KNOWING YOUR PULSE OXIMETRY MONITORS

The widespread use of pulse oximeters to continuously monitor oxygen saturation of arterial hemoglobin is recognized worldwide. Pulse oximetry is now considered a standard of care in anesthesiology and has significantly reduced anesthesia related cardiac deaths.[1] In the United States alone it is estimated that there are 300,000 pulse oximeters presently in use. A typical hospital may use several different makes and models of pulse oximeter, depending on the location and application. The 1994 Medical Device Register lists more than 35 companies that manufacture and distribute pulse oximeters in North America alone. Since the introduction of the first commercially viable pulse oximeter in 1983, for use in anesthesiology, the only practical way for a clinical engineer or biomedical technician to verify the performance of these devices was to use it on themselves. While there have been test methods available, until recently many of these test methods and apparatus were not practical.[2] With the tools now available, it is possible to verify and compare the performance of most pulse oximeters.

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A typical pulse oximeter finger probe has two LEDs, one that transmits infrared light at a wavelength of approximately 940 nm and the other transmitting light at approximately 660 nm. The absorption of these select wavelengths of light through living tissues is significantly different for Oxygenated Hemoglobin (HbO_2) and reduced Hemoglobin (Hb). It is this known relationship that makes it possible to calculate (HbO_2). The photo sensor shown in Figure 1 measures the absorption of the selected wavelengths of light passed through living tissue.

The pulse oximeter probe is a critical part of the measurement system and has been identified as the source of occasional measurement inaccuracies. Probes may be reusable or disposable, used on different body parts (ear, finger, scalp, etc.), and come in a variety of forms. A new development (from Medical Taping Systems) is the possible reuse of disposable probes. A patented technology has been developed to modify select commonly used disposable probes by developing a sterile shield and new adhesives for continued reuse. The purpose of this product is to reduce the cost to the healthcare institution through the extended life of lower cost disposable probes. This product recently received an FDA 510(k). If accepted and generally used, it will be important to verify that the modified probes work according to their original specifications throughout their life.

PULSING SCHEMES

The red and infrared LEDs within a particular probe are driven in different ways, depending on the manufacturer. Most probes have a single photodetector, so the light sources are generally sequenced on and off. Figure 2 shows an example of a typical pulsing scheme. To compensate for ambient light during the time when both LEDs are off, the light level is measured and then subtracted from each light channel between cycles. This minimizes the effects due to ambient conditions which may vary during monitoring.

Depending on the make and model of pulse oximeter, the drive currents of LED pulse widths, off and on cycles between pulses, and cycle times can all vary. Wide variations in pulsing schemes used by the various manufacturers optimize individual performance and avoid patent litigation. These design differences also lead to varying performance between models.

ABSORPTION

The output of the photodiode in a typical probe will have a raw signal that is represented in Figure 3. There will be one signal that represents the absorption of red light and one that represents infrared. The AC signal is due to the pulsing of arterial blood while the DC signal is due to all the non-pulsing absorbers in tissue. SpO_2 is

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estimated from the ratio (R) of pulse-added red absorbance at 660 nm to the pulse-added infrared absorbances at 940 nm.

$$R = \frac{AC\ 660 / DC\ 660}{AC\ 940 / DC\ 940}$$

R-CURVES

The typical R-curve calibration of a pulse oximeter is shown in Figure 4. An R-curve is a collection of R value coefficients that range from approximately .4 to 3.5 that the pulse oximeter will display as an SpO_2 (0-100%) reading based on the calculated R value. An R value of 3.50 is an SpO_2 reading of 0%, while an R value of 1.00 is an SpO_2 reading of 85% and an R value of .4 is an SpO_2 reading of 100%. All R value and SpO_2 relationships are approximate.

MANUFACTURERS' ALGORITHMS AND CALIBRATION METHODS

There are several ways in which the pulse oximeter designer can obtain data for the calibration of the pulse oximeter. Traditionally, data for the calibration was obtained empirically through in-vivo experiments on human subjects. This produced a product that was clinically acceptable but comparison between manufacturers and even a manufacturer's own models revealed differences. The second method is the in-vitro test system which is closer to a "gold standard" than other methods.

IN-VIVO EXPERIMENTS

In-vivo experiments consist of lowering a live patient's saturation level and simultaneously comparing an arterial blood sample on a co-oximeter to a pulse oximeter attached to the patient. These experiments are good for obtaining data on a patient from 100% to 80% SpO_2, yet it is difficult to generate sufficient clinical data on a patient below 80%. Therefore, manufacturers using in-vivo test results might be forced to extrapolate their calibration curves below 80%. This creates the potential for saturation inaccuracies below 80%.

IN-VITRO TEST SYSTEMS

In-vitro test systems are quite elaborate systems that require whole blood, but ultimately produce the most clinically valid results (Figure 5). The test setup consists of a series of tubing that transfers whole blood

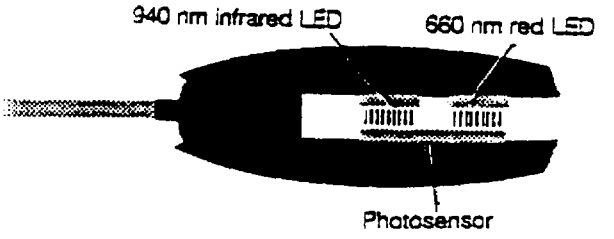


FIGURE 1. A typical pulse oximeter probe.

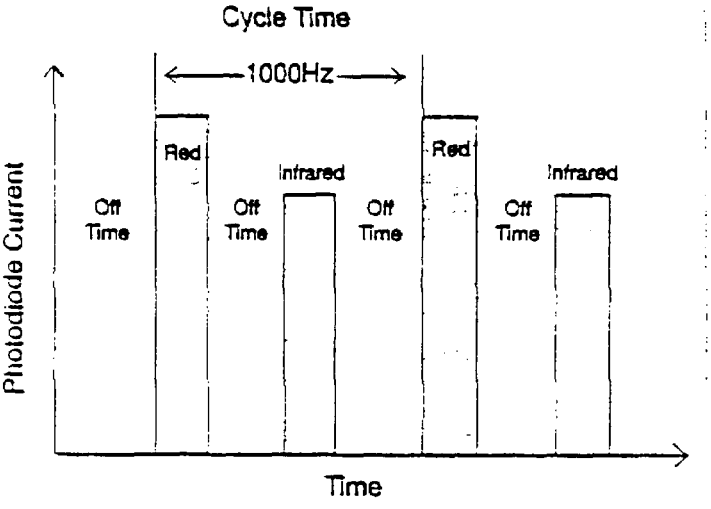


FIGURE 2. Typical pulsing of red and infrared LEDs by a pulse oximeter.

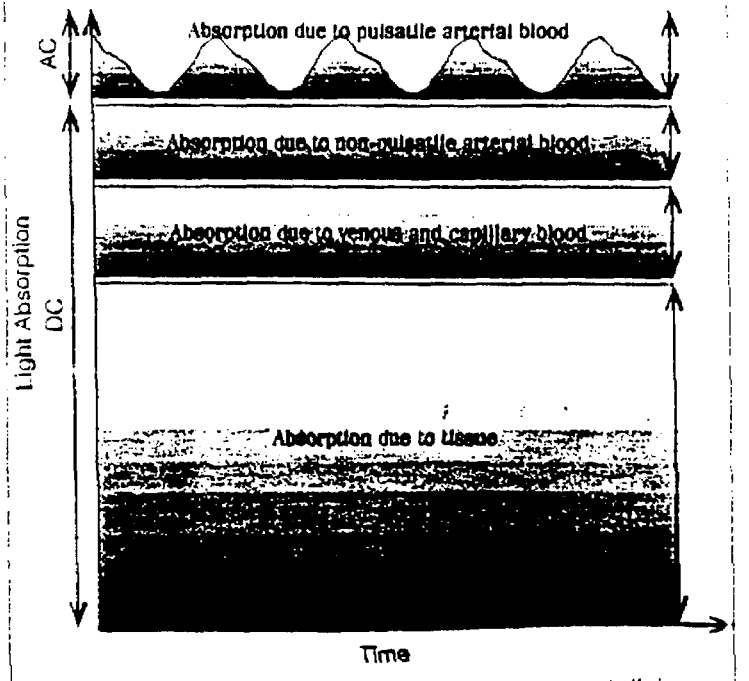


FIGURE 3. Illustrates the light absorption through living tissue.

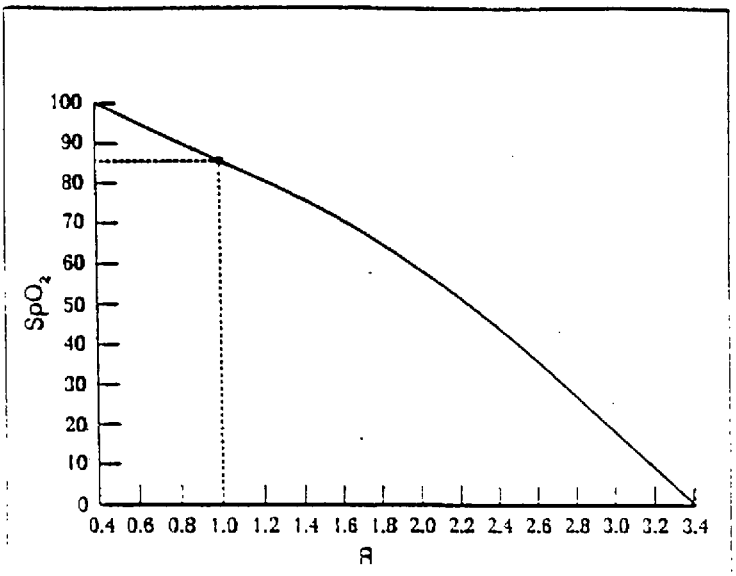


FIGURE 4. Typical R-curve calibration of a pulse oximeter.

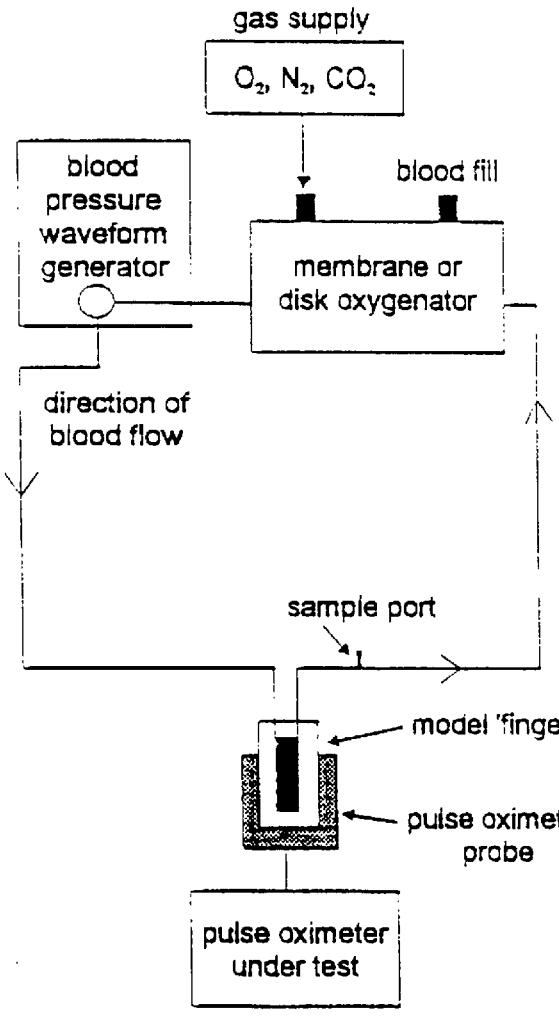


FIGURE 5. In-vitro test system for verifying pulse oximeters.

to a "model" finger. The pulse oximeter to be tested or calibrated is connected to the finger model. The blood within the system is pulsed using a blood pressure waveform simulator. The blood within the system is oxygenated using an external gas mixture of O_2, N_2,CO_2, and a membrane or disk type oxygenator. This system allows the user to change the shape of the pressure waveform and vary the heart rate. The reading on the pulse oximeter is recorded and simultaneously a sample of blood from within the system is analyzed by a co-oximeter and compared with the reading on the pulse oximeter. This system yields a pulse oximeter calibration that is accurate down to 50% SpO_2 and lower. Most pulse oximeters have no specified accuracy below 50%.

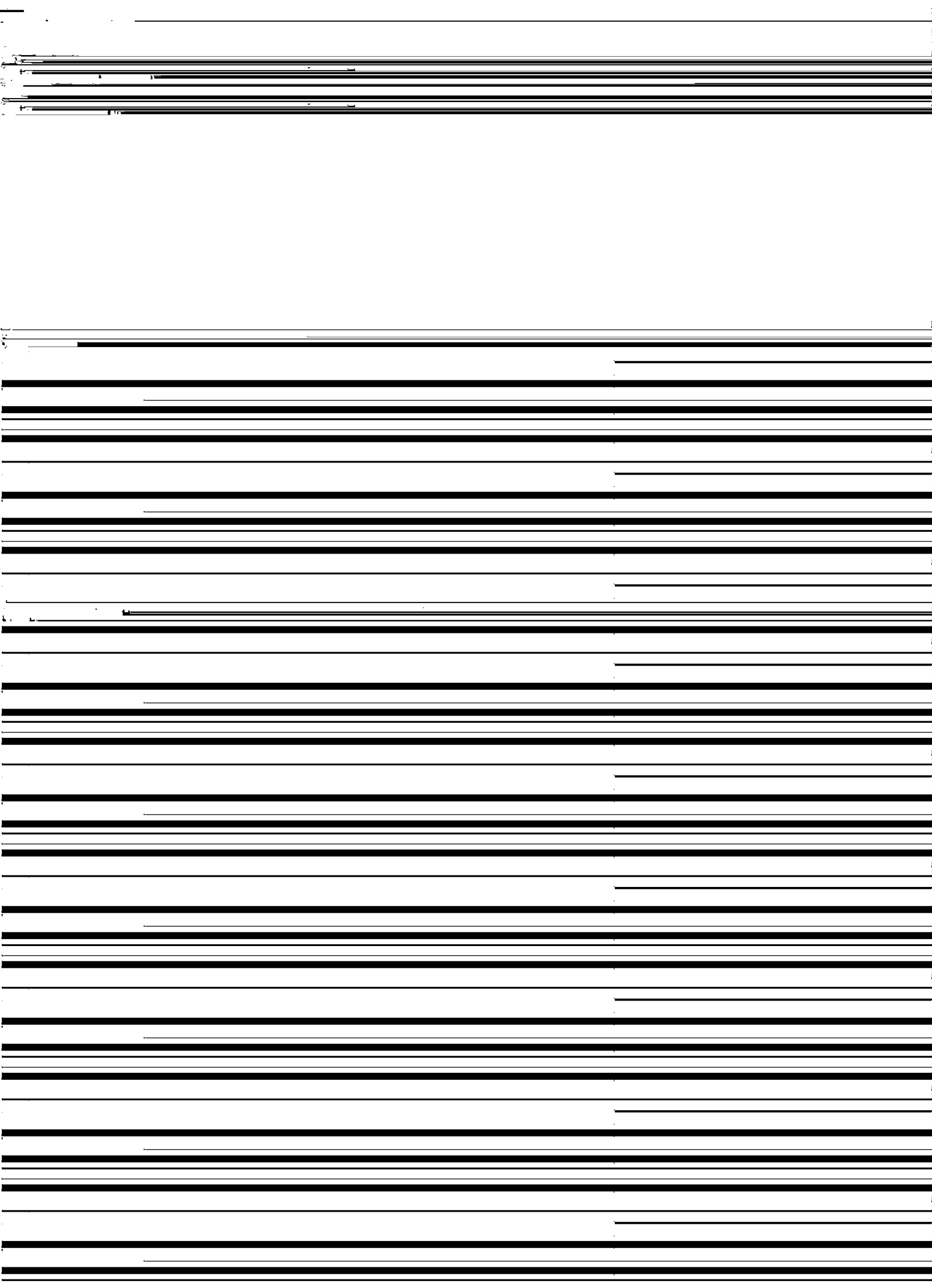
WAVELENGTH OF LEDs

The R-curve or calibration of a pulse oximeter can be shifted or affected by the wavelength of the LEDs used in making the probe. LEDs of the same type from the same manufacturer can vary as much as ±15 nm in wavelength. Certain manufacturers of pulse oximeters buy LEDs already screened to ±1 nm. For the manufacturers that use LEDs with a ±15 nm variation in wavelength, each probe is manufactured with a unique identifier. When these probes are plugged into a pulse oximeter, it identifies the probe and modifies the calibration factor. There can be as many as 30 different probes for a single manufacturer. The manufacturers of probes with tight tolerance LEDs don't face this problem. It should be realized that a pulse oximeter cannot detect a shift in wavelength in an LED.

Clinical studies clearly show significant performance differences between makes, especially below 80% or during profound hypoxia. As the manufacturer strives to improve performance in updated versions, users need to realize older products may still be in use.

ACCURACY AND PERFORMANCE OF PULSE OXIMETERS IN DIFFERENT CLINICAL SETTINGS

Pulse oximeters measure the presence of oxyhemoglobin (HbO_2) and reduced hemoglobin (Hb) only. Increased amounts of carboxyhemoglobin (HbCO) and methemoglobin (MetHb) will cause the pulse oximeter readings to be different than one produced by laboratory equipment or a co-oximeter.



CONCLUSIONS

The importance and universal application of pulse oximetry monitoring is clear and uncontested. While the technology itself is relatively well understood, each manufacturer's product has utilized the common fundamentals differently. These differences include probe variations, unique pulsing schemes, and proprietary algorithm and calibration methods. Recent reports from the FDA have shown measurement irregularities in the presence of motion artifact. Other irregularities such as pulse strength and ambient light have been shown to affect pulse oximeter results.

With the advent of opto-electronic simulators, field-based biomedical and clinical engineers can now adequately compare products under a wide variety of conditions. In addition, since the entire system can be tested, electronic versus probe problems can be segregated. Finally, documentation, preventative maintenance and quality assurance testing can be performed as prescribed. □

AVAILABLE STANDARDS FOR PULSE OXIMETERS

Guidelines and standards available for pulse oximeters are listed below. In addition, over 500 articles have been published on various issues related to pulse oximeters.

- American Society of Anesthesiologists, Standards for Basic Intra-Operative Monitoring, 1986 (0696-ASA).
- American Society of Anesthesiologists, Standards for Post-Anesthesia Care, 1989 (0697-ASA).
- American Society for Testing & Materials, Specifications for Pulse Oximeters, 1992 (F1415).
- International Organization for Standardization, Pulse Oximeters for Medical Use — Requirements, 1992 (ISO9919).

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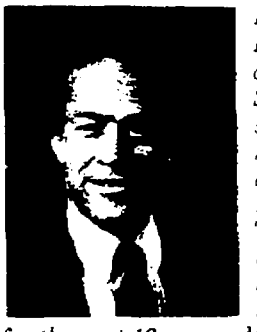

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