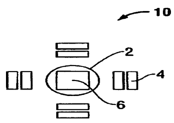

FIG. 1

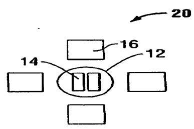

FIG. 2

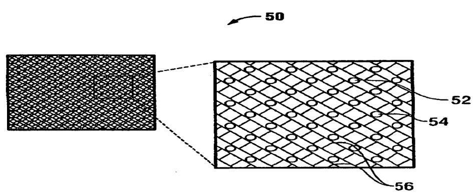

FIG. 2A