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(54) **TISSUE OXIMETRY PROBE WITH TISSUE MARKING FEATURE**

(71) Applicant: **VIOPTIX, INC.**, (US)

(72) Inventors: **Kate LeeAnn Bechtel**, Pleasant Hill, CA (US); **Joseph Anthony Heanue**, Oakland, CA (US); **Lester John Lloyd**, Orinda, CA (US)

(73) Assignee: **VIOPTIX, INC.**, Fremont, CA (US)

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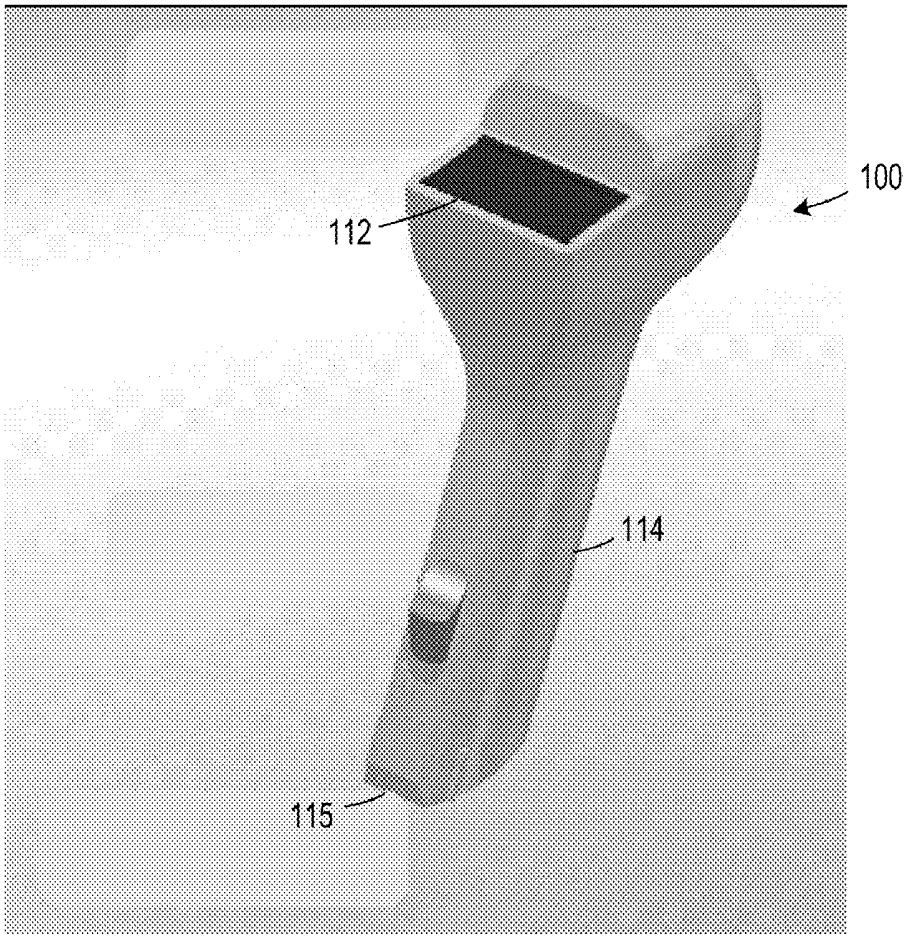
(57) **ABSTRACT**

An intraoperative tissue oximetry device includes a tissue marker that includes one or more pens or one or more similar ink sources, such that the tissue marker can mark tissue according to oxygen saturation measurements made by the tissue oximetry device, thereby visually delineating regions of potentially viable tissue from regions of potentially non-viable tissue.



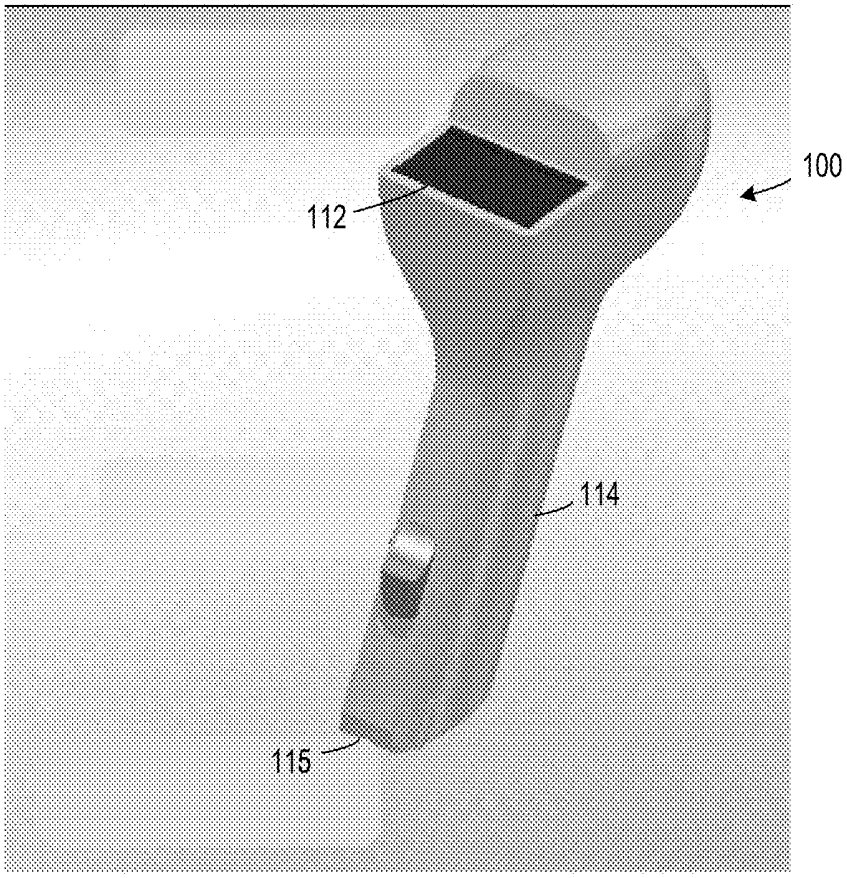


Figure 1A

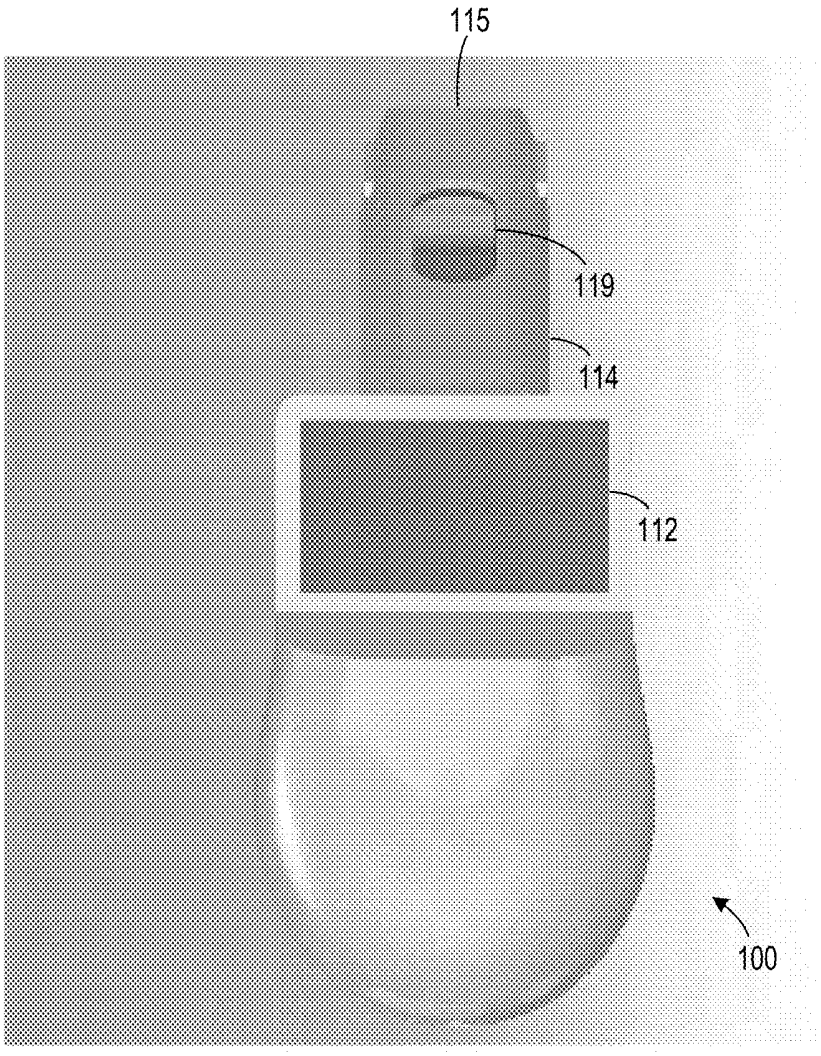


Figure 1B

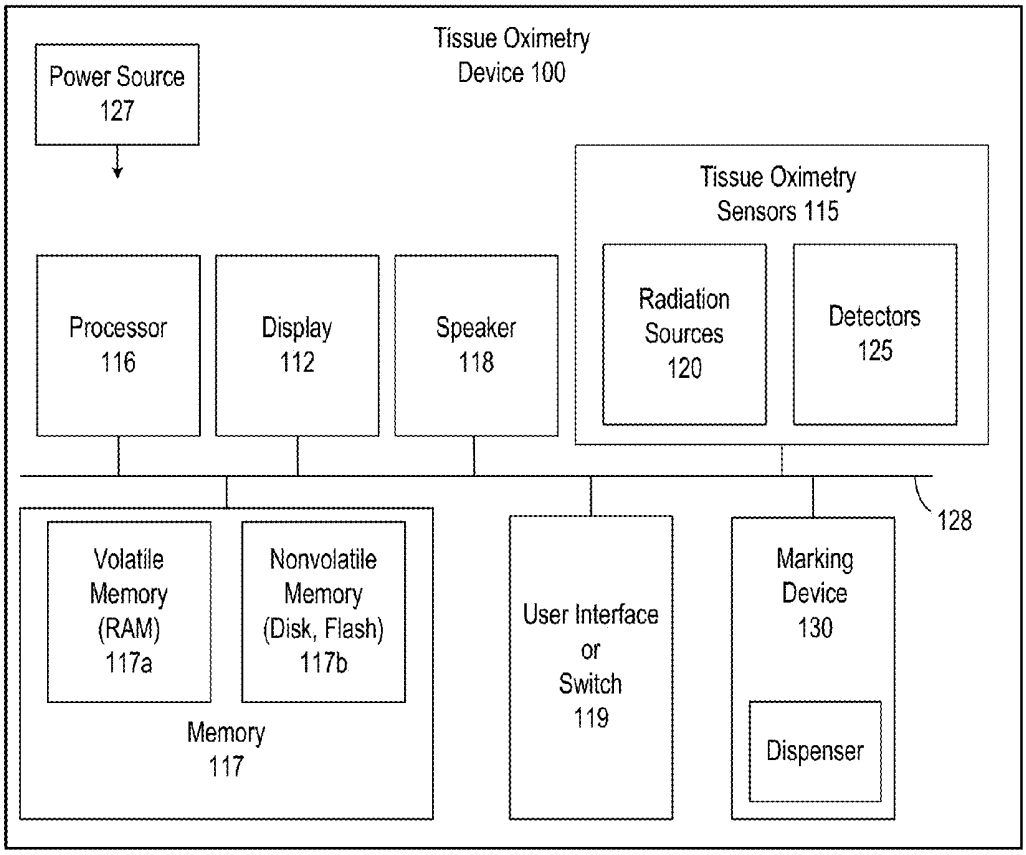

Tissue Oximetry
Device 100
Power Source
127
Tissue Oximetry
Sensors 115
Processor
116
Display
112
Speaker
118
Radiation
Sources
120
Detectors
125
128
Volatile
Memory
(RAM)
117a
Nonvolatile
Memory
(Disk, Flash)
117b
Memory
117
User Interface
or
Switch
119
Marking
Device
130
Dispenser

Figure 1C

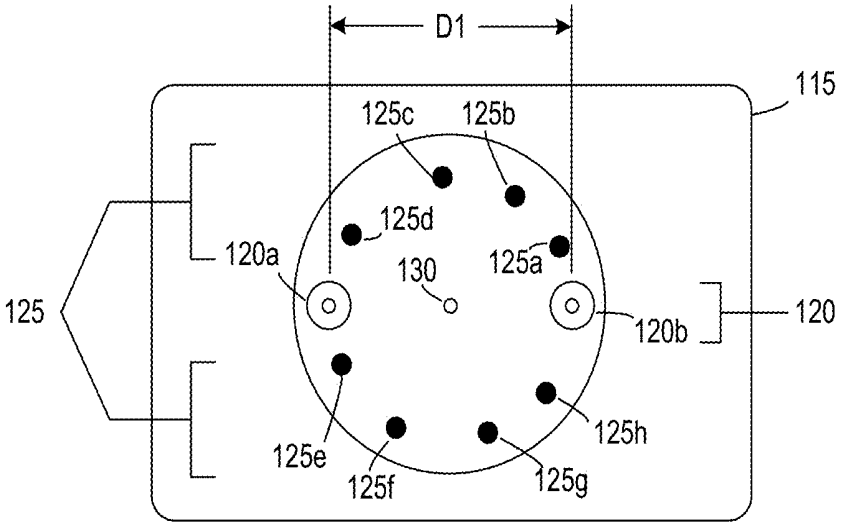


Figure 2A

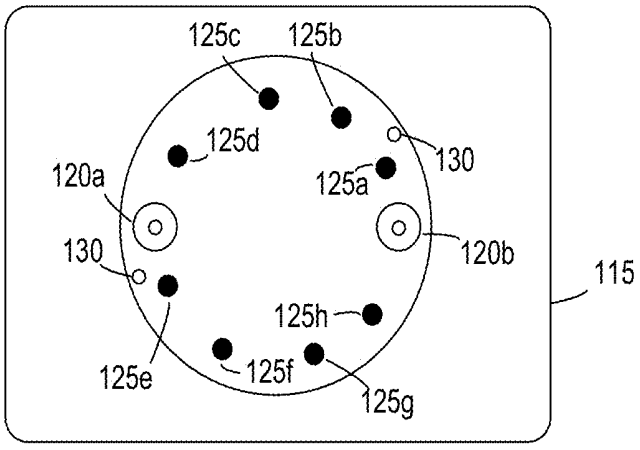


Figure 2B

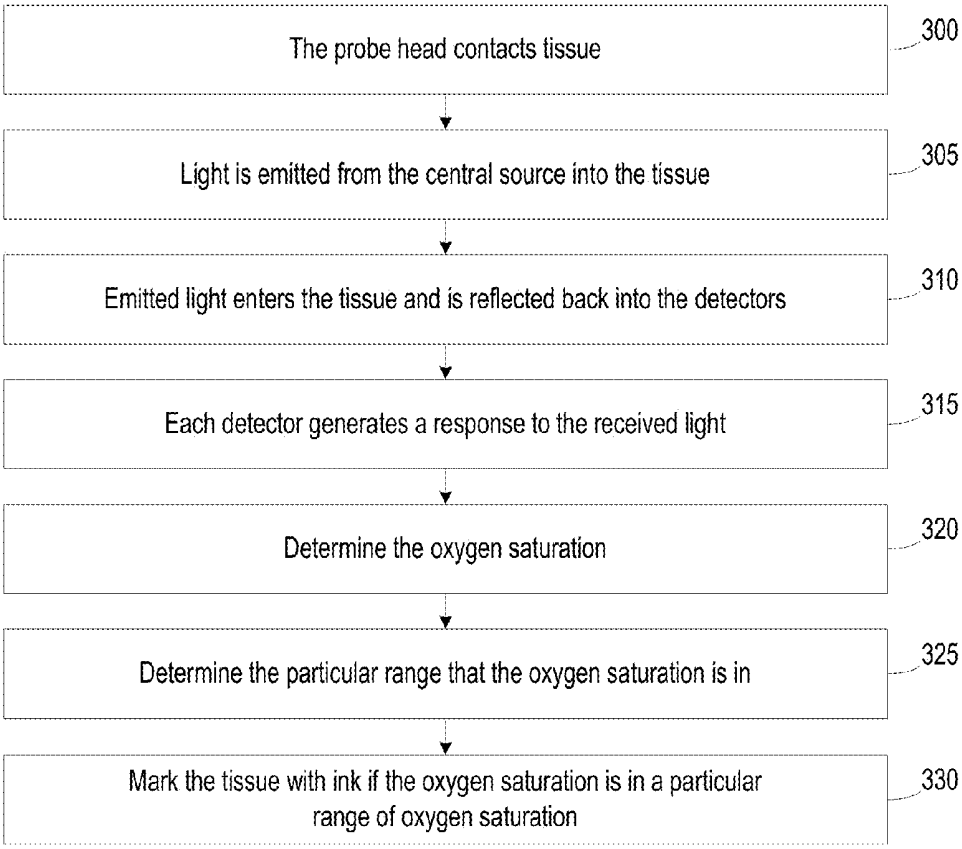

The probe head contacts tissue
300
Light is emitted from the central source into the tissue
305
Emitted light enters the tissue and is reflected back into the detectors
310
Each detector generates a response to the received light
315
Determine the oxygen saturation
320
Determine the particular range that the oxygen saturation is in
325
Mark the tissue with ink if the oxygen saturation is in a particular range of oxygen saturation
330

Figure 3

TISSUE OXIMETRY PROBE WITH TISSUE MARKING FEATURE

BACKGROUND OF THE INVENTION

[0001] This patent application claims the benefit of U.S. provisional patent applications 61/642,389, 61/642,393, 61/642,395, and 61/642,399, filed May 3, 2012, and 61/682,146, filed Aug. 10, 2012, which are incorporated by reference along with all other references cited in this application.

BACKGROUND OF THE INVENTION

[0002] The present invention relates generally to optical systems that monitor oxygen levels in tissue. More specifically, the present invention relates to an optical probe that includes light sources, detectors, and a marking apparatus for marking local tissue regions that are probed by the optical probe.

[0003] Oximeters are medical devices used to measure oxygen saturation of tissue in humans and living things for various purposes. For example, oximeters are used for medical and diagnostic purposes in hospitals and other medical facilities (e.g., surgery, patient monitoring, or ambulance or other mobile monitoring, such as for hypoxia); sports and athletics purposes at a sports arena (e.g., professional athlete monitoring); personal or at-home monitoring of individuals (e.g., general health monitoring, or personal training, such as for a marathon); and veterinary purposes (e.g., animal monitoring).

[0004] In particular, assessing a patient's oxygenation state is important as it is an indicator of the state of the patient's health. Thus, oximeters are often used in clinical settings, such as during surgery and recovery, where it may be suspected that the patient's tissue oxygenation state is unstable. For example, in reconstruction surgeries, it is desirable to distinguish between tissue that is viable and non-viable to save as much viable tissue as possible. Via the use of oximeters, physicians can attempt to distinguish between viable and non-viable tissue. However, physicians typically have to remember a map of viable tissue and non-viable tissue, which may slow down medical procedures.

[0005] Pulse oximeters and tissue oximeters are two types of oximeters that operate on different principles. A pulse oximeter requires a pulse in order to function. A pulse oximeter typically measures the absorbance of light due to pulsing arterial blood. In contrast, a tissue oximeter does not require a pulse in order to function, and can be used to make oxygen saturation measurements of a tissue flap that has been disconnected from a blood supply.

[0006] Human tissue, as an example, includes a variety of molecules that can interact with light via scattering or absorption (e.g., via light-absorbing chromophores). Such chromophores include oxygenated and deoxygenated hemoglobins, melanin, water, lipid, and cytochrome. Oxygenated and deoxygenated hemoglobins are the most dominant chromophores in the spectrum range of 600 nanometers to 900 nanometers. Light absorption differs significantly for oxygenated and deoxygenated hemoglobins at certain wavelengths of light. Tissue oximeters can measure oxygen levels in human tissue by exploiting these light-absorption differences.

[0007] Despite the success of existing oximeters, there is a continuing desire to improve oximeters by, for example, improving measurement accuracy; reducing measurement time; lowering cost; reducing size, weight, or form factor; reducing power consumption; and for other reasons, and any combination of these.

[0008] Therefore, there is a need for oximeters that have improved form factors and that relieve physicians and medical personal of having to remember of map of tissue scanned by an oximeter.

BRIEF SUMMARY OF THE INVENTION

[0009] An intraoperative tissue oximetry device includes a pen or pens or similar ink source (or sources) such that tissue can be marked according to oxygenation measurements made by the tissue oximetry device, thereby visually delineating regions of potentially viable tissue from regions of potentially nonviable tissue.

[0010] According to an embodiment, the device is a handheld, self-contained, oximeter device. The oximeter probe is contained within a single housing including all the components, so that it is self-contained. No external connections via wires or wireless connectivity are needed. The probe has a compact size and is relatively light weight so that it can be held easily by a person's hand. The probe can include a handle for a person's hand to grip, or fingers to grip.

[0011] The probe includes a plurality of light sources configured to generate and emit light into a portion of an extended tissue region, and a plurality of detectors having a circular arrangement and configured to detect the light subsequent to reflection from the portion and generate reflectance data based on detection of the light. The handheld, self-contained, oximeter further includes a processor configured to determine the oxygen saturation of the portion based on the reflectance data, and includes a tissue marker. The tissue marker includes a dispenser that is located at substantially a center of a circle of the circular arrangement where the dispenser is configured to deposit ink onto the portion to indicate that the probe has probed the portion.

[0012] According to a specific embodiment, the dispenser is configured to deposit ink based on one or more ranges of the oxygen saturation. The processor may be configured to determine whether the oxygen saturation is in the one or more ranges and control the dispenser to deposit the ink based on the one or more ranges that the oxygen saturation is in.

[0013] According to a specific embodiment, the dispenser is configured to deposit a plurality of colors of ink; the processor is configured to control the tissue marker to deposit the colors of ink based on ranges of the oxygen saturation; and the ranges of the oxygen saturation are respectively associated with the colors of the ink. The processor may be configured to control the tissue marker to deposit the ink onto the portion, or alternatively, a user selection device, such as a switch, is configured to be activated by a user to control the tissue marker to deposit the ink.

[0014] According to another embodiment, a handheld, self-contained, oximeter includes a probe that in-turn includes: (i) a plurality of light sources configured to generate and emit light into a portion of an extended tissue region, and (ii) a plurality of detectors that has a circular arrangement and is configured to detect the light subsequent to reflection from the portion and generate reflectance data based on detection of the light. The handheld, self-contained, oximeter further includes a processor configured to determine oxygen saturation of the portion based on the reflectance data. The handheld, self-contained, oximeter further includes a tissue marker having a plurality of dispensers. The dispensers are

located outside of a circle of the circular arrangement and are configured to deposit ink onto the portion to indicate that the portion has been probed by the probe.

[0015] According to one embodiment, a method of operation of a handheld, self-contained oximeter includes emitting light into tissue, detecting the light subsequent to reflection of the light from the tissue, and generating reflectance data based on detecting the light. The method further includes determining an oxygen saturation of the tissue based on the reflectance data, and determining a range of oxygen saturation from a plurality of ranges of oxygen saturation in which the oxygen saturation lies. The method includes marking the tissue with ink based on the range that the oxygen saturation is in.

[0016] Oximeter embodiments of the present invention are capable of accurately measuring oxygenation saturation of tissue and marking regions of the tissue to indicate their viability or nonviability. Relatively quickly and easily determining viability from the markings is useful for a plastic surgeon, for example, where in intraoperative situations the plastic surgeon must quickly make determinations to distinguish between tissue that can be used for reconstruction and tissue that should be removed.

[0017] With the incorporation of the tissue marker, the tissue oximetry device may be used to fully examine multiple regions of tissue for viability prior to the creation of further surgical incisions or the removal or reconstruction of tissue. The tissue marker of the present invention allows for relatively precisely marking regions of tissue based on their oxygen saturation readings thus alleviating physicians from having to recall exactly which tissue may be considered viable based on oxygenation measurements once the physician has set aside the tissue oximetry device or has moved the tissue oximetry device to other tissue regions.

[0018] In an implementation, an oximeter probe is contained within a single housing. The oximeter probe includes: a number of light or radiation sources, positioned on a probe face of the housing, configured to generate and emit light or radiation into a portion of an extended tissue region; a number of detectors, positioned on the probe face, wherein the detectors are positioned in a circular arrangement and configured to detect the light subsequent to reflection from the portion; a processor, connected to the light sources and detectors, configured to process reflectance data received from the detectors and determine oxygen saturation of the portion based on the reflectance data; a battery power source, contained within the housing and connected to the light sources, detectors, and processor; and a tissue marking component having a dispenser or inking tip or head, connected to the probe face, where the dispenser is located within the circular arrangement (e.g., inside the circle) and is configured to deposit ink onto the portion, thereby indicating that the portion has been evaluated by the probe.

[0019] In another implementation, a method of operating an oximeter probe includes: emitting light into tissue from radiation sources positioned on a probe face of the oximeter probe housing; detecting the light subsequent to reflection of the light from the tissue using from detectors sources positioned on a probe face of an oximeter probe housing; generating reflectance data based on detecting the light by way of a processor contained with the oximeter probe housing; using the processor (e.g., without needing to use an external processor), determining an oxygen saturation of the tissue based on the reflectance data; using the processor, determining a range of oxygen saturation from a plurality of ranges of oxygen saturation in which the oxygen saturation lies; and marking the tissue with ink (or other fluid) based on the range in which the oxygen saturation is in using ink (or other fluid) stored in a reservoir contained within the oximeter probe housing and a inking tip positioned on the probe face.

[0020] Other objects, features, and advantages of the present invention will become apparent upon consideration of the following detailed description and the accompanying drawings, in which like reference designations represent like features throughout the figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIGS. **1**A and **1**B show a simplified perspective view and a top view, respectively, of a tissue oximetry device according to one embodiment.

[0022] FIG. **1**C shows a block diagram of the tissue oximetry device.

[0023] FIG. **2**A shows a simplified end view of a tissue oximetry probe of the tissue oximetry device according to one embodiment where the ink dispenser is centered on the tissue oximetry probe.

[0024] FIG. **2**B shows a simplified end view of the tissue oximetry probe where first and second dispensers are located outside of a circle of detectors.

[0025] FIG. **3** shows a high-level flow diagram of a method for marking tissue to indicate ranges of oxygen saturation of the tissue.

DETAILED DESCRIPTION OF THE INVENTION

[0026] The present invention relates generally to a tissue oximetry device for measuring oxygen saturation in a local tissue volume. More specifically, the present invention relates to a wireless, handheld, tissue oximetry device that has self-contained optics (lights sources and detectors), computer processing, a display, a power-supply, and a tissue marker for marking tissue as the tissue is probed by the self-contained optics.

[0027] FIGS. **1**A and **1**B are a simplified perspective view and a top view, respectively, of a tissue oximetry device **100** according to one embodiment. The figures show an enclosure or housing of an oximeter probe device. Tissue oximetry device **100** is configured to make tissue oximetry measurements, such as intraoperatively and postoperatively.

[0028] In an implementation, the tissue oximetry device is handheld device and can make tissue oximetry measurements and display these measurements, without needing to connect to another external component either via a cable or wirelessly. The electronics to make measurements and calculations is contained entirely within the housing of the tissue oximetry device. The device may be a standalone handheld tissue oximetry device, without a cable or wireless connection.

[0029] Tissue oximetry device **100** may be a handheld device that includes a tissue oximetry probe **115** (also referred to as a sensor head), which may be positioned at an end of a sensing arm **114**. Tissue oximetry device **100** is configured to measure the oxygen saturation of tissue by emitting light, such as red and near-infrared light, from tissue oximetry probe **115** into tissue, and collecting light reflected from the tissue at the tissue oximetry probe.

[0030] Tissue oximetry device **100** may include a display **112** or other notification device (e.g., a speaker for audible notification) that notifies a user of oxygen saturation values

measured by the tissue oximetry device. While tissue oximetry probe **115** is described as being configured for use with tissue oximetry device **100**, which is a handheld device, tissue oximetry probe **115** may be used with other tissue oximetry devices, such as a modular tissue oximetry device where the tissue oximetry probe is at the end of a cable device that couples to a base unit. The cable device might be a disposable device that is configured for use with a single patient and the base unit might be a device that is configured for repeated use. Such modular tissue oximetry devices are well understood by those of skill in the art and are not described further.

[0031] Tissue oximetry device **100** does not require a pulsing blood flow to make an oxygen saturation measurement as compared with pulse oximeters that require a pulsing blood flow to make such measurements. While the description of the example embodiments is directed toward tissue oximetry probes that do not require a pulsing blood flow for oxygen saturation measurements, embodiments of the present invention are not so limited and may be utilized with pulse oximeters.

[0032] FIG. **1**C is a block diagram that shows tissue oximetry device **100** in further detail according to one embodiment. The components of device **100** are contained in a single enclosure or housing. Tissue oximetry device **100** may include display **112**, a processor **116**, a memory **117**, a speaker **118** (described briefly above), one or more input devices **119** (e.g., one or more switches, input buttons, keypad, display **112**, if for example, the display is a touch screen, or the like), a set of light sources **120**, a set of detectors **125**, a power source **127**, and a tissue marker **130**. Processor **116** may be a microcontroller, a microprocessor, control logic, a multicore processor, or the like, and may control the operation of light sources **120** and detectors **125**. Processor **116** may also control the operation of tissue marker **130**. Memory **117** may include a variety of memories, such as a volatile memory **117***a* (e.g., a RAM), a nonvolatile memory **117** (e.g., a disk, Flash, PROM, or others), or both. User input may be by way of the input devices **119** (e.g., switches, touchpad, or the like).

[0033] Power source **127** can be a battery, such as a disposable battery. Disposable batteries are discarded after their stored charge is expended. Some disposable battery chemistry technologies include alkaline, zinc carbon, or silver oxide. The battery has sufficient stored charged to allow use of the tissue oximetry device for several hours. After use, the tissue oximetry device is discarded.

[0034] In other implementations, the battery can also be rechargeable where the battery can be recharged multiple times after the stored charge is expended. Some rechargeable battery chemistry technologies include nickel cadmium (NiCd), nickel metal hydride (NiMH), lithium ion (Li-ion), and zinc air. The battery can be recharged, for example, via an AC adapter with cord that connects to the handheld unit. The circuitry in the tissue oximetry device can include a recharger circuit (not shown). Batteries with rechargeable battery chemistry may be sometimes used as disposable batteries, where the batteries are not recharged but disposed of after use.

[0035] Aspects of the invention may include software executable code or firmware (e.g., code stored in a read only memory or ROM chip). The software executable code or firmware may embody algorithms used in making oxygen saturation measurements of the tissue. The software executable code or firmware may include code to implement a user interface by which a user uses the system, displays results on the display, and selects or specifies parameters that affect the operation of the system.

[0036] The components may be linked together via a bus **128**, which may be the system bus architecture of tissue oximetry device **100**. Although this figure shows one bus that connects to each component, the busing is illustrative of any interconnection scheme serving to link these components or other components included in tissue oximetry device **100**. For example, speaker **118**, according to one specific implementation, could be connected to a subsystem through a port or have an internal direct connection to processor **116**.

[0037] The foregoing listed components may be housed in a mobile housing (see FIG. **1**A) of tissue oximetry device **100**. However, different implementations of tissue oximetry device **100** may include alternative housing (such as the cables and the base units of modular oximeters described briefly above) and may include any number of the listed components, in any combination or configuration, and may also include other components not shown.

Tissue Oximetry Probe

[0038] FIG. **2**A is a simplified end view of tissue oximetry probe **115** according to one embodiment. Tissue oximetry probe **115** is configured to contact tissue (e.g., a patient's skin) for which a tissue oximetry measurement is to be made. Tissue oximetry probe **115** includes the set of light sources **120** and the set of detectors **125**. The set of light sources **120** may include two or more light sources, such as light sources **120***a* and **120***b*.

[0039] Light sources **120** may be linearly positioned across tissue oximetry probe **115** and detectors **125** may be arranged in an arc or a circle (i.e., circular arrangement) on the tissue oximetry probe. More specifically, light sources **120** may be arranged linearly, such as on a line (e.g., a diameter) that bisects a circle on which detectors **125** may be arranged. The light sources **120***a* and **120***b* are spaced a distance D1 apart where D1 may range from about 3 millimeters to about 10 millimeters. That is, the circle on which detectors **125** are arranged may have a diameter of about 3 millimeters to about 10 millimeters (e.g., 4 millimeters according to one specific embodiment). While detectors **125** are described as being arranged in an arc or circle, tissue oximetry device **100** may have other configurations of detectors, such as linear, square, rectangular, ovoid, pseudo-random, or others.

[0040] Propagation depth increases with increasing source-to-detector distance, with 4-5 millimeters generally being a sufficient upper limit between light sources **120***a* and detectors **125** to ensure few detected photons propagated in lower tissue layers. For example, these distances between light sources **120** and detectors **125** limits reflectance data to light that propagated within the top layer of tissue where little or no underlying subcutaneous fat or muscular layers contributes to the reflectance data.

[0041] The set of detectors **125** may include four or more detectors. According to a specific embodiment, the set of detectors **125** includes eight detectors **125***a*, **125***b*, **125***c*, **125***d*, **125***e*, **125***f*, **125***g*, and **125***h* as shown. Detectors **125** are solid-state detectors and may be mounted to a PCB (not shown). Further, detectors **125** may be combined devices or discrete devices.

[0042] In a specific implementation, detectors **125** are positioned with respect to outer light sources **120***a* and **120***c* such that four or more (e.g., fourteen) unique source-to-detector

distances are created. With greater numbers of source-to-detector distances, this can be used to obtain greater accuracy, faster calibration, and redundancy (when duplicate source-to-detector distances are provided). At least two source-to-detectors distances are 1.5 millimeters or closer, and at least two more two source-to-detectors distances are 2.5 millimeters or farther.

[0043] In other words, a first source-to-detector distance is about 1.5 millimeters or less. A second source-to-detector distance is about 1.5 millimeters or less. A third source-to-detector distance is about 2.5 millimeters or greater. A fourth source-to-detector distance is about 2.5 millimeters or greater. There can be various numbers of sources and detector arrangements to obtain these four source-to-detector distances, such as one source and four detectors, two sources and two detectors, one detector and four sources, or other arrangements and combinations.

[0044] For example, an implementation includes at least two sources and at least two detectors, where a maximum distance between a source and a detector is about 4 millimeters (or about 5 millimeters). At least two source-to-detector are about 2.5 millimeters or greater. At least two source-to-detector distances are about 1.5 millimeters or less.

[0045] When a greater number of sources and detectors are used, greater numbers of source-to-detector distances are available. As discussed, these can be used to provide greater accuracy, faster calibration, or redundancy, or a combination. The arrangement of the sources and detectors can be in circular pattern, such as at points along the arc of a circle with radius (e.g., 4 millimeters, or 5 millimeters). In an implementation, a tolerance of the detector or source positions on the arc is within 10 microns of the arc curve. In other implementations, the tolerance is within about 0.25 millimeters.

Tissue Marking

[0046] Turning now to tissue marker **130**, tissue oximetry probe **115** includes at least a dispenser portion of tissue marker **130**. FIG. **2** shows an end view of the dispenser that can dispense a marking material on a local tissue region (e.g., of an extended portion of tissue) that has been probed by tissue oximetry device **100**. The location of the marking material on tissue allows a user to subsequently identify the particular, local tissue region that has been probed.

[0047] The dispenser may be located at a variety positions on the face of tissue oximetry probe **115**. According to one specific embodiment, the dispenser is located between light sources **120***a* and **120***b*, and may be located at the approximate center of the circular arrangement of detectors **125**. With the dispenser at the approximate center of light sources **120** and detectors **125**, a mark made by the dispenser will be substantially at a center of the local tissue region that has been probed by tissue oximetry device **100**. With the mark at the center of the probed tissue region, the mark is not displaced from the location on the local tissue region probed.

[0048] According to one implementation, tissue marker **130** includes one or more dispensers that may be located at different positions on the head of tissue oximetry probe **115**. FIG. **2**B shows an embodiment where two dispensers are located "outside" of light sources **120** and detectors **125**. That is, the dispensers are located at the ends of radii that are longer than the radii of light sources **120** and detectors **125**. Further, the dispensers may lie on a line that passes through the center of the circle of the circular arrangement of dispensers **125**. With the dispensers located along such a line, marks made by these dispensers allow a user to readily identify the region between the marks as the local tissue region that has been probed by tissue oximetry device **100**.

[0049] While the dispensers shown in FIGS. **2**A and **2**B are shown as relatively localized devices (e.g., pen, pens, inker, inkers, and the like) that may be configured to mark tissue with relatively small marks (e.g., dots), a dispenser may be an extended device configured to make an extended mark, such as a line. For example, a dispenser may be an extended device configured to mark tissue with a circle or other closed shape, or may mark tissue with an open shape, such as a u-shape, a v-shape, or others.

[0050] The dispenser may be fixed within tissue oximetry probe **115** or may be configured to be lowered when tissue is marked. Various mechanical or electromechanical devices may be utilized by tissue oximetry probe **115** for lowering the dispenser. Such mechanical and electro-mechanical devices are well understood by those of skill in the art and are not described in detail herein.

[0051] Tissue marker **130** may mark tissue with a variety inks having a variety of colors, such as gentian violet, which is the tissue marking ink approved by the FDA. Variations in the gentian violet chemistry constituents can give different characteristics to the ink and cause changes in color or shade. Any of these colors or shades of gentian violet may be utilized by tissue marker **130**.

[0052] One or more of the ink colors utilized by tissue oximetry device **100** may indicate one or more oxygen saturation ranges. For example, tissue marker **130** might be configured to: (i) mark tissue with a first color of ink if the tissue's oxygen saturation is at or below a first threshold, (ii) mark the tissue with a second color of ink if the tissue's oxygen saturation is above the first threshold and at or below a second threshold, and (iii) mark the tissue with a third color of ink if the tissue's oxygen saturation is above the second threshold. The foregoing example describes the use of three colors of ink for marking tissue for visually identifying three ranges of oxygen saturation, however more or fewer colors may be utilized by tissue marker **130** for identifying more or fewer oxygen saturation ranges.

[0053] Processor **116** may determine the oxygen saturation of a local tissue region based on an analysis of the reflection data that has been generated by detectors **125**, and may control tissue marker **130** to mark the local tissue region with a select color of ink that identifies the range that the oxygen saturation is within. Tissue marker **130** may include a variety of devices that provide marking material having one or more colors, such as ink reservoirs, pens, or the like. U.S. patent application Ser. No. 12/178,359, filed Jul. 23, 2008, of Heaton, titled "Oximeter with Marking Feature", which is incorporated by reference in its entirety, describes a variety of devices that are configured for marking tissue with one or more colors of marking material.

[0054] A reservoir of the marking device can be connected to the dispenser, such as through tubing or channels, and is contains ink or other fluid (e.g., ink) dispensed through the dispenser. Ink can be urged from the reservoir to and through the dispenser and deposited on skin through pressure or low-frequency sound (such using a piezoelectric transducer). The reservoir is contained within the same housing as the processor, battery, sources, detectors, and other components of the oximeter probe. For the disposable probe, the reservoir is not refillable.

[0055] According to one alternative, tissue marker **130**, under control of processor **116**, marks tissue for one or more oxygen saturation ranges, but does not mark the tissue for one or more other oxygen saturation regions. For example, tissue marker **130** might mark a local tissue region if the oxygen saturation of the local tissue region is at or below a threshold level, or alternatively might not mark the local tissue region if the oxygen saturation level is above the threshold level. Markings that are made on tissue according to the above method allow a user to relatively quickly identify tissue that might have a low chance of viability if the threshold level is relatively low. Alternatively, tissue marker **130** might mark a local tissue region if the oxygen saturation of the local tissue region is at or above a threshold level, and might not mark the local tissue region if the oxygen saturation level is below the threshold level. Marks made from this method allow a user to relatively quickly identify tissue that might have a relatively high chance of viability if the threshold level is relatively high.

[0056] Information for the foregoing described threshold levels (i.e., ranges) may be stored in memory **117** and accessed by processor **116** for use. The threshold levels may be stored in memory **117** during manufacture of tissue oximetry device **100**, or may be stored in the memory thereafter. For example, tissue oximetry device **100** may be configured to receive a user input for one or more user defined threshold levels and store information for these threshold levels in memory **117**. One or more input devices **119** (or the like) may be configured to receive a user input for a user defined threshold level and for storing the user defined threshold level in memory **117**.

[0057] FIG. **3** is a high-level flow diagram of a method for marking tissue to indicate ranges of oxygen saturation of the tissue. The high-level flow diagram represents one example embodiment. Steps may be added to, removed from, or combined in the high-level flow diagram without deviating from the scope of the embodiment.

[0058] At **300**, tissue oximetry probe **115** contacts the tissue. Light (e.g., near-infrared light) is emitted from one or more of the light sources **120**, step **305**, into the tissue and at least some of the light is reflected back by the tissue. Each detector **125** receives a portion of the light reflected from the tissue, step **310**, and each detector generates reflectance data (i.e., a response) for the portion of reflected light received, step **315**. At **320**, processor **305** determines an oxygen saturation value for the tissue based on the reflectance data. At **325**, processor **116** determines a range of oxygen saturation from a plurality of ranges of oxygen saturation in which the oxygen saturation lies. At **330**, processor **116** controls tissue marker **130** to mark the tissue with ink based on a range in which the oxygen saturation is in. For example, the processor may be configured to control the dispenser to mark the tissue with ink if the oxygen saturation is in a first range of oxygen saturation, but not mark the tissue if the oxygen saturation in a second range of oxygen saturation where the first range and second range are different, such as not overlapping ranges. While the foregoing example embodiment, discusses the utilization of two ranges of oxygen saturation by the tissue oximetry device, the tissue oximetry device may utilize more than two ranges of oxygen saturation for determining whether to mark the tissue with ink.

[0059] According to one embodiment, the processor may control the dispenser to mark the tissue with a specific color of ink based on the range of oxygen saturation that the oxygen saturation is in. The particular color of ink allows a user to relatively quickly determine the ranges of oxygen saturation for the tissue without the need for re-probing the tissue or looking at a chart of the tissue that includes oxygen saturation values and matching the chart to the tissue.

[0060] Tissue oximetry device **100** may be configured to allow a user to manually control the tissue oximetry device to mark tissue, allow processor **116** to control marking the tissue, or both. For example, one of input devices **119** may be configured to control tissue marker **130** to mark a local tissue region if a user activates the input device. The input device may be conveniently located for a user to operate tissue oximetry device **100** to make an oxygen saturation measurement, and operate the input device without moving tissue oximetry probe **115** from the local tissue region that was probed.

[0061] Tissue oximetry device **100** may be switched between the processor controlled method of marking tissue and the manually controlled method (e.g., activating one of the switches) of marking tissue. One or more other of input devices **119** may be configured for switching tissue oximetry device **100** between these two methods of marking tissue.

[0062] This description of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form described, and many modifications and variations are possible in light of the teaching above. The embodiments were chosen and described in order to best explain the principles of the invention and its practical applications. This description will enable others skilled in the art to best utilize and practice the invention in various embodiments and with various modifications as are suited to a particular use. The scope of the invention is defined by the following claims.

The invention claimed is:

1. A device comprising:

an oximeter probe contained within a single housing comprising:

a plurality of light sources, coupled to a probe face of the housing, configured to generate and emit light into a portion of an extended tissue region;

a plurality of detectors, coupled to the probe face, wherein the detectors are positioned in a circular arrangement and configured to detect the light subsequent to reflection from the portion;

a processor, coupled to the light sources and detectors, configured to process reflectance data received from the detectors and determine oxygen saturation of the portion based on the reflectance data;

a battery power source, contained within the housing and coupled to the light sources, detectors, and processor; and

a tissue marking component having a dispenser, coupled to the probe face, wherein the dispenser is located within the circular arrangement and is configured to deposit ink onto the portion, thereby indicating that the portion has been evaluated by the probe.

2. The device of claim **1** comprising a notification device configured to provide a notification of the oxygen saturation.

3. The device of claim **1** wherein the dispenser is configured to deposit ink based on one or more ranges of the oxygen saturation.

4. The device of claim **3** wherein the processor is configured to determine whether the oxygen saturation is in the one

or more ranges and control the dispenser to deposit the ink based on the one or more ranges that the oxygen saturation is in.

5. The device of claim **1** wherein the dispenser is configured to deposit a plurality of colors of ink,

the processor is configured to control the tissue marker to deposit the colors of ink based on ranges of the oxygen saturation, and

the ranges of the oxygen saturation are respectively associated with the colors of the ink.

6. The device of claim **5** wherein the ranges of the oxygen saturation are user programmable.

7. The device of claim **1** wherein the processor is configured to control the tissue marker to deposit the ink onto the portion.

8. The device of claim **7** comprising:

a user selection device configured to be activated by a user, wherein the user selection device is configured to enable and disable the processor for controlling the tissue marker for depositing the ink.

9. The device of claim **1** comprising:

a user selection device configured to be activated by a user, wherein activation of the user selection device controls the tissue marker to deposit the ink onto the portion.

10. The device of claim **1** comprising:

a user selection device configured to initiate movement of the dispenser from a first position to a second position in the probe, wherein in the second position the dispenser is configured to deposit the ink onto the portion.

11. The device of claim **10** wherein the processor is configured to initiate movement of the dispenser from the first position to the second position subsequent to an oxygen saturation measurement.

12. A device comprising:

an oximeter probe contained within a single housing comprising:

a plurality of light sources configured to generate and emit light into a portion of an extended tissue region;

a plurality of detectors having a circular arrangement and configured to detect the light subsequent to reflection from the portion and generate reflectance data based on detection of the light;

a processor configured to determine oxygen saturation of the portion based on the reflectance data; and

a tissue marker having a plurality of dispensers, wherein the dispensers are located outside of a circle of the circular arrangement and are configured to deposit ink onto the portion to indicate that the portion has been probed by the probe.

13. The device of claim **12** wherein the dispensers are configured to deposit ink based on one or more ranges of the oxygen saturation.

14. The device of claim **13** wherein the processor is configured to determine whether the oxygen saturation is in the one or more ranges and control the dispensers to deposit the ink based on the one or more ranges that the oxygen saturation is in.

15. The device of claim **12** comprising a notification device configured to provide a notification of the oxygen saturation.

16. The device of claim **12** wherein the dispenser is configured to deposit a plurality of colors of ink,

the processor is configured to control the tissue marker to deposit the colors of ink based on ranges of the oxygen saturation, and

the ranges of the oxygen saturation are respectively associated with the colors of the ink.

17. The device of claim **12** wherein the ranges of the oxygen saturation are user programmable.

18. The device of claim **12** further comprising a memory configured to store information for the ranges.

19. The device of claim **12** wherein the processor is configured to control the tissue marker to deposit the ink onto the portion.

20. The device of claim **19** comprising a user selection device configured to be activated by a user, wherein the user selection device is configured to enable and disable the processor for controlling the tissue marker for depositing the ink.

21. The device of claim **12** comprising a user selection device configured to be activated by a user, wherein activation of the user selection device controls the tissue marker to deposit the ink onto the portion.

22. The device of claim **12** comprising a user selection device configured to initiate movement of the dispenser from a first position to a second position in the probe, wherein in the second position the dispenser is configured to deposit the ink onto the portion.

23. The device of claim **22** wherein the processor is configured to initiate movement of the dispenser from the first position to the second position subsequent to an oxygen saturation measurement.

24. A method of operating an oximeter probe comprising:

emitting light into tissue from radiation sources positioned on a probe face of the oximeter probe housing;

detecting the light subsequent to reflection of the light from the tissue using from detectors sources positioned on a probe face of the oximeter probe housing;

generating reflectance data based on detecting the light by way of a processor contained with the oximeter probe housing;

using the processor, determining an oxygen saturation of the tissue based on the reflectance data;

using the processor, determining a range of oxygen saturation from a plurality of ranges of oxygen saturation in which the oxygen saturation lies; and

marking the tissue with ink based on the range in which the oxygen saturation is in using ink stored in a reservoir contained within the oximeter probe housing and a inking tip positioned on the probe face.

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摘要(译)

术中组织血氧测量装置包括组织标记，其包括一个或多个笔或一个或多个类似的墨源，使得组织标记可以根据组织血氧测定装置进行的氧饱和度测量来标记组织，从而在视觉上描绘可能存活的区域。来自潜在无活力组织区域的组织。