

## OXIMETER PROBES AND METHODS FOR THE INVASIVE USE THEREOF

### CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of U.S. Ser. No. 08/412,287 filed Mar. 28, 1995, which in turn was a continuation-in-part of U.S. Ser. No. 08/163,052 filed Dec. 6, 1993, now U.S. Pat. No. 5,417,207 issued May 23, 1995; the subject matter of application Ser. No. 08/412,287 and application Ser. No. 08/163,052 are incorporated herein by reference.

### TECHNICAL FIELD

The present invention relates, generally, to pulse oximetry, and more particularly to the invasive, in vivo use of oximeter probes in anatomical Canals of humans and animals.

### BACKGROUND OF THE INVENTION

Pulse oximetry, involving the continuous, non-invasive monitoring of oxygen saturation level in blood perfused tissue, is becoming an increasingly important mechanism for determining patient condition both during and following medical procedures. Indeed, the use of pulse oximeters has expanded in recent years to the point where they are now considered essential in the context of many surgical, emergency room, intensive care, and neonatal applications. The use of pulse oximetry is also expanding into the areas of out-patient surgery centers, oral maxillofacial surgery, home care, and in the veterinary environment.

Pulse oximetry typically involves the use of an oximeter probe (sensor) in contact with the patient. The sensor provides an electrical output signal to an oximeter box, which houses electronic circuitry used to process the electrical signal and generate human-readable indicia of various physiological parameters, including the patient's blood oxygen saturation level and pulse rate. Pulse oximetry systems are currently available from a number of manufacturers, including model No. N-200 manufactured by Nellcor of Chula Vista, Calif.

Non-invasive pulse oximeter probes have traditionally employed transmittance technology, whereby light is passed through a portion of the patient's blood perfused tissue and analyzed to determine the blood saturation level of the tissue. More particularly, traditional oximeter probes comprise an LED assembly and a photodetector assembly spaced apart from each other and mounted to a flexible substrate. This substrate is configured to be attached to a convex portion of the patient's anatomy, for example a finger, toe, ear, and in the case of neonatal applications, to the ball of the foot. The oximeter probe may be conveniently attached to the patient by adhesives, a spring clip, Velcro, and the like. See, for example, Young, et al., U.S. Pat. No. 5,217,012 issued Jun. 8, 1993.

When properly attached to a patient, a transmittance oximeter probe is configured such that light emitted by the LED assembly passes through the patient's blood perfused tissue and is received by the photosensor assembly. The absorption characteristics of the transilluminated tissue are related to the oxygen saturation level of hemoglobin flowing through the tissue. Changes in the hemoglobin absorption characteristics influence the amount of light received by the photosensor, thus permitting the direct, non-invasive monitoring of arterial oxygen content. The photosensor assembly produces an output signal indicative of blood oxygen saturation level.

More recently, reflectance technology has been employed in the context of oximeter probes. Reflectance technology involves the use of an emitter assembly and a detector assembly mounted on a substrate and attached to the patient in an essentially co-planar fashion, for example on a patient's forehead or chest. When so mounted, light emitted by the emitter assembly passes through the patient's epidermis and is variously scattered and absorbed by the capillary and arterial beds, sweat glands, sebaceous glands, hair follicles, and the like beneath the patient's skin. During steady state operation of a reflectance probe, changes in the blood oxygen level of the blood perfused tissue proximate the sensor influence the amount of light received by the photosensor assembly in a manner analogous to transmission probes.

The theory of pulse oximetry, whether employed in the context of reflection or transmission sensing devices, is that the light received by the photosensor assembly and, hence, the blood oxygen level of the associated tissue, is a function of, inter alia, the relatively constant absorption characteristics of tissue, venous blood, and the like, as well as the variable absorption characteristics resulting from pulsations in arterial blood flow. Stated another way, the signal emitted by the photosensor assembly includes a DC component which is substantially independent of changes in blood oxygen saturation level, as well as a pulsatile AC component reflective of changes in blood oxygen saturation level.

In order to properly interpret changes in the oxygen saturation level of blood perfused tissue, a reasonably stable arterial pulsation is desired; indeed, an optical differencing measurement is typically made in accordance with this pulsation to determine the patient's pulse rate and oxygen saturation level. Moreover, a certain minimum threshold level of perfusion is generally needed in order to accurately detect changes in blood oxygen saturation level.

While suitable perfusion often exists at extremity sites (e.g., fingers, toes), a number of circumstances inhibit proper perfusion. For example, even in healthy pediatric and neonatal patients, lower mean arterial pressure and smaller arterial pathways inherently restrict the level of perfusion available for interrogation, particularly at the extremities. Moreover, in adults, conditions of critical illness, lowered body temperature, shock, trauma, burn, and other circumstances limit perfusion level as well as the ability to properly interface a sensor to a particular anatomical site. Accordingly, in many risk groups, conventional pulse oximeters are poorly adapted to situations wherein they are most needed. Moreover, many environmental factors, including the effects of changes in ambient light, humidity, and patient movement limit the practical utility of conventional oximeter sensors.

Thus, there exists a long felt need for an alternate site and monitoring configuration that positively addresses the limitations of presently known sensors.

### SUMMARY OF THE INVENTION

An invasive electro-optical sensor probe according to the present invention addresses many of the shortcomings of the prior art.

In accordance with one aspect of the present invention, an oximeter sensing system is suitably disposed on an elongated, flexible chassis. The chassis is suitably configured for insertion into an anatomical canal, for example in the esophagus, rectum, or vaginal cavity of a human patient. Inasmuch as the hemoglobin oxygen transport mechanism is substantially identical for all mammals as well as many