



US008073517B1

(12) **United States Patent**
Burchman

(10) **Patent No.:** **US 8,073,517 B1**
(45) **Date of Patent:** ***Dec. 6, 2011**

(54) **SYSTEM AND METHOD FOR MEASURING
BLOOD CONSTITUENTS USING A
CATHETER**

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(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-
claimer.

(21) Appl. No.: **12/791,843**

(22) Filed: **Jun. 1, 2010**

Related U.S. Application Data

(63) Continuation-in-part of application No. 11/565,321,
filed on Nov. 30, 2006, now Pat. No. 7,729,735.

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

(52) **U.S. Cl.** **600/341**

(58) **Field of Classification Search** 600/339
See application file for complete search history.

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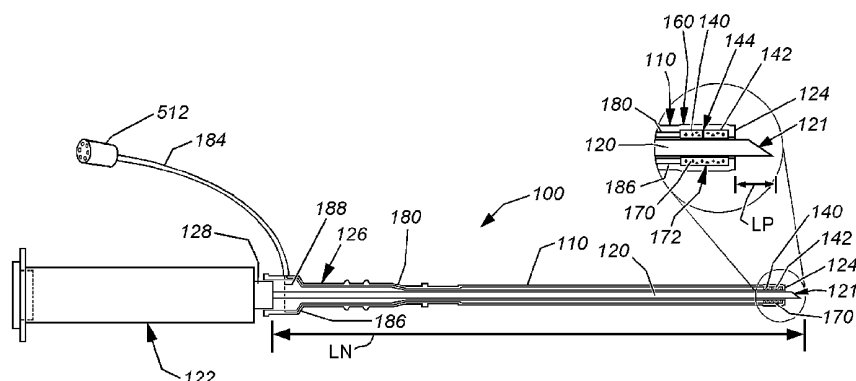
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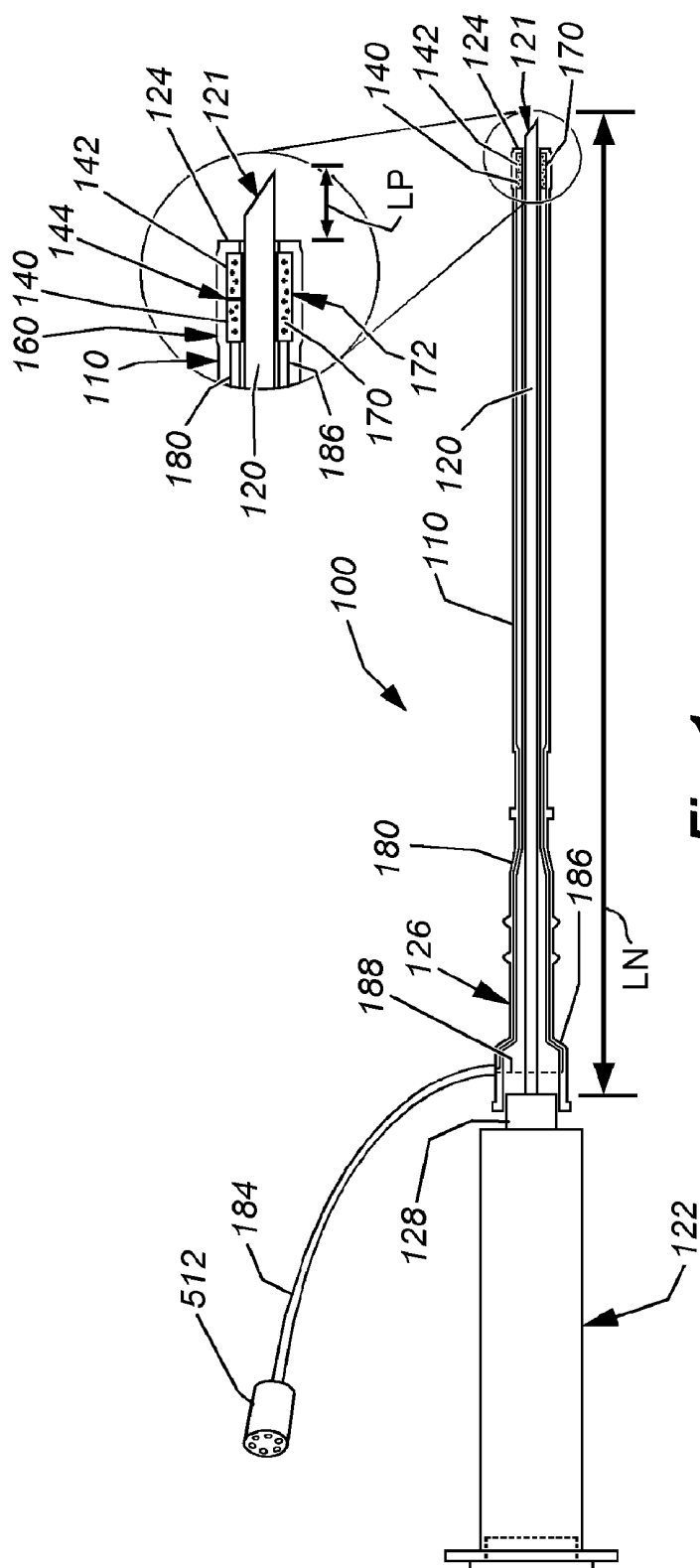
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(57) **ABSTRACT**

A system and method for confirming the proper placement of
a penetrating catheter into a venous region using principles of
oximetry in which blood is subjected to light of a plurality of
wavelengths and detected for absorption levels. The result is
analyzed by a processor and the level oxygen saturation of the
blood is indicated. The characteristic level of saturation
informs the practitioner whether oxygenated arterial blood is
present due to an inadvertent puncture. The catheter is intro-
duced using an introduction needle and thereafter removed to
allow blood to communicate with sensing elements that con-
sist of a light-emitter and opposed photodetector. Light in the
infrared and visible red wavelengths can be provided by sepa-
rate LED units. Aspiration of blood through the catheter by an
attached syringe allows the processor to compute the level of
oxygen saturation or other blood constituent, based upon
detected light absorption of passing blood.

30 Claims, 10 Drawing Sheets





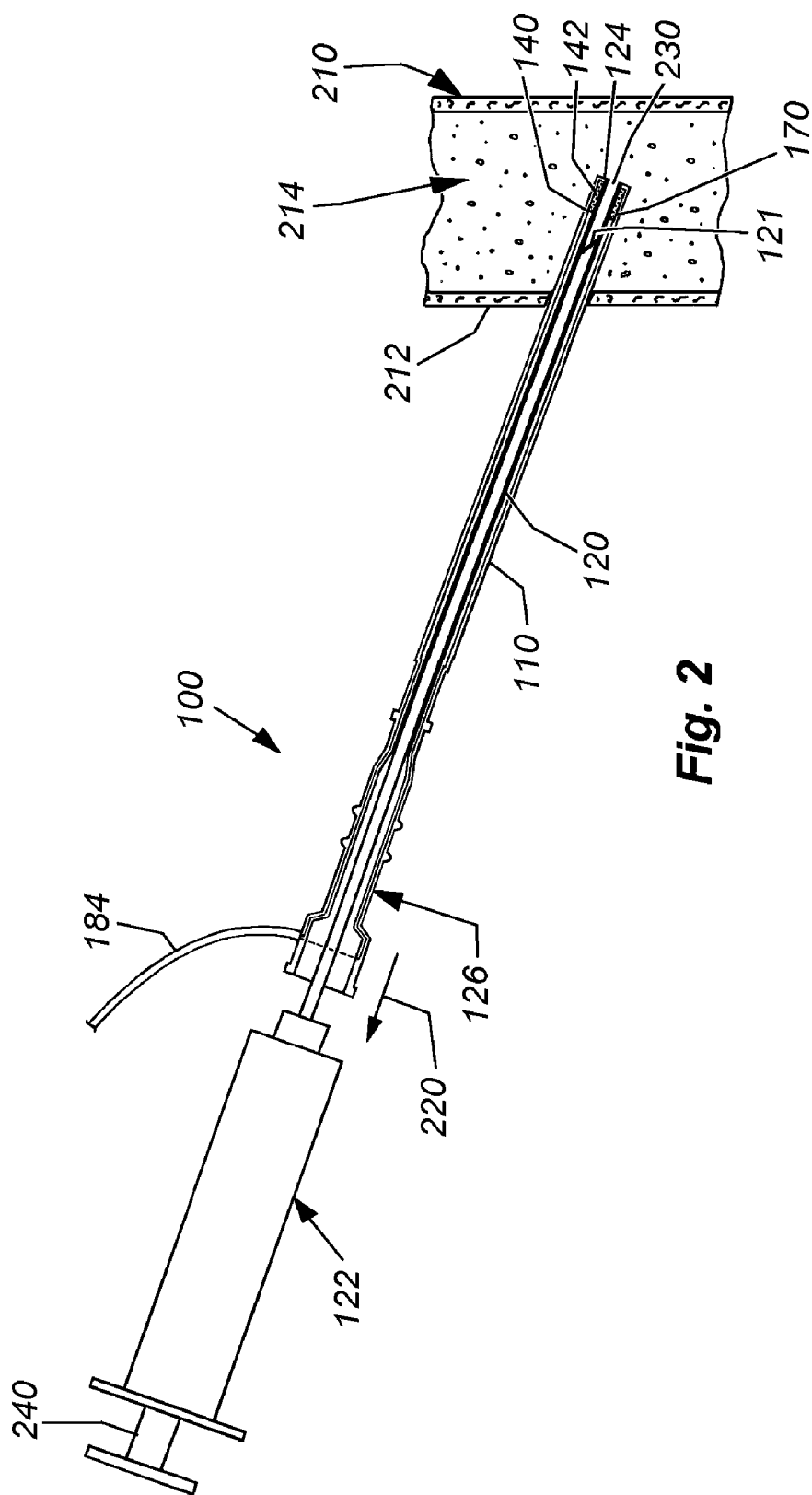
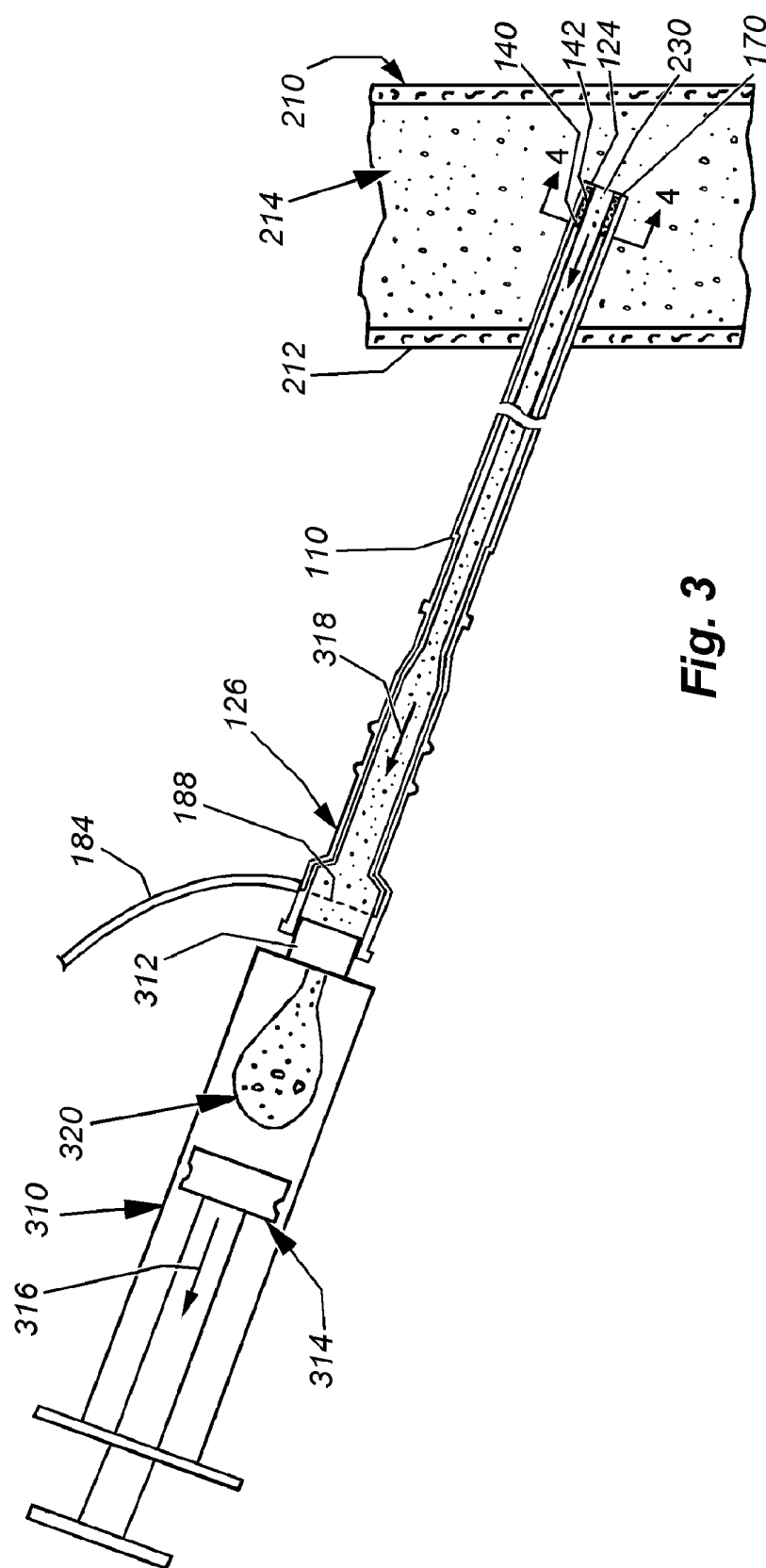
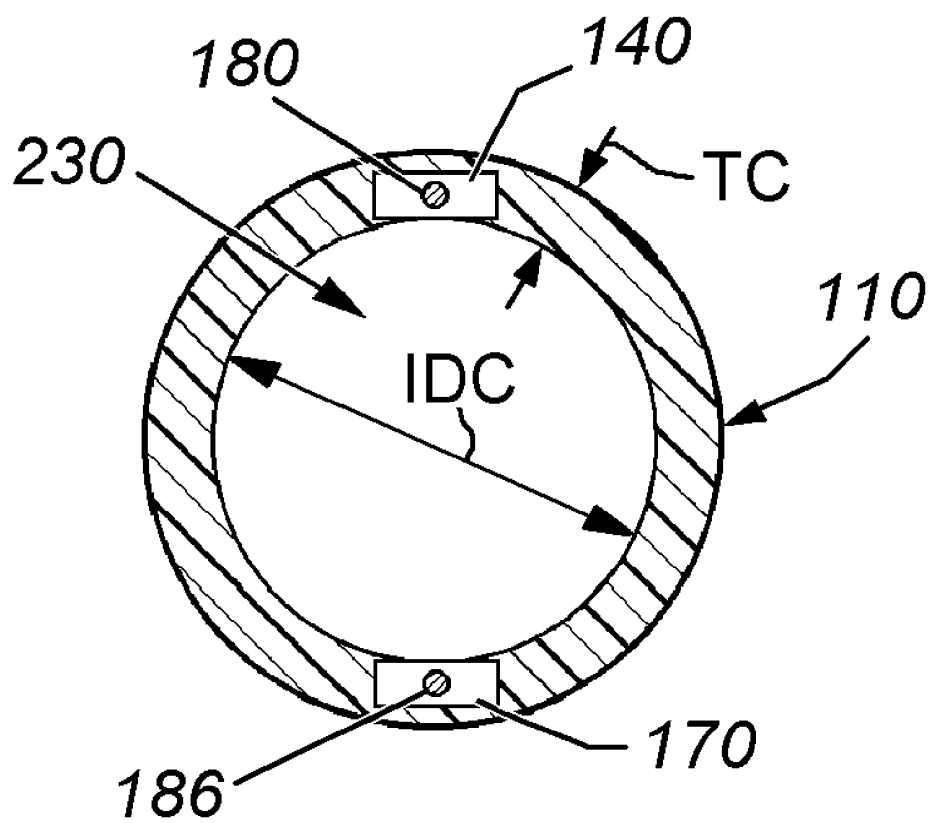
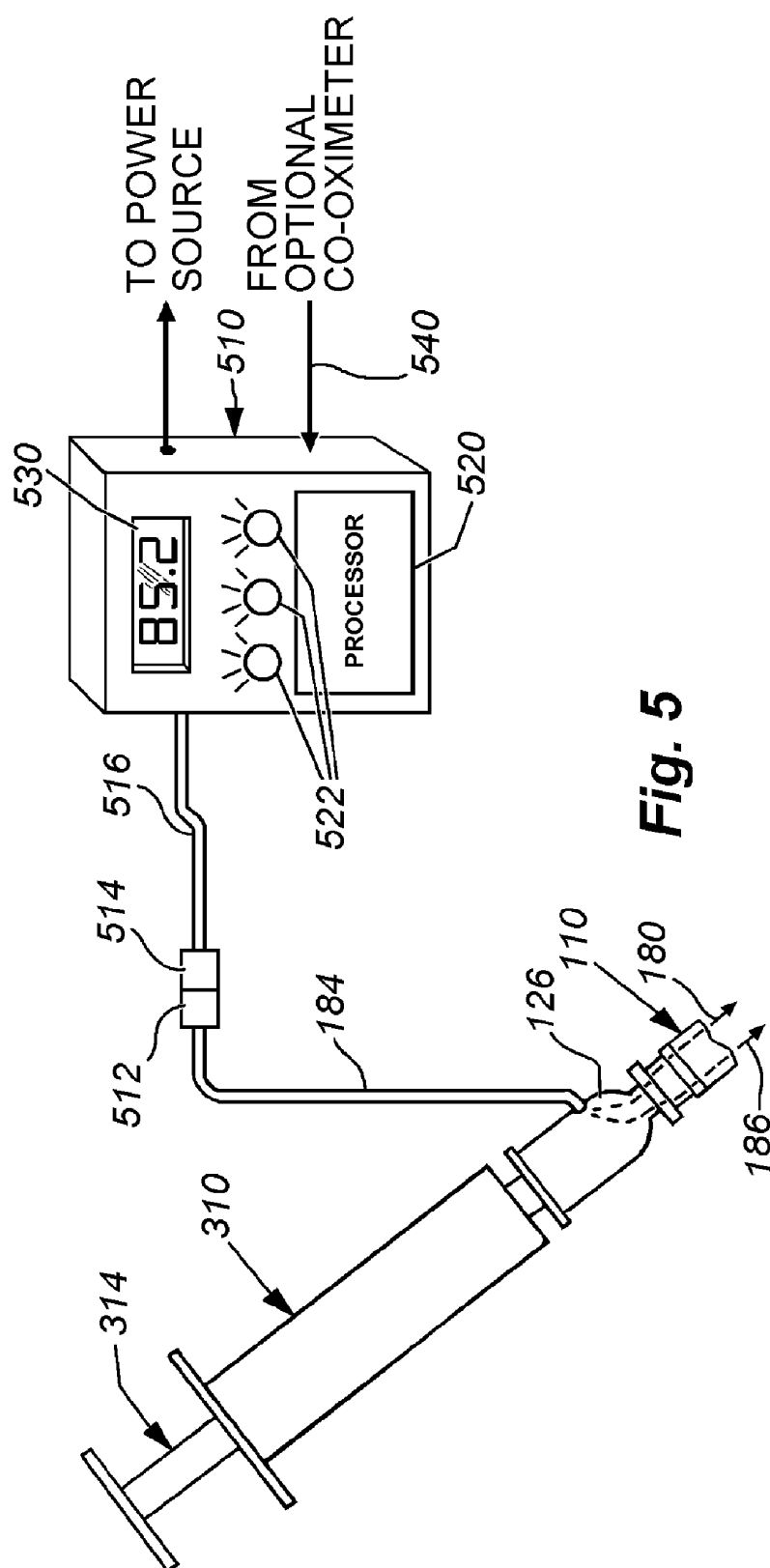
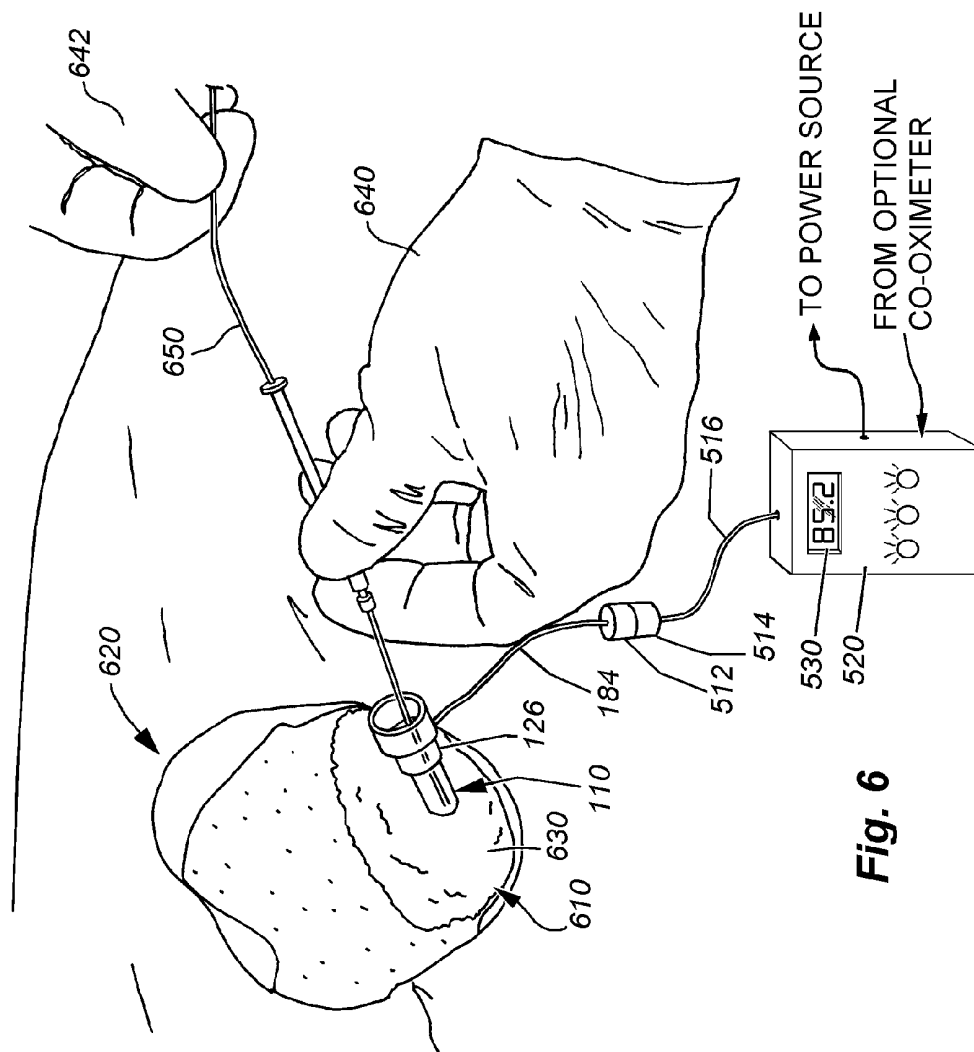


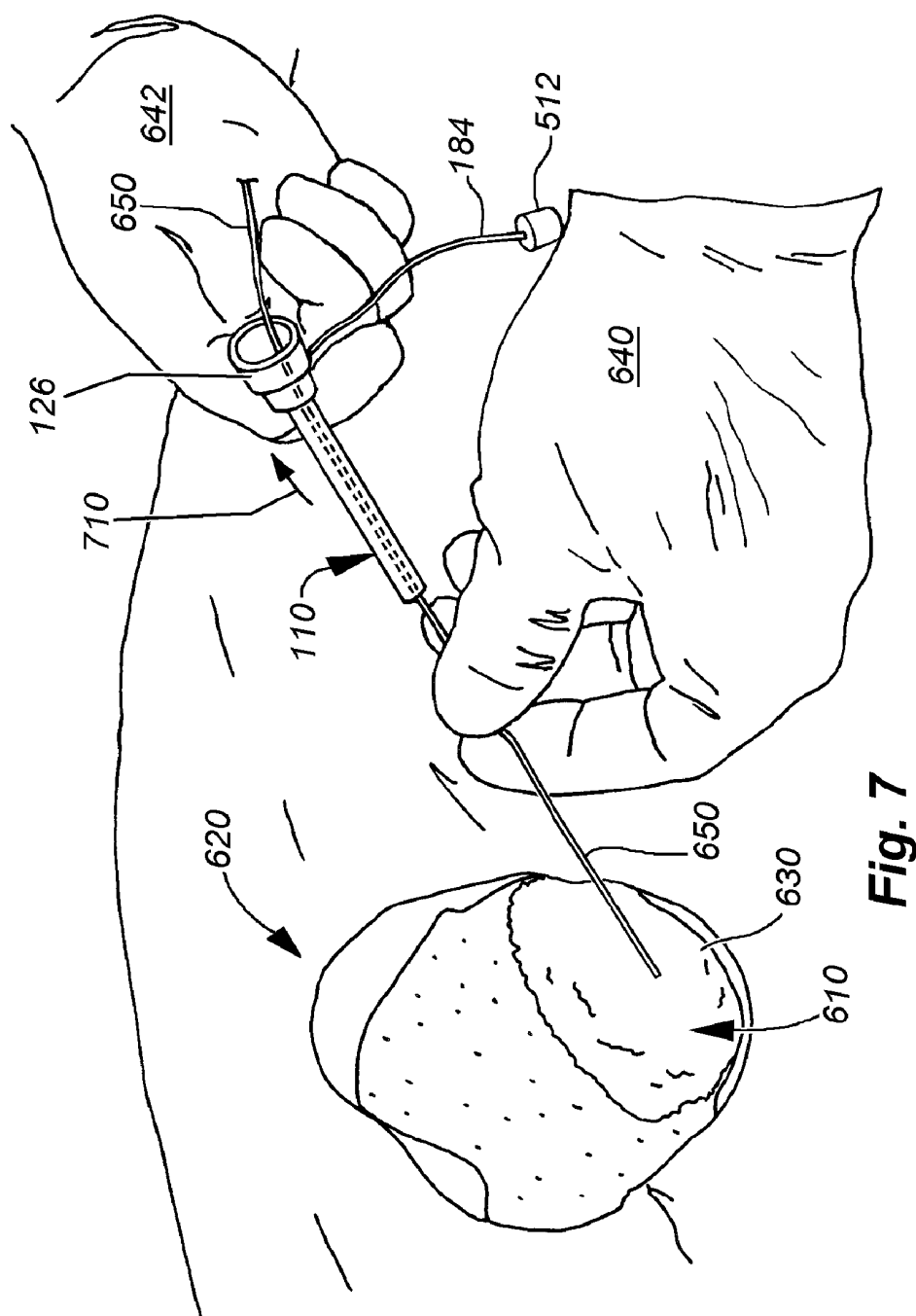
Fig. 2



**Fig. 4**







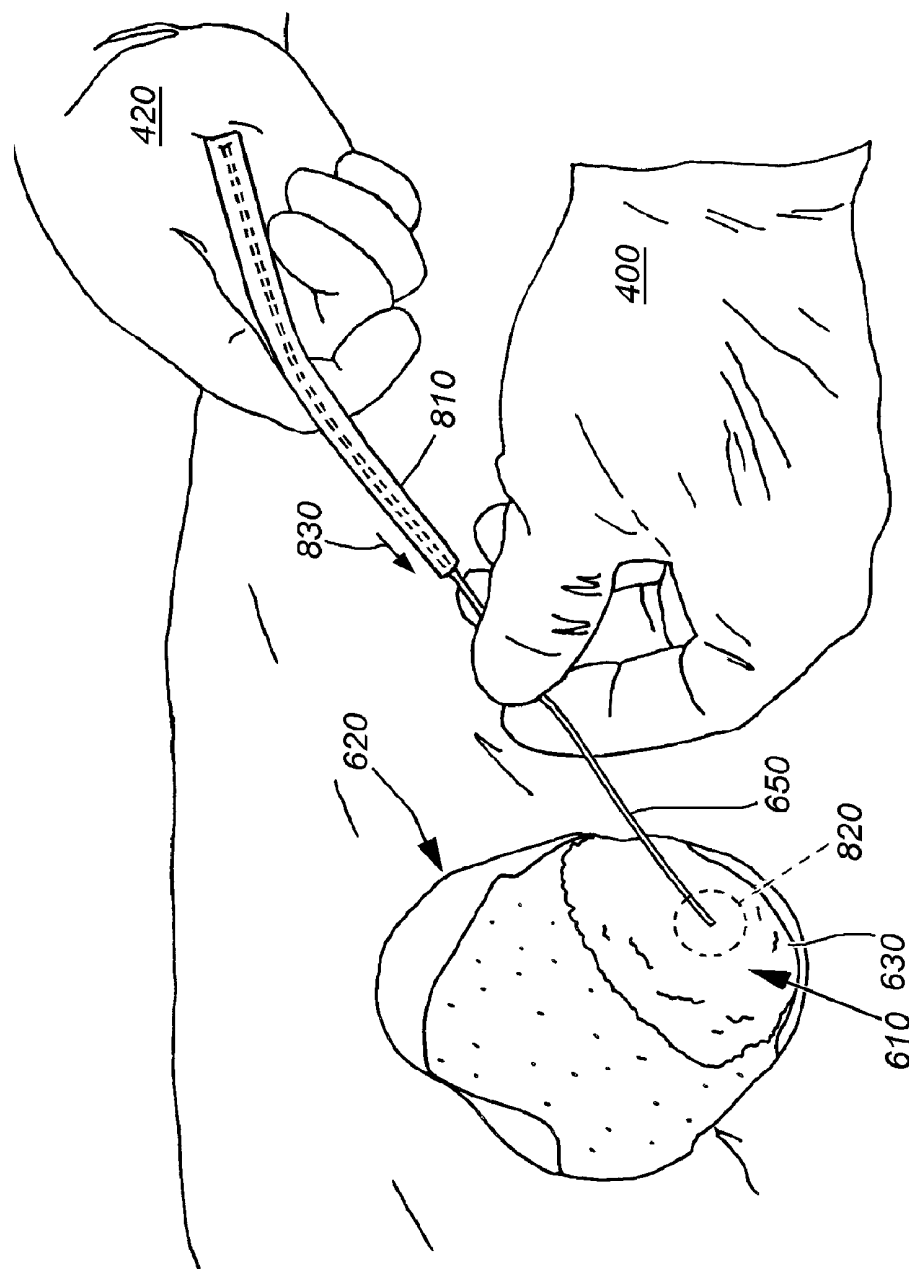
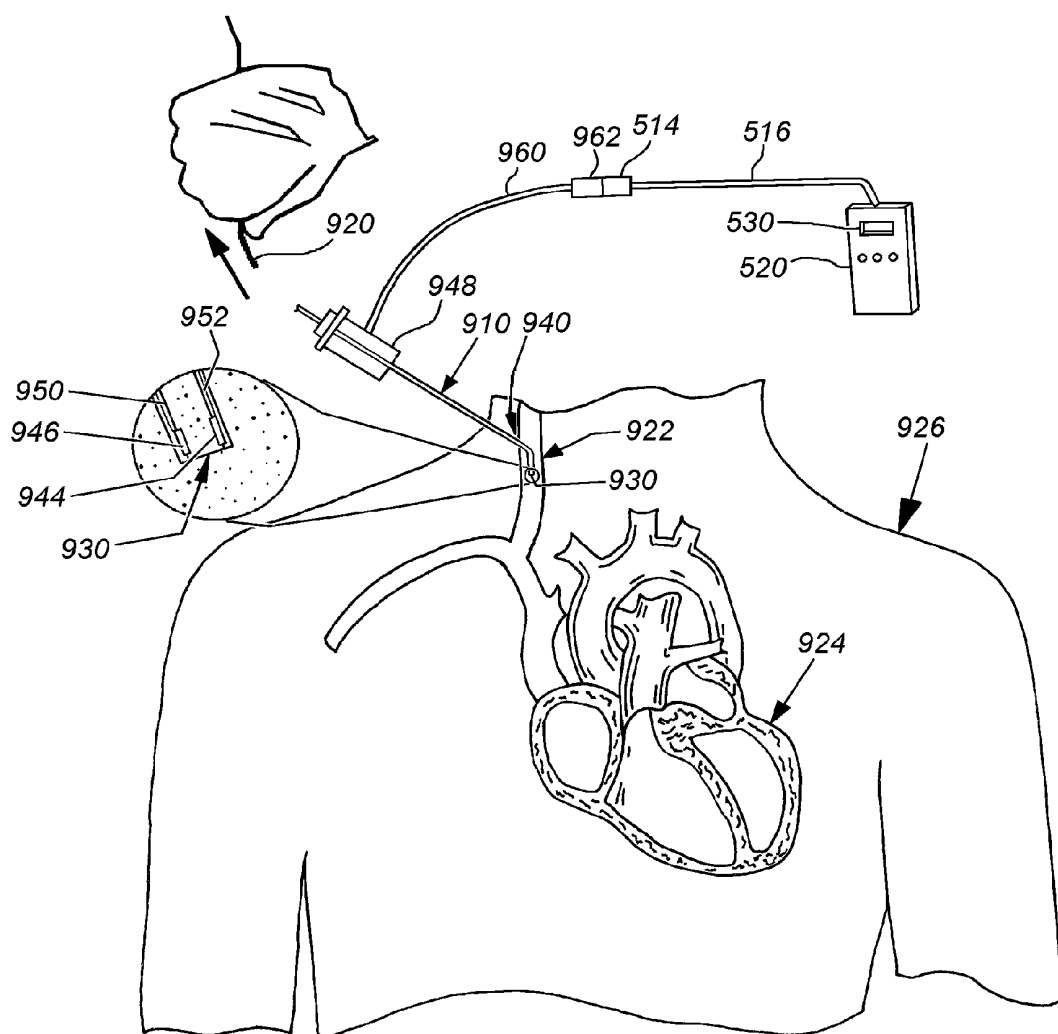


Fig. 8

**Fig. 9**

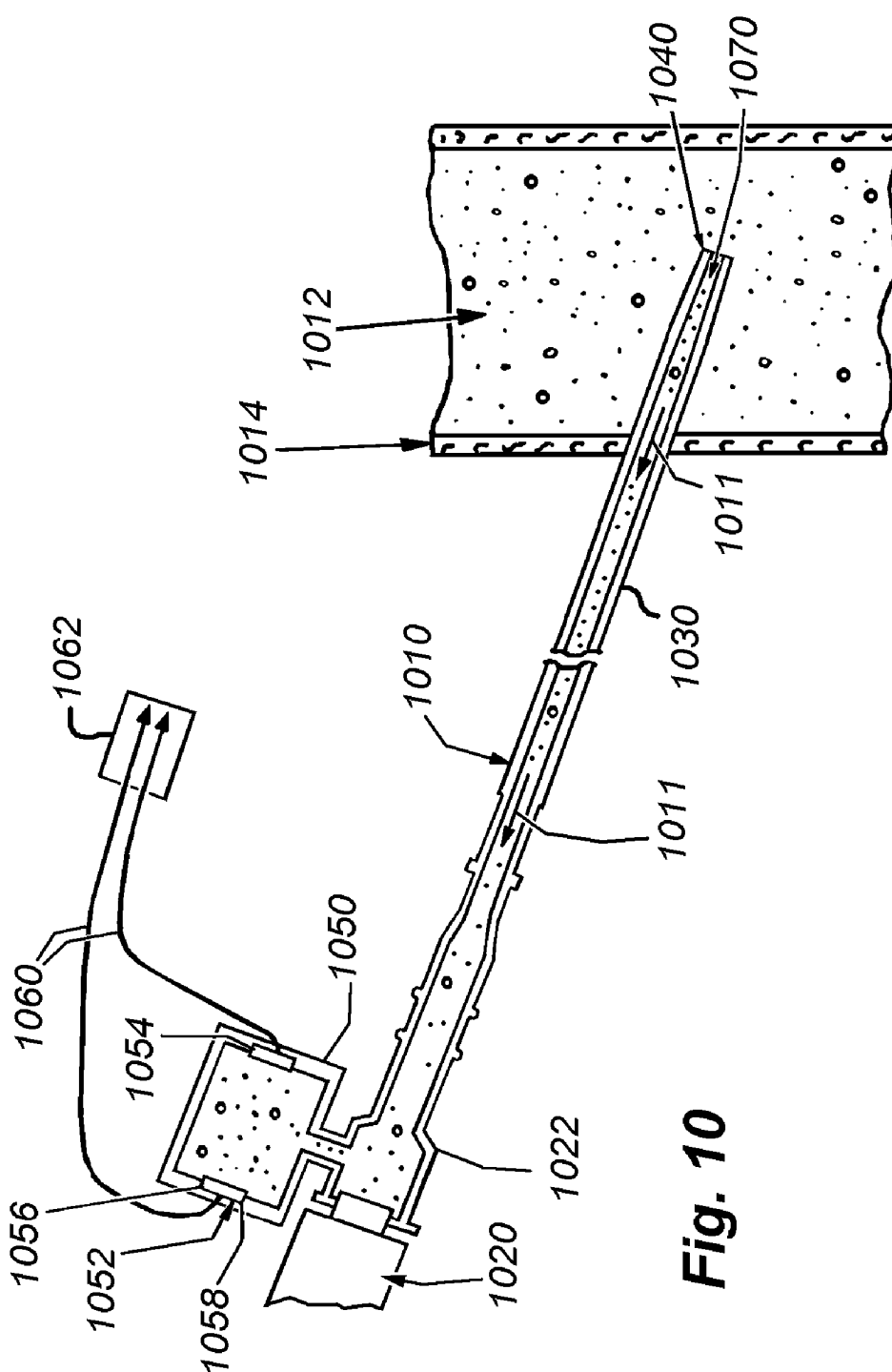


Fig. 10

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SYSTEM AND METHOD FOR MEASURING BLOOD CONSTITUENTS USING A CATHETER

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 11/565,321, filed Nov. 30, 2006, entitled SYSTEM AND METHOD FOR VENOUS OXIMETRY USING A CATHETER, the entire disclosure of which is herein incorporated by reference.

FIELD OF THE INVENTION

This invention relates to the accurate placement of central venous catheters within a central venous compartment of the body, and more particularly to novel techniques described herein employing venous oximetry to facilitate such accurate placement.

BACKGROUND OF THE INVENTION

Central venous catheters (CVCs) are placed in excess of ten million times annually in the United States. Access to the central venous compartment (e.g. Great veins interconnected to the cardiopulmonary system) by such CVCs is acquired to allow for the administration of fluids, nutritional support and medications that are not necessarily suitable for peripheral venous delivery. CVCs may also be employed to access the central venous compartment to enable measurement of certain hemodynamic variables that are otherwise unobtainable by accessing peripheral veins, or by non-invasive techniques.

There are certain risks associated with the insertion of CVCs, which include pneumothorax (the collection of gas in the space surrounding the lungs), hemothorax (the collection of blood/fluid in that space), failed insertion and inadvertent arterial puncture. Where a CVC is inserted via an internal jugular venous approach, the most commonly described, and very dangerous, complication is inadvertent carotid artery puncture. This is the second most commonly described complication in the subclavian venous approach.

There are several current approaches to percutaneous CVC placement. In Seldinger's Method, the skin is prepped, and under sterile conditions, the percutaneous vein is punctured with a thin needle (for example, 20-gauge, or approximately 1 mm in outer diameter). A flexible guide wire is then introduced through the needle lumen and the needle is removed. A larger diameter dilator is then guided over the wire to facilitate passage of a larger bore (for example, 8-9 French, or up to approximately 3-4 mm in outer diameter). An alternate insertion approach entails venipuncture by the thin needle followed by guidewire placement. The larger-diameter catheter is then inserted while the guide wire is removed. Other approaches may also be employed, depending upon the type of device being inserted. Each of these approaches requires perforation of the target vessel using a needle.

While inadvertent arterial puncture using the introducing needle is usually an obvious condition, because of the arterial bleeding that results from even a small puncture, it often is not. Subsequent placement of a large-bore catheter or introducer into the carotid artery or another arterial structure can have lethal consequences. There have been reports of thromboembolic sequelae (broken blood clots leading to stroke, embolism, etc.) as a result of such punctures. Once damage has occurred, the neck or other region may require surgical exploration to assess and repair the damage. This can lead to

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further risk, expense and delays in attending the initial surgical problem which necessitated the CVC insertion.

One approach to reducing the risk in placing a percutaneous CVC is to monitor the insertion using interoperative imaging with an ultrasound or another type of internal imaging device. In some situations, radiopaque markers on the catheter/needle can be employed to assist guidance under fluoroscopy or similar scanning techniques. However, the surrounding structures of the neck may obscure a clear view of the target vein. Thus, while the needle appears clearly, the walls of the vein may not. Hence, reports of inadvertent carotid artery puncture, subsequent arterial cannulation and morbidity persist, even when employing interoperative imaging.

Another possible approach to reducing the risk of arterial cannulation is to employ a scout needle, in which a short, 20-gauge catheter is operatively connected to a pressure transducer before insertion of a guidewire. A variation or differential in pressure may indicate a

A technique that more reliably ensures the needle is in communication with the vein, and not an artery is highly desirable.

SUMMARY OF THE INVENTION

This invention overcomes the disadvantages of the prior art by providing a system and method for confirming the proper placement of a penetrating catheter into a venous region without undesirable arterial cannulation using principles of oximetry in which blood from the penetrated region is subjected to light of a plurality of wavelengths and detected for absorption levels. The result is analyzed by a processor and the level oxygen saturation of the blood is indicated. The characteristic level of saturation informs the practitioner whether oxygenated arterial blood is present due to, for example, an inadvertent puncture. Other measurements of blood constituents can also be obtained using varying wavelengths, such as for determining the level of solutes, electrolytes, complex molecules, and pharmacologic agents.

In an illustrative embodiment, the catheter is introduced using an introduction needle. Thereafter the needle is removed to allow blood to communicate with sensing elements that consist of a light-emitting LED (or other light source of characteristic wavelength) array and opposed photodetector. In an illustrative embodiment, light in the infrared and visible red wavelengths can be provided by separate LED units within the overall array. Aspiration of blood through the catheter by an attached syringe allows the processor to compute the level of oxygen saturation or other blood constituent, based upon detected light absorption of passing blood, using the Beer-Lambert law. The sensing elements can be miniaturized so as to be located in the distal tip of the catheter, and can be operatively connected to an external connector via embedded leads. The processor connects to the leads through cables and the like, and also connects to a display. An optional non-invasive co-oximeter can also be connected to the processor to provide a compared value for oxygen saturation or other blood constituent of arterial blood by which the readout of the display is calibrated. The catheter is approximately 1 mm in inner diameter in an illustrative embodiment. Following confirmation of a safe location, it can guide a conventional guide wire and is then removed, leaving the guidewire in place in the vein. A larger diameter CVC can then be safely inserted into the vein over the guidewire, which is then, itself, removed leaving the CVC in place.

In further embodiments, the catheter can include a bulb that supports externally mounted sensing elements into which

blood from the vein is aspirated. The external sensing elements can measure absorption of light by the blood passing between the light emitter and the photodetector and determining a level of blood constituents, including solutes, electrolytes, complex molecules, and pharmacologic agents, among others. The sensing elements can be larger scale in such an embodiment. Alternatively, an elongated flexible version of the catheter with either internal or external sensing elements can be employed. It is adapted to be guided into a more remote location within the vascular system using conventional guiding techniques.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention description below refers to the accompanying drawings, of which:

FIG. 1 is an exposed side view of a central venous oximetry catheter according to an illustrative embodiment of this invention;

FIG. 2 is an exposed side view of the catheter of FIG. 1 showing the insertion thereof into a central venous region and the subsequent of an introduction needle associated therewith;

FIG. 3 is an exposed side view of the catheter of FIG. 1 showing the aspiration of blood from the central venous region to perform an oximetry function;

FIG. 4 is a cross section through the LED and sensor array taken along line 4-4 of FIG. 3;

FIG. 5 is a partial perspective view of the proximal end of the catheter of FIG. 1 interconnected with an exemplary oximetry data display device according to an illustrative embodiment;

FIG. 6 is a perspective view of a procedure for inserting a guidewire into the catheter of FIG. 1 following the withdrawal on the introduction needle;

FIG. 7 is a perspective view of a procedure for removing the catheter of FIG. 1 along the inserted guidewire of FIG. 6;

FIG. 8 is a perspective view of the insertion of a large bore CVC along the guidewire of FIG. 6 following removal of the catheter of FIG. 1;

FIG. 9 is an exposed front view of the insertion of an elongate flexible venous oximetry catheter via a guidewire according to an alternate embodiment; and

FIG. 10 is an exposed side view of a central venous oximetry catheter employing an external oximetry sensing cell according to an alternate embodiment of this invention.

DETAILED DESCRIPTION

A. Oxygenation of Hemoglobin and Principles of Oximetry

The vast majority of oxygen in blood is carried on the hemoglobin molecule with minimal amounts dissolved in the plasma. Due to the unique characteristics of hemoglobin, arterial blood and venous blood generally carry substantially differing amounts of oxygen. For example, in a healthy body arterial blood oxygenated hemoglobin (oxyhemoglobin) is between 96-100% of the total hemoglobin concentration. Conversely, venous blood (deoxyhemoglobin) typically reads a maximum saturation in the 80 percent range. In an unhealthy body, venous blood may read in the 60 percent range. Thus, there is a clear delineation between concentrations of oxygenated hemoglobin in venous versus arterial blood.

The measurement of blood oxygen levels through use of oximetry is well-known. One such device is the pulse oxime-

ter, which non-invasively detects the subject's blood-oxygen level. The pulse oximeter operates on the principle of the Beer-Lambert law. Briefly, the law states that the absorption of light of a given wavelength passing through a non-absorbing solvent, which contains an absorbing solute, is proportional to the product of the solute concentration, the light path length and an extinction coefficient. The law can be expressed as:

$$A=bc$$

where A is absorbance (no units, since $A=\log_{10} P_0/P$); is the molar absorptivity with units of $L\ mol^{-1}\ cm^{-1}$; b is the path length of the sample—that is, the path length of the vessel in which the sample is contained (typically in millimeters, centimeters, etc.); and c is the concentration of the compound in solution, expressed in $mol\ L^{-1}$.

A pulse oximeter is placed in contact with skin containing sufficient blood vessels (a finger, for example), light of at least two wavelengths is transmitted so as to pass through the blood vessels. Typically the oximeter has a pair of small light-emitting diodes (LEDs) facing a photodiode through a translucent part of the patient's body, usually a fingertip or an earlobe. One LED is red, with wavelength of 660 nm, and the other is infrared, 910 nm. Absorption at these wavelengths differs significantly between oxyhemoglobin and deoxyhemoglobin. In particular, oxyhemoglobin absorbs maximally in the infrared band (850-1000 nm), while deoxyhemoglobin absorbs light maximally in the visible red band (600-750 nm). By employing the Beer-Lambert law in association with the detected values for absorption, the ratio of the absorption of the red and infrared light the oxy/deoxyhemoglobin ratio can be calculated using known techniques.

In non-invasive, pulse oximetry the monitored signal bounces in time with the heart beat (hence, the term pulse oximeter) because the arterial blood vessels expand and contract with each heartbeat. By examining only the varying part of the absorption spectrum (essentially, subtracting minimum absorption from peak absorption), an interconnected monitor can ignore other tissues or other intervening materials (for example, nail polish), and discern only the absorption caused by arterial blood.

More recently, special spectrophotometric oximetry catheters have been developed that allow in vivo measurement of central venous blood oxygenation. They can be employed for a variety of purposes including the continuous monitoring of brain blood-oxygen saturation (also termed SjVO₂) via insertion into the jugular bulb. In general they employ fiberoptic wave guides in communication with an external base unit to perform oximetric monitoring of blood near the catheter's distal end. Two or more waveguides transmit the appropriate, corresponding wavelengths of light from the base while another light waveguide receives the modulated (absorbed) light and transmits it back to the base for analysis. Such monitoring techniques, and commercially available oximetry systems, are discussed in *Continuous jugular venous oximetry in the neurointensive care unit—a brief review*, Canadian Journal of Anesthesia, 2002 (pages 623-629). These SjVO₂ monitoring catheters are designed for permanent insertion into the patient's central vascular system and can be of relatively large-diameter, similar in size and form to other CVCs. Hence, the insertion of monitoring catheters dictates the same initial puncture and guidance procedures, and therefore entails the same risks of inadvertent arterial puncture, as with the insertion other types of CVCs.

B. The Oximetry Catheter and Insertion/Use Procedure

FIG. 1 details an oximetry catheter assembly 100 in accordance with an illustrative embodiment of this invention. The

catheter assembly consists of the outer oximetry catheter **110** (termed hereinafter generally, the “catheter”) and an inner introduction needle **120**, over which the catheter **110** resides, in relatively close conformance. The distal/sharp end **121** of needle **120** projects beyond the distal end **124** of the catheter **110** a distance LP of approximately 2-4 millimeters. The needle **120** includes a conventional syringe body or hub **122** at its opposing proximal end. This body/hub **122** is suitable for grasping and manipulating the assembly **100** in the manner of a conventional introducer catheter. The catheter **110** includes its own proximal hub **126** that can be adapted to engage the distal end **128** of the needle hub **122** as shown. In this manner, a substantially fluid-tight seal is maintained between the hubs **122**, **126**. Note that the catheter hub **126** can be constructed to include a variety of external bases, flanges, side connections and other structures that facilitate its use in a particular procedure.

The needle **120** is substantially rigid and can be constructed from stainless steel or another biocompatible material in this embodiment. It is a 20-gauge (approximately 1 mm O.D.) needle in this embodiment. Other relatively thin-outer-diameter needle sizes are also contemplated. The needle **120** defines an overall length LN of between approximately 10 and 100 millimeters. The actual needle length is dependent upon the precise point of insertion of the needle, as some vascular bodies are more or less deeply located than others. The length should be defined so that the catheter hub **126** engages the external skin when the distal tip is positioned within the vein. The overall length of the catheter **110** is proportional to that of the needle, with appropriate allowance needle’s distal end **121** to project slightly so as to allow it to puncture external tissue and the vascular wall (refer below).

With brief reference also to the cross section of FIG. 4, the catheter **110** is relatively thin. Its wall thickness TC can be approximately 100-200 microns in an illustrative embodiment. Other thicknesses are contemplated however. The catheter is constructed from an appropriate, typically polymeric, material, and can include low-friction surface coatings, such as PTFE along the interior and/or exterior surfaces. A variety of surface coatings that are generally known to those of ordinary skill can be employed.

The catheter inner diameter IDC allows it to closely conform to the outer surface of the needle **120**. For a 20-gauge introduction needle, the inner diameter IDC is approximately 1 mm. This should be sufficient to accommodate a conventional catheter guidewire as described further below. The relatively thin wall thickness TC of the catheter **110** provides a low-profile that, in essence, enables its own distal end **124** to piggy-back on the needle distal end and pass through tissue without causing trauma as the needle’s tip is driven inwardly/distally. In other words, the catheter’s low-profile distal end **124** does not overly distend the surrounding tissue boundaries that are initially defined by the sharp needle tip.

With reference also to FIG. 2, the insertion of the assembled needle **120** and catheter **110** into a central vascular region (for example, the jugular) **210** is further detailed in FIG. 2. The needle has been appropriately oriented and driven distally within a sterile field so as to puncture and pass through surrounding tissue and the vascular wall **212**. Using ultrasound, or similar imaging techniques, the distal tip has been guided to reside within the bloodstream **214**. Within the bloodstream, the distal tip is in communication with surrounding blood, containing deoxyhemoglobin. As shown, once properly positioned, the practitioner can grasp the catheter hub **126**, holding it in place against the external skin, while withdrawing (arrow **220**) the needle **120** via simultaneous grasping of the syringe body **122**. The overlying catheter **110**

remains in place within the vein **210** and its inner lumen **230** is now in fluid communication with the surrounding blood (**214**).

Notably, the distal end **124** of the catheter **110** includes at least two embedded light emitters **140**, **142** (FIG. 1). Recent developments in micro-LED technology have rendered it possible to embed one or more micro-LEDs in an array unit **144** that is readily molded-into, or applied to the inner luminal wall of the catheter **110**. At present, bright LEDs as small as 20 microns in diameter can be formed from gallium nitride (GaN) material in accordance with research conducted at Scotland’s University of Strathclyde, Institute of Photonics. Larger micro-LEDs that conform to the needed form factor may be obtained from other sources. As shown, a luminal surface mounted array **144** is provided, which may slightly bulge the outer surface of the catheter’s distal end when combined with the needle **120**. The projection of his bulge **160** is still small enough to enable ready insertion of the assembly **100** into tissue.

Positioned in diametrical opposition (180 degrees) to the LED array **144** is a photodetector **170**. The photodetector **170** resides on the luminal surface of the catheter and also forms a small, non-interfering bulge **172**. The photodetector can comprise one or more photo-detecting cells that generate a variable voltage, current or other signal proportional to the intensity of received light within a given operating wavelength. The LEDs **140**, **142** each emit at a characteristic wavelength—one in the infrared band (for oxyhemoglobin detection), and one in the visible-red band (for deoxyhemoglobin detection). The detector **170** is sensitive to both wavelengths.

The LEDs **140**, **142** are connected to one or more leads **180** that pass proximally along, or within, the luminal wall to an external connector cable **184** mounted on the hub **126**. The photodetector **170** is connected to a lead **186**, which joins the cable **184** via a bridge **188** (shown in phantom). The leads **180**, **186** and bridge **188** can be formed from thin metal, conductive ink, embedded metal or graphite powder, or another appropriate conductor of electricity. In certain embodiments, the catheter wall can be doped with conductive material to provide integral leads from the array **144** and photodetector **170** to the hub **126**.

With reference to FIG. 3, the catheter is now in place with the distal tip **124** located within the bloodstream **214** of the (supposed) venous region, and the needle **120** is completely withdrawn. The distal end **312** of a new syringe **310**, without needle covering the array **144** and photodetector **170**, is attached to the proximal end of the catheter hub **126**. The syringe can be a conventional 5 ml syringe in this embodiment. This forms a substantially fluid-tight seal therebetween. The plunger **314** of the syringe **310** is now withdrawn proximally (arrow **316**) by the practitioner to aspirate (arrow **318**) supposed venous blood **320**. By aspirating blood, a fresh supply is slowly passed through the catheter lumen **230** between the LED array **144** and photodetector **170**. Light emitted from the LEDs is received by the detector with appropriate levels of absorption from which the oxygen saturation of the hemoglobin therein may be calculated.

Note that, in another embodiment, the introduction needle **120** can be withdrawn partially so as to expose the array **144** and photodetector **170**, with the conformance between the needle shaft and inner lumen of the catheter **110** forming a fluid seal. This is a simpler technique, as attachment of a new separate syringe (**310**) is not required. The introduction needle’s syringe base is provided with a plunger **240** (FIG. 2) that allows aspiration of blood.

Referring to FIG. 5, the calculation of oxygen saturation level is performed by a powered base unit **510** that is interconnected with the catheter **110** when a reading of saturation level is desired. Appropriate, mating connectors **512** and **514** are provided on the catheter cable **184** and base unit cable **516**, respectively. The length of each cable is highly variable. In one embodiment, the catheter **110** contains a cable having a length of approximately 300-500 mm and the base unit **510** has a cable of approximately 1-2 meters. One of the cables can be omitted in favor of a device mounted connector. In most embodiments, the single-use nature of the catheter **110** and multi-use nature of the base unit **510** make a removable connection desirable. The connector can be a conventional multipin male/female connector, or another desirable type that is capable of providing multiple lead connections. Within the base unit is a processor **520** that is activated by various switches and activates appropriate status lights (shown generally as items **522**). The processor provides power to the LEDs in the array **144** and photodetector **170** so that absorption of light therebetween can be measured.

Using the above-described Beer-Lambert relationship, the processor **520** employs conventional algorithms to calculate the measured oxygen saturation level. In one implementation, each LED **140**, **142** is alternately cycled (multiple times per second, for example), and the processor differentiates between pulses received from each LED wavelength to calculate the saturation level. The processor **520** can comprise a variety of implementations of hardware, software (program instructions executing on a computer) and firmware. It can include one or more microprocessors, microcontrollers and/or state machines that carry out the required algorithms. The processor and its functions can be implemented according to ordinary skill using well-known circuit and software design techniques. In one example, the processor can be similar in structure and function to any one of a number of commercially available pulse oximetry and/or SjVO₂ monitoring devices.

Optionally, the signal from a connected (connection **540**) co-oximeter can be employed to provide a value for arterial blood saturation against which the measured value of the catheter-derived value is compared. This co-oximeter can be a peripheral, non-invasive pulse oximeter of conventional design (not shown). The processor is adapted, using known circuits and processes, to recognize and correlate the co-oximeter's measured value. The measured saturation values derived from the catheter are, thus, scaled in accordance with the input co-oximeter value.

The processor **520** uses other known procedures and circuits to provide the value to a display **530**. The display **530** can include a numeric readout as shown, which provides the actual saturation level as a percentage, or in accordance with another metric. In addition, or alternatively, the display can provide a simple go/no-go indicator that indicates whether the saturation level comports with venous or arterial blood. As discussed above, a saturation percentage that is near or into the 90s indicates the presence of arterial blood (ostensibly present due to a puncture or misdirected needle), while a measured saturation percentage at or below the mid-80s indicates venous blood without a suspected puncture.

Thus, the practitioner is provided with a highly reliable, internally derived indication as to whether arterial cannulation has occurred based upon the displayed saturation level. If cannulation has occurred, standard pressure is applied to the area to shunt any bleeding and a new attempt is made to acquire a proper vein. Notably, the small diameter of the catheter **110** and introduction needle **120** generally limit the potential for arterial damage and excessive bleeding. As dis-

cussed above, that damage would be far greater if a full-sized CVC were subsequently introduced to the improper area.

Where the display **530** indicates that proper vein acquisition has occurred, the practitioner can now employ the catheter **110** to insert a conventional guide wire as shown in FIG. 6. A sterile field is provided at the introduction area **610**, with a drape **620** provided therearound. The hub **126** of the catheter **110** rests on the skin **630** thereby interfering with further distal movement of the catheter **110** into the vein. The hub **126** can be further secured with sterile tape or another removable mechanism. The syringe **310** has been removed, opening the catheter lumen to the interior of the vein. At this time the practitioner manipulates (with hands **640**, **642**) a small-diameter guidewire **650** through the catheter lumen and into the vein via the proximal end of the hub **126**. At some time before or during this stage of the procedure, the catheter connector **512** can be disconnected from the base unit connector **514**.

Next, as shown in FIG. 7, the catheter **110** is removed from the site **610** by drawing it proximally (arrow **710**) along the guidewire **650** while the guidewire is held firmly in place within the vein. The catheter **110** is drawn completely off the proximal end of the guidewire **650**, thereby freeing the guidewire for insertion of a larger diameter catheter.

Referring now to FIG. 8, insertion of a full-sized CVC **810** along the guidewire **650** is detailed. While not shown, a dilator may be introduced beforehand along the guidewire to increase the size of the introduction site **820** (shown in phantom). The CVC, which can have a size of 8-9 French is now moved distally (arrow **830**) along the guidewire. It is inserted through the introduction site and driven into the vein until it reaches the appropriate location therein. The CVC can then be secured to the skin **630** using tape and other mechanisms so as to perform its needed function (i.e. nutrition, medication monitoring, and the like). The guidewire is then removed.

C. Extended Oximetry Catheter

With reference to FIG. 9, according to an alternate embodiment, an oximetry catheter **910** that is adapted to be guided via a previously inserted (now removed) guide wire **920** is shown. The guide wire can comprise a conventional steerable or unsteered guide wire. The catheter **910** is longer and sufficiently flexible to allow it to be inserted more deeply into a vessel **922** of the central circulatory system (in closer proximity to the cardiopulmonary system) **924** of the body **926**. In this manner the distal tip **930** can be located further from a convenient insertion site **940** to provide desired data on oxygen saturation. This data can be used to confirm lack of arterial cannulation prior to replacement of the guidewire and insertion thereon of a CVC. Alternatively, the catheter **910** can be used to monitor oxygen saturation on a more permanent basis. The distal tip **930** contains an LED array **944** and photodetector **946** similar or identical to those (**144**, **170**) described above for the catheter **110**. These sensing elements **944**, **946** are connected to the hub **948** by embedded leads **944**, **946**. The hub is connected to a cable **960** and associated connector **962**. The connector can mate with the above-described base unit connector **514** or another monitoring device that performs a similar measurement and display function. The materials used to construct the distal shaft and hub of this catheter are typically polymer, and can be adapted to provide needed flexibility over a long length. The diameters and thickness of the catheter **910** can be similar to those of the above-described catheter **110** or differ as needed for the particular application.

D. Oximetry Catheter with Remote Sensing Bulb

In accordance with the alternate embodiment shown in FIG. 10, it is contemplated that the sensing elements can be

placed external of the body and still attain a good result, provided the aspirated blood remains free of oxygen. In this embodiment, the catheter **1010** draws (arrows **1011**) blood from the bloodstream **1012** of a supposed vein **1014** using a syringe **1020**. The syringe is connected in a fluid-tight arrangement to the catheter hub **1022**. The size and shape of the catheter shaft **1030** and hub **1022** can be similar or identical to those of the above-described catheter **110**. It can be introduced using a needle similar to the introduction needle **120** described above. In this embodiment, the distal tip **1040** is free of sensing devices. Rather, the sensing devices are provided in a sealed bulb in communication with the hub. This enables use of a larger scale LED array **1052**, consisting of at least two discrete LED units **1056** and **1058** each emitting a corresponding discrete wavelengths. A larger scale photodetector **1054** is diametrically opposed to the array **1052** in the bulb **1050** and receives the absorbed light therefrom. The elements **1052**, **1054** are connected via cabling **1060** to a connector **1062** that can interconnect with a base unit such as the above described unit **520**. In a further embodiment, within the above-described extended catheter **910**, provided with external sensing elements similar in spectrophotometric principle, but utilizing differing wavelengths as previously described, the sensing window is useful to ascertain concentrations of blood constituents, including but not limited to solutes, electrolytes, complex molecules, and pharmacologic agents. Accordingly, the external sensing elements **1052**, **1052**, disposed within a proximal end of the catheter, such as a remote sensing bulb, can measure absorption of light by the blood passing between the light emitter and photodetector to determine the level of blood constituents. It is well established that different blood constituent levels can be measured by differing the wavelengths. These wavelengths can be ascertained using conventional techniques through trial and error experimentation.

While a separate bulb **1050** is used in this embodiment to house the sensing elements, these larger scale elements can also be located in the hub itself, or in a special syringe body according to further embodiments. As in the above-described embodiment, a guidewire and CVC can be subsequently inserted using the lumen **1070** of this catheter **1010**.

Note that the above-described extended catheter **910** can be provided with external sensing elements similar to those described herein as opposed to the depicted distal-tip-mounted elements.

E. General Conclusions and Considerations

It should be clear that the above-described embodiments each desirably employ concepts of oximetry, with relatively direct sensing of venous blood at the site of CVC placement, to ensure avoidance of arterial cannulation. A variety of arrangements can be employed to such perform the sensing, either within the vein interior, or at a remote location still relatively proximate thereto. The catheter used for accessing the bloodstream is relatively small in diameter and less potentially damaging than a conventional CVC, thereby lowering the risks associated with initial acquisition of the vein. The small-diameter catheter then enables the guidance of larger-diameter (and potentially more damaging) structures to a confirmed safe location within a vein.

The foregoing has been a detailed description of a plurality of embodiments of the invention. Various modifications and additions can be made without departing from the spirit and scope thereof. In an alternate embodiment, some or all of the electrical components can be external. According to such an example, the leads for the emitters and detectors can be sub-

stituted with small-diameter light-waveguides and the emitters and detectors can be waveguide tips. The external cable is a fiber optic that connects to a base unit with a fiber optic-to-electric-signal interface. In addition, in alternate embodiments, it is contemplated that the LED array can include light transmitted in three or more wavelengths for better resolution. Each wavelength can be transmitted and sensed as a separate pulse in a continuous cycle. Also, while a particular insertion procedure for the oximetry catheter and CVC is shown and described herein, this procedure can be varied or augmented as need to satisfy the needs of the treatment protocol, practitioner or patient. Accordingly this description is meant to be taken only by way of example, and not to otherwise limit the scope of the invention.

What is claimed is:

1. A system for determining constituents of blood in a vascular region comprising:

a small diameter catheter adapted to be introduced to the vascular region using an introduction needle over which the catheter is mounted, the catheter including a distal shaft defining a lumen and a hub;

a light emitter and a photodetector constructed and arranged to pass light through blood from the emitter to the photodetector when the blood is drawn through the lumen and into the hub from the vascular region; and a processor operatively connected to at least one of the light emitter and the photodetector that measures and indicates a level of blood constituents of the blood drawn from the vascular region;

wherein the light emitter and photodetector are both positioned on a surface of the lumen, such that when the blood is drawn through the lumen, the light passes from the light emitter through the blood in the lumen to the photodetector, to allow measurement of light absorbed by the blood moving between the light emitter and the photodetector as blood is drawn through the lumen.

2. The system as set forth in claim 1 wherein the lumen is adapted to receive a guide wire and is in a range of approximately 1 mm in diameter.

3. The system as set forth in claim 2 wherein further comprising leads embedded in the shaft and extending to a cable and connector that extends remotely from a location proximate to the hub.

4. The system as set forth in claim 2 wherein the light emitter comprises a micro LED assembly located within the lumen proximate to the distal tip of the catheter and the photodetector comprises a miniature photodetector located within the lumen diametrically opposed to the LED assembly.

5. The system as set forth in claim 4 wherein the LED assembly comprises LEDs that emit light in at least two discrete ranges of wavelengths at predetermined times.

6. The system as set forth in claim 5 wherein the discrete ranges of wavelengths comprise the infra red band and the visible red light band.

7. The system as set forth in claim 2 wherein the processor is constructed and arranged to receive a signal from a co-oximeter and to compare a value for oxygen saturation from the co-oximeter to a measured value based upon the light emitter and the photodetector.

8. The system as set forth in claim 2 wherein the light emitter and the photodetector are located at a position in fluid communication with the lumen that is external to a vascular region.

9. The system as set forth in claim 8 wherein the light emitter and the photo detector are located in a structure proximate to the hub.

10. The system as set forth in claim 1 wherein the level of blood constituents is determined for at least one of solutes, electrolytes, complex molecules, and pharmacologic agents.

11. A method for introducing a central venous catheter (CVC) to a vascular region comprising the steps of:

introducing a small diameter catheter that is mounted on an introducer needle, through tissue and into the vascular region;

removing the needle so as to place a light emitter and a photodetector in communication with a lumen of the catheter, a distal tip of the lumen being located within the vascular region;

aspirating blood through the lumen so as to pass between the light emitter and photodetector;

measuring absorption of light by the blood passing between the light emitter and the photodetector such that when the blood is drawn through the lumen, the light passes from the light emitter through the blood in the lumen to the photodetector, so as to determine a level of blood constituents of the blood moving within the lumen, between the light emitter and the photodetector; and

when venous blood is detected, free of arterial blood, directing a guidewire through the lumen, removing the catheter and guiding a CVC over the guide wire into the vascular region.

12. The method as set forth in claim 11 further comprising analyzing a signal from a non-invasive co-oximeter to provide a comparison for the step of determining.

13. The method as set forth in claim 11 wherein the step of aspirating includes drawing blood with a syringe attached to a proximal hub of the catheter.

14. The method as set forth in claim 11 wherein the step of measuring includes emitting light from at least two discrete LED units that emit light at each of infra red range and a visible red range at predetermined times.

15. The method as set forth in claim 11 wherein the step of measuring absorption of light includes emitting light from at least two discrete LED units at two discrete wavelengths and measuring absorption of light by the blood passing between the light emitter and the photodetector and determining a level of blood constituents, including at least one of solutes, electrolytes, complex molecules, and pharmacologic agents.

16. The system as set forth in claim 1 wherein the light emitter and photodetector are disposed in opposed positions about the lumen.

17. The system as set forth in claim 1 wherein the light emitter and photodetector are disposed in diametrically opposed positions about the lumen.

18. The system as set forth in claim 1 wherein the light emitter comprises an LED assembly located within the lumen proximate to a distal tip of the catheter and the photodetector comprises a miniature photodetector located within the lumen diametrically opposed to the LED assembly.

19. The system as set forth in claim 18 wherein the LED assembly comprises LEDs that emit light in at least two discrete ranges of wavelengths at predetermined times.

20. The system as set forth in claim 19 wherein the discrete ranges of wavelengths comprise the infra red band and the visible red light band.

21. The system as set forth in claim 1 wherein the light emitter and the photodetector are located at a position in fluid communication with the lumen that is external to a vascular region.

22. The system as set forth in claim 21 including a separate sealed bulb in communication with the hub with the light emitters and photodetector provided at the sealed bulb.

23. The system as set forth in claim 22 wherein the photodetector is diametrically opposed to the light emitter, and the light emitter includes an LED array.

24. A system for measuring blood constituents in a vascular region comprising:

a small diameter catheter adapted to be introduced to the vascular region using an introduction needle over which the catheter is mounted, the catheter including a distal shaft defining a lumen and a hub;

a light emitter and a photodetector disposed proximate the hub of the catheter, the light emitter and the photodetector being constructed and arranged to pass light through blood from the emitter to the photodetector when the blood is drawn through the lumen and into the hub from the vascular region; and

a processor operatively connected to at least one of the light emitter and the photodetector that measures and indicates a level of blood constituents of the blood drawn from the vascular region;

wherein the light emitter and photodetector are positioned so that when the blood is drawn through the lumen, the light passes from the light emitter through the blood in the lumen to the photodetector, to allow measurement of light absorbed by the blood moving between the light emitter and the photodetector as blood is drawn through the lumen.

25. The system as set forth in claim 24 wherein the light emitter and photodetector are disposed proximate the hub of the catheter by means of a separate sealed bulb in communication with the hub.

26. The system as set forth in claim 25 wherein the light emitters and photodetector are provided at the sealed bulb.

27. The system as set forth in claim 26 wherein the photodetector is diametrically opposed to the light emitter, and the light emitter includes an LED array.

28. The system as set forth in claim 24 wherein the level of blood constituents is determined for at least one of solutes, electrolytes, complex molecules, and pharmacologic agents.

29. The method as set forth in claim 11 wherein the step of introducing a small diameter catheter that is mounted on an introducer needle includes providing the needle having a diameter of approximately 20 gauge.

30. The method as set forth in claim 11 wherein the step of determining the level of blood constituents includes determining for at least one of solutes, electrolytes, complex molecules, and pharmacologic agents.

* * * * *

专利名称(译)	使用导管测量血液成分的系统和方法		
公开(公告)号	US8073517	公开(公告)日	2011-12-06
申请号	US12/791843	申请日	2010-06-01
[标]申请(专利权)人(译)	达特茅斯希区柯克诊所		
申请(专利权)人(译)	达特茅斯 - 希契科克诊所		
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发明人	BURCHMAN, COREY A.		
IPC分类号	A61B5/00		
CPC分类号	A61B5/14542 A61B5/1459 A61B5/6852 A61M25/0606		
优先权	11/565321 2010-06-01 US		
外部链接	Espacenet USPTO		

摘要(译)

一种使用血氧测定法原理确认穿透导管正确放置到静脉区域的系统和方法，其中血液经受多个波长的光并检测吸收水平。处理器分析结果并指示血液的氧饱和度。特征饱和度水平告知医生是否由于无意的穿刺而存在氧合动脉血。使用引入针引入导管，然后移除导管以允许血液与由光发射器和相对的光电探测器组成的传感元件连通。红外和可见红色波长的光可以由单独的LED单元提供。通过附接的注射器抽取血液通过导管允许处理器基于检测到的通过的血液的光吸收来计算氧饱和度或其他血液成分的水平。

