PULSE OXIMETRY: ANALYSIS OF THEORY, TECHNOLOGY, AND PRACTICE

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ABSTRACT. Interest in two-wavelength classic, that is, nonpulse, oximetry began early in the 20th century. Noninvasive in vivo measurements of oxygen saturation showed promise, but the methods were beset by several problems. The pulse oximetry technique, by focusing on the pulsatile arterial component, neatly circumvented many of the problems of the classic nonpulse arterial approach. Today's pulse oximeter owes a good measure of its success to the technologic advances in light emission and detection and the ready availability of microcomputers and their software. Many clinicians have recognized how valuable the assessment of the patient's oxygenation in real time can be. This appreciation has propelled the use of pulse oximeters into many clinical fields, as well as nonclinical fields such as sports training and aviation. Understanding how and what pulse oximetry measures, how pulse oximetry data compare with data derived from laboratory analysis, and how the pulse oximeter responds to dyshemoglobins, dyes, and other interfering conditions must be understood for the correct application and interpretation of this revolutionary monitor.

KEY WORDS. Measurement techniques: pulse oximetry. Monitoring: oxygen. Equipment: pulse oximeters.

THE THEORY

> I placed my prism at this [light] entrance, that it might be refracted to the opposite wall. It was at first a pleasing divertissement to view the vivid and intense colours produced thereby . . . [Sir Isaac Newton (1642 to 1727), in a report in the *Philosophical Transactions* for 1672]

Light was, therefore, recognized to contain all colors of the visible spectrum of electromagnetic energy. Measurements of electromagnetic vibrations are frequency, expressed in hertz (Hz) (1 Hz = one cycle per second) and wavelength, expressed in nanometers (nm) (1 nm = one thousand millionth [1×10^{-9}] of 1 m). Red light, as used in PULSE OXIMETRY, can be measured at a frequency of 4.3×10^{14} Hz or a wavelength of 660 nm. The nanometer, yielding numbers much easier to deal with, is the unit typically used when discussing this part of the spectrum.

Newton's theory fostered the techniques of spectral analysis—that is, the ability to detect elemental composition by defining the unique light absorption "fingerprints." A major theoretic statement in early laboratory spectral analysis was the Beer-Lambert (or Bouguet's) law. Simply, this law states that the concentration of absorbant in solution can be determined as a mathematical function of the amount of light transmitted through the solution, providing that the intensity of incident light, the path length, and the EXTINCTION CO-

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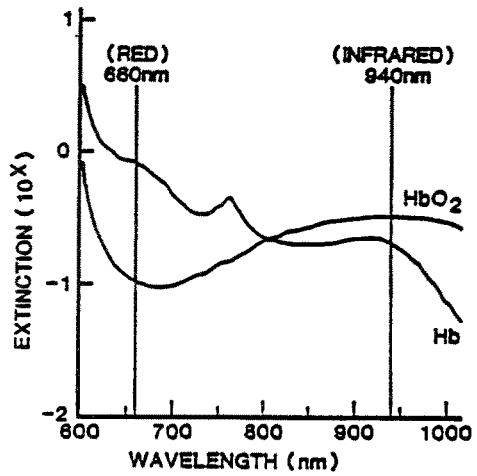


Fig 1. Oxyhemoglobin (HbO_2) *and reduced hemoglobin* (Hb) *exhibit markedly different absorption (extinction) characteristics relative to red light at 660 nm and infrared light at 940 nm. (Courtesy of Ohmeda)*

EFFICIENT of a substance at a particular wavelength are known. The absorbance of light by HEMOGLOBIN (Hb) and oxyhemoglobin (HbO_2) as a function of wavelength is shown in Figure 1. The absorbance or, more correctly, extinction of HbO_2 at the red wavelengths (650 to 750 nm) is less than that for Hb. Hence, HbO_2 is more transparent to red light than Hb is. Figure 1 also shows that the reverse is true, to a lesser degree, in the infrared region (900 to 1,000 nm). Research led by Nicolai, Kramer, Elam, Matthes, Millikan, and Wood in the early to mid-1900s sought ways to apply these facts to determine the HbO_2 concentration, or arterial blood oxygen saturation (SaO_2) [1].

Complex and numerous problems of applying the Beer-Lambert law to in vivo analysis brought the development of two-wavelength, in vivo oximetry to a halt during the 1950s. Why the Beer-Lambert law was not totally effective becomes apparent when we examine how light behaves in this application.

As the law of conservation of energy states, energy cannot be "created or destroyed"—and this applies to light energy. For the Beer-Lambert law to work, all light in the system should be accounted for, that is, incident light = light transmitted + light absorbed. This can work in a very controlled experiment with relatively short path lengths. Experiments with human tissue present several obstacles. Consider: incident light = light transmitted + light absorbed + light scattered + light reflected. On human subjects:

- Light is scattered by the skin surface, tissue, muscle, bone, and blood.
- Light is reflected by the skin surface, which can be a function of skin surface texture and color.
- Light is absorbed by tissue components other than the blood and absorption is also dependent on pigmentation and thickness of the test site.
- The blood is a nonhomogeneous liquid capable of nonlinear absorption of light, particularly as hematocrit varies.

The CLASSIC OXIMETRY (that is, nonpulse, two-wavelength, in vivo oximetry) could not deal effectively with all the variables.

EVOLUTION OF PULSE OXIMETRY

The prominent forerunner to the pulse oximeter was the Hewlett-Packard ear oximeter (HP 47201A), which used a tour de force of technology to solve the problems found in the two-wavelength approach. By using eight wavelengths (from 650 to 1,050 nm), this unit compensated for all the effects of "skin pigmentation, ear thickness, or earprobe motion" [2]. Featuring precalibration, ear vascularization via heat, and a fixed path length, this unit solved many of the problems that plagued earlier devices [3].

Clinical accuracy tests pointed to the ear oximeter as an acceptable device that was a boon to the pulmonologists and sleep researchers of the mid-1970s. Although it was thought to be the "gold standard" for oximeters, recent tests at low saturations uncovered unstable performance below an arterial oxygen saturation (SaO_2) of 70%, and its inability to deal with carboxyhemoglobin (HbCO) is documented [4,5].

A major advance came with the recognition that the pulsatile nature of the arterial blood can be exploited in oximetry. Pulse oximetry uses the physiologic activity of the cardiac pulse as the basis for a system to determine SaO_2. The idea of using the cardiac rhythm as a "filter" for in vivo measurement was first attempted in Japan. This new concept took commercial form in the Mochida Oximet (eventually Minolta), the first pulse oximeter manufactured and marketed. This unit relied on analog electrical circuitry and had bulky fiberoptic cables similar to those of the Hewlett-Packard ear oximeter. Its performance was nearly acceptable clinically, with marginal accuracy, "$\pm 5\%$ of that obtained from the blood gas method" [6], and it exhibited some problems with artifacts: "The measurement is interrupted when the fingertip changes its position against the light beam. This frequently occurs when the patient is shivering" [6]. As with classic oximetry, early pulse oximetry had to contend with limitations inherent in the hardware.

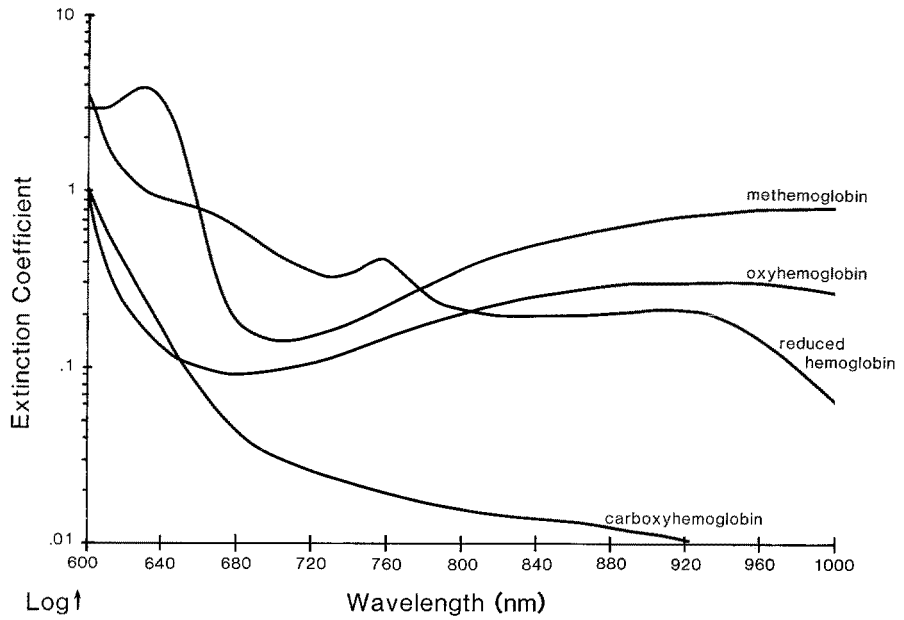


Fig 2. Hemoglobin extinction curves showing relationship of reduced hemoglobin, oxyhemoglobin, carboxyhemoglobin, and methemoglobin to light absorption. (Courtesy of Ohmeda)

The first successful new-breed pulse oximeter, the Biox II (Ohmeda), ushered in a new era. The Biox II was a microprocessor-based, convenient-to-use, smaller, and less expensive device having clinically acceptable accuracy [7,8]. Major interest in pulse oximetry in the United States was sparked by the efforts of Dr William New (Nellcor), who saw the advantage of oxygenation monitoring during anesthesia. Optimizing one of the key elements of this new approach—small, inexpensive light emitters and detectors—the Nellcor N100 featured disposable sensors.

PULSE OXIMETRY: PRINCIPLES

In order for spectrophotometric measurements of blood to be made in vivo a number of criteria must be met:

1. The tissue must be reasonably transparent to the wavelengths of light that are to be considered for the measurement.
2. The absorption characteristics must be different between the specific species for each wavelength that is to be considered.
3. There must be a reasonable method for producing the wavelengths that are being considered.
4. There must be an acceptable means of detecting the wavelengths of interest.
5. The minimum number of discrete wavelengths that are required must be equal to the number of significant absorbers that are present.

The first criterion limits the range of wavelengths that are reasonable choices to the red and near-infrared regions. Tissue and pigmentation absorb the blues, greens, and yellows, and water absorbs the longer infrared wavelength. As can be seen in Figure 1, Hb and HbO_2 vary substantially relative to each other in the 600- to 1,000-nm range (red to near infrared)—this meets the second criterion. The availability of light sources in this region is quite good. There are a variety of light-emitting diodes (LEDs) with outputs in this wavelength region; they are commonly used for displays and optical communication applications. In addition, they are small, efficient, and reasonably stable. Two common LEDs have nominal wavelengths of 660 and 940 nm. The wavelengths in the range of 600 to 1,000 nm are also easy to detect with a silicon photodiode, thus fulfilling the fourth criterion. The last criterion is less straightforward. Obviously there are absorbers other than Hb and HbO_2 in the blood. (Figure 2 shows the absorption characteristics of methemoglobin [MetHb], HbO_2, reduced Hb, and HbCO.) Fortunately these four types of Hb are the only significant absorbers *normally* found in blood. Note that at 660 nm, the MetHb and the Hb have similar extinctions (a measure of absorption), as do HbCO and HbO_2. If only two

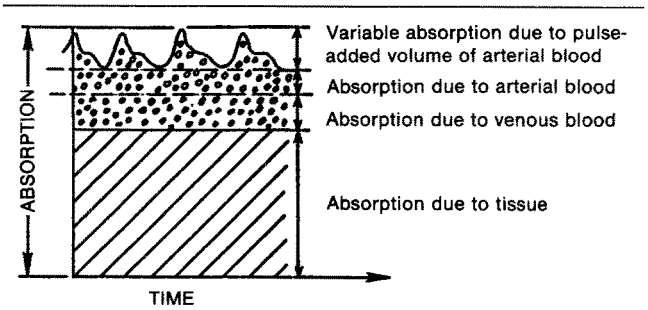


Fig 3. Tissue composite shows dynamic and static components affecting light absorption. (Courtesy of Ohmeda)

wavelengths are used the effect is, very roughly, to "lump" or combine MetHb with Hb and HbCO with HbO_2.

The MetHb being seen as Hb usually is not clinically significant; because it is not carrying oxygen the oxygen saturation value is still correct. HbCO does present a problem because it will be "counted" as an oxygen-carrying form and thus cause the measured oxygen saturation value to be reported larger than it actually is. The effects of these and other absorbers, such as dyes, are discussed later.

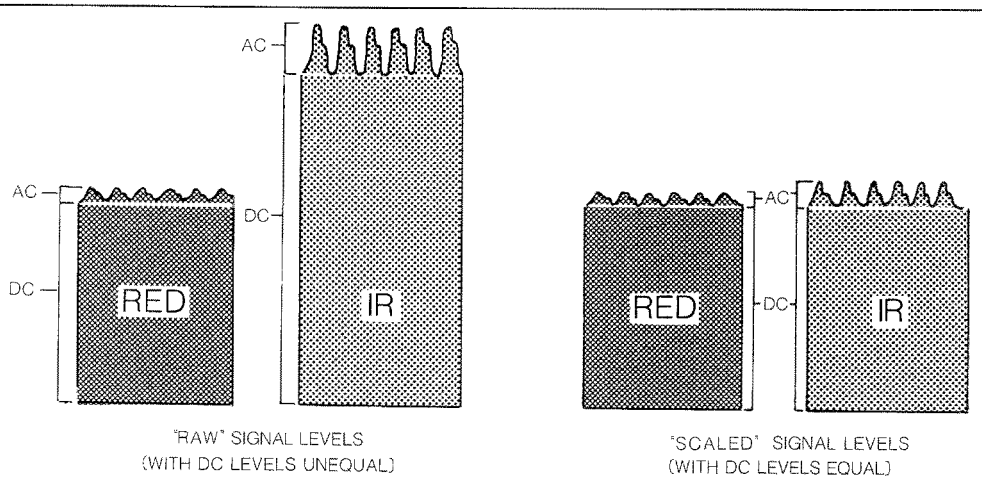
For a workable system, the signals coming from arterial blood must be isolated from those representing venous blood, tissue, and other absorbing material. The method by which this is accomplished is responsible for the term *pulse oximetry*. Figure 3 represents a tissue cross section. Note that light absorption by the various substances is constant over time, with the notable exception of arterial blood. The absorption signals from arterial blood vary with each contraction of the heart as the volume of arterial blood changes.

It is convenient to define the varying or dynamic part of the signal as the alternating current (AC) signal and the static component as the direct current (DC) signal. The amplitude of the DC signal is affected by the intensity of the light source, sensitivity of the detector, and amount of constant absorbers that are present (sample thickness). These same factors will affect the AC signal amplitude, as will the perfusion (amount of blood volume change per pulse) and the oxygen saturation. To make any useful comparisons between the absorption as the red wavelength and the infrared wavelength the AC signals must be scaled by the DC signals. Dividing the AC level by the DC level (at each wavelength) gives a corrected or scaled AC level that is no longer a function of the incident intensity [9].

This scaling process, performed by electronics, mathematics, or otherwise, yields values that are compensated for variations in incident light intensity and represent the relative absorption of light at two wavelengths that is due to only the hemoglobin in the arterial blood (see Fig 4). The numeric ratio of the corrected red value to that of the corrected infrared value yields a result that is easily converted to oxygen saturation, as shown in Figure 5. Figure 6 shows what the relative red and infrared AC signals would look like for various saturations.

The pulse oximeter's focus on just the "dynamic" arterial flow, along with the compensation process, neatly circumvent nearly all of the obstacles that have plagued the classic oximetry technique. Like all elegant solutions, pulse oximetry uses a simple concept to defeat complex problems. The simplicity, however, is deceptive.

Fig 4. Graphic representation of compensation process that must occur before light intensities at two wavelengths can be used for calculation of arterial oxygen saturation. This scaling process can be accomplished by several methods, electrically or mathematically. AC = *alternating current;* DC = *direct current;* IR = *infrared. (Courtesy of Ohmeda)*



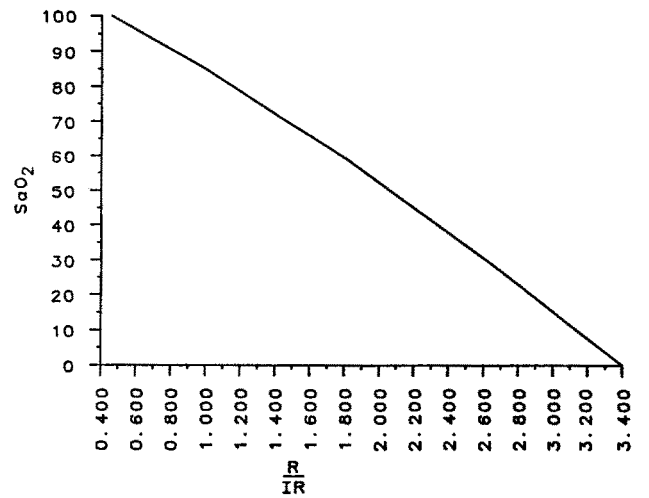


Fig 5. Relationship of red (R)*/infrared* (IR) *numeric ratio value to arterial oxygen saturation* (SaO_2).

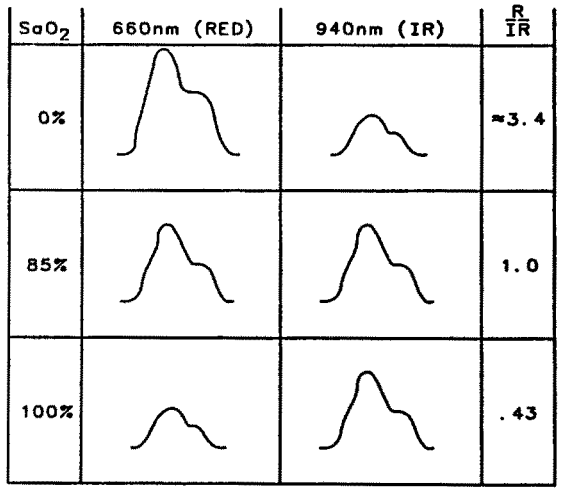


Fig 6. Relative plethysmographic signal amplitudes and arterial oxygen saturation (SaO_2) *values assuming the transmission intensities are equal.* R = *red;* IR = *infrared.*

PULSE OXIMETRY: PRACTICE

Converting the principles just described into a practical device for clinical application involves many additional considerations. These include technical issues related to optics, signal-to-noise ratios, data acquisition, signal processing, mechanical configuration, and human interface.

The oximeter probe consists of light sources (LEDs), a detector (photodiode), and an appropriate mounting structure to support the specific method of application. Electronically, the probe is quite simple in that the only necessary function is the ability to turn the LEDs on and off and to provide for the detected signal to be returned to the main electronics for processing. In addition, the probe provides a means of identifying itself to the system for calibration purposes. The mechanical structure today (owing much flexibility to the ideal light emitters and detectors that are available) is optimized on the basis of the intended application.

Electronically, the pulse oximeter consists of the following:

1. LED timing and probe control
2. Analog signal conditioning and/or processing
3. Data acquisition
4. Digital signal conditioning and/or processing
5. Display and control system
6. Internal system diagnostic functions

Three different light levels are measured by the detector: the red light level, the infrared light level, and the ambient light level. To accomplish this with a single detector the light sources must be sequenced on and off. Figure 7 shows the light timing sequence used in the Ohmeda 3700 oximeter. Each time the red LED is on, the analog electronics obtain a sample of the red intensity. This occurs likewise for the infrared LED. By measuring the light level when both LEDs are off, it is possible to subtract this level from each channel (red and infrared) on an instant-by-instant basis. This serves to compensate for ambient, or room, lighting, which may

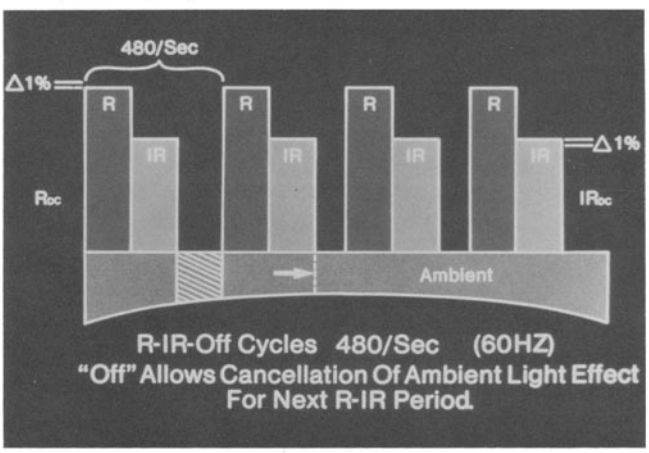


Fig 7. Ohmeda light-emitting diode timing sequence shows frequency and first step of ambient light filtration process. R = *red;* IR = *infrared;* DC = *direct current. From Wukitsch MW. Pulse Oximetry: Historical Review and Ohmeda Functional Analysis.* International Journal of Clinical Monitoring and Computing, *Vol 4, pp 161–166, 1987. Used with permission.*

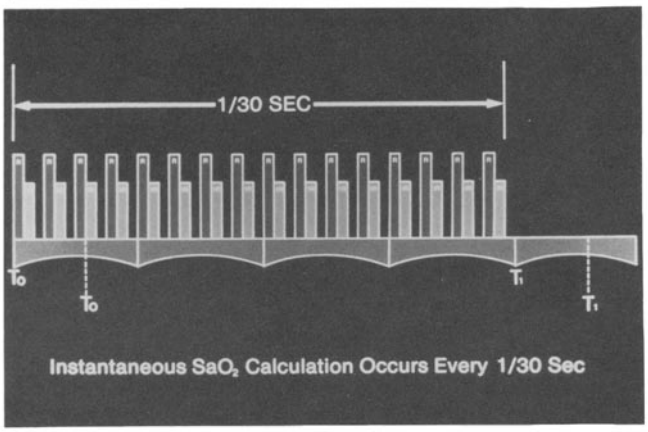


Fig 8. Representation of light-emitting diode sequencing occurring over 1/30 of 1 second as it relates to red (R)*-infrared* (IR) *intensity sampling and the instantaneous arterial oxygen saturation* (SaO_2) *calculation and the second step of ambient light filtering.* T_0 = *time zero, or "start";* T_1 = *time one, or "finish." From Wukitsch MW. Pulse Oximetry: Historical Review and Ohmeda Functional Analysis.* International Journal of Clinical Monitoring and Computing, *Vol 4, pp 161–166, 1987. Used with permission.*

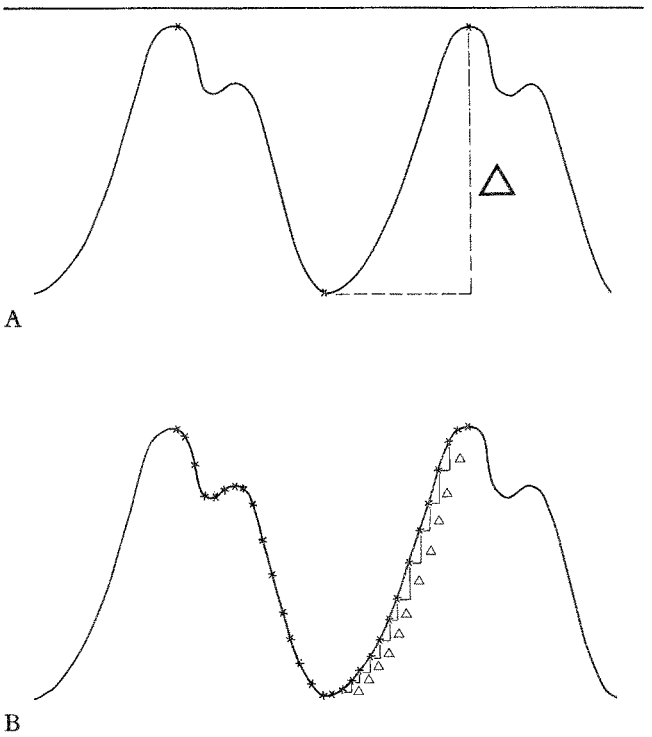


Fig 9. Changes in light intensity can be measured at the minima and maxima points of the pulse wave or many times along the wave. X–X produces a change in intensities (Δ) on both red and infrared wavelengths. (A) represents the change in light intensity from the minima to the maxima point on the arterial pressure wave form from which saturation can be calculated once per heart beat. The multiple measurements depicted in (B) allow many sample points that can be subject to validation schemes such as the running weighted average. (Courtesy of Ohmeda)

change during the course of routine monitoring. Sequencing the LEDs at a frequency that is an integer multiple of the power line frequency allows the system to operate "synchronously" with "flickering" room lights (fluorescent lights normally generate a 120-Hz flicker on 60-Hz power). This avoids light flicker–induced fluctuations on the probe's photodetector, which could distort or disguise the tiny signals representing actual arterial blood flow.

The light timing sequence, shown in Figure 7, cycles at 480 times per second (60-Hz power). A "stream" of these sequences, as depicted in Figure 8, shows the timing as it relates to the INSTANTANEOUS ARTERIAL OXYGEN SATURATION (SaO_{2i}) CALCULATION, which occurs thirty times per second (60-Hz power):* It is significant that the 480-Hz timing, 60-Hz power, and 30-Hz SaO_{2i} calculation are numerically related. The timing and sequencing frequencies serve as a filter against environmentally induced error [10].

Why SaO_{2i} at 30 times per second? Since the pulse oximeter is making use of pulsatile flow signal, the simplest approach might be to measure the minimum to maximum value (delta [Δ]) at the red and infrared wavelengths for each pulse and use this Δ red/Δ infrared value to calculate SaO_2 (Fig 9A). This method works but has a number of unacceptable side effects. The first is that a calculation of oxygen saturation is possible only once per heart beat. Because some method of averaging the saturation values is required to minimize the effects of artifacts, and because there is a clinical requirement that the response time to changes in saturation be reasonably fast, one measurement per beat allows no more than ten measurements to be averaged for the system to maintain an acceptably short response time (10 s at 60 beats/min). However, it is possible to make use of the principle that the sum of the parts equals the whole. By calculating the Δ, or change, in the signals 30 times per second, we can calculate the SaO_{2i} value regardless of pulse rate (Fig 9B). With this method the Ohmeda pulse oximeter provides 180 saturation values in a 6-second interval (90 values in a 3-second interval). Having this large number of data points allows the use of a comprehensive scheme to selectively "weight" each sample to further enhance the stability of the calculation while maintaining acceptable responsiveness.

*The light timing sequence and SaO_{2i} calculation occur at 480 and 30 Hz, respectively, with 60-Hz power. With 50-Hz power, these numbers are 400 and 25 Hz, respectively.

Table 1. Simplified Representation of Ten SaO_{2i} Values with Assigned Weights

Variable	At One-Third of 1 Second									
SaO_{2i} (%)	94	93	94	95	72	30	45	85	95	94
wt_i	10	10	10	9	5	1	1	7	9	10
$SaO_{2i} \times wt_i$	940	930	940	855	360	30	45	595	855	940

Table 2. Displayed Arterial Oxygen Saturation Values Derived from Averaging of Processed Average Values over Three Seconds

	Second 1			Second 2			Second 3			
Processed average (avg^P)	92	93	93	92	93	94	93	94	94	90
	Displayed Value 1 = 93.1[a]									
		Displayed Value 2 = 92.8[a]								

[a]The Ohmeda Biox pulse oximeters round decimals up or down.

Analysis of the SaO_{2i} values showed that several factors identify the validity of an individual SaO_{2i} value. These include the magnitude of the Δ of AC signal for the sample, the point in the cardiac cycle where the data were taken, and the correlation of the SaO_{2i} value with the current displayed "average" saturation value. For example, if SaO_{2i} = 72% and the present 3-second average is 93%, this instantaneous value would be assigned a comparatively low weight. The following example shows a simplification of the processing that uses the WEIGHTED AVERAGING scheme. We assume here a 3-second processing time. Data points taken at 1/30-second intervals are first "weighted" and then "averaged." This produces what we will call a "PROCESSED" AVERAGE (avg^P) every 0.33 seconds. Each avg^P value is again averaged with the previous eight avg^P values, yielding a new SaO_2 value that is sent to update the displayed SaO_2—in the 3-second mode, every 0.33 seconds.

Table 1 is a simplified representation of ten SaO_{2i} values with assigned INSTANTANEOUS WEIGHTING FACTORS (wt_is) of 1 to 10 (1 = low value, 10 = high value), indicating SaO_{2i} values over 0.33 second. The wt_i is based on the perceived validity of the SaO_{2i} value. The following formula is used to determine avg^P:

$$avg^P = \sum_{j=1}^{10}(SaO_{2i}{}^j \times wt_i{}^j) \Big/ \sum_{j=1}^{10} wt_i{}^j,$$

where j is the number of sample pairs being multiplied. From the values shown in Table 1, we can determine that

$$\sum_{j=1}^{10}(SaO_{2i}{}^j \times wt_i{}^j) = 6{,}490 \text{ and } \sum_{j=1}^{10} wt_i{}^j = 72.$$

Applying the above formula would yield an avg^P value of 90.1 for this 0.33-second period. In the 3-second averaging mode, this avg^P (90.1, rounded to 90) is averaged with the previous 2.66 seconds worth of avg^P values, producing the new displayed SaO_2 values shown in Table 2.

Light transmission measurements during portions of the cardiac cycle showing the greatest Δ (that is, the rising portion) produce the most valuable SaO_{2i} values. Where the Δ is small (the flat part of the cardiac cycle, see Fig 9), the SaO_{2i} values can be inaccurate and misleading. It can be seen from the preceding example that, because of this weighted averaging process, the SaO_{2i} values of 72, 30, and 45% have little effect on the total mathematics.

Intuitively, we appreciate that the actual saturation did not change 23% (95 to 72%) in 1/30 second. By using a series of criteria, the microprocessor can assign a value to each instantaneous SaO_2 value, thereby placing it appropriately within the system, enhancing both accuracy and stability. The weighted averaging system allows stability over short, sharp aberrations (something like an automobile shock absorber) by filtering out the suspect values. During periods of rapidly changing actual clinical SaO_2 values, all "weights" will tend to be reduced, thereby facilitating rapid response and close tracking of patient conditions.

SIGNAL STRENGTH

The signal strength indication can help in judging oximeter function. To return to the AC/DC fraction, our tests have shown that pulsatile strength is adequate when this fraction exceeds 0.2%. (The infrared channel is used in this case as it changes minimally within the normal range of PULSE OXIMETER ARTERIAL OXYGEN SAT-

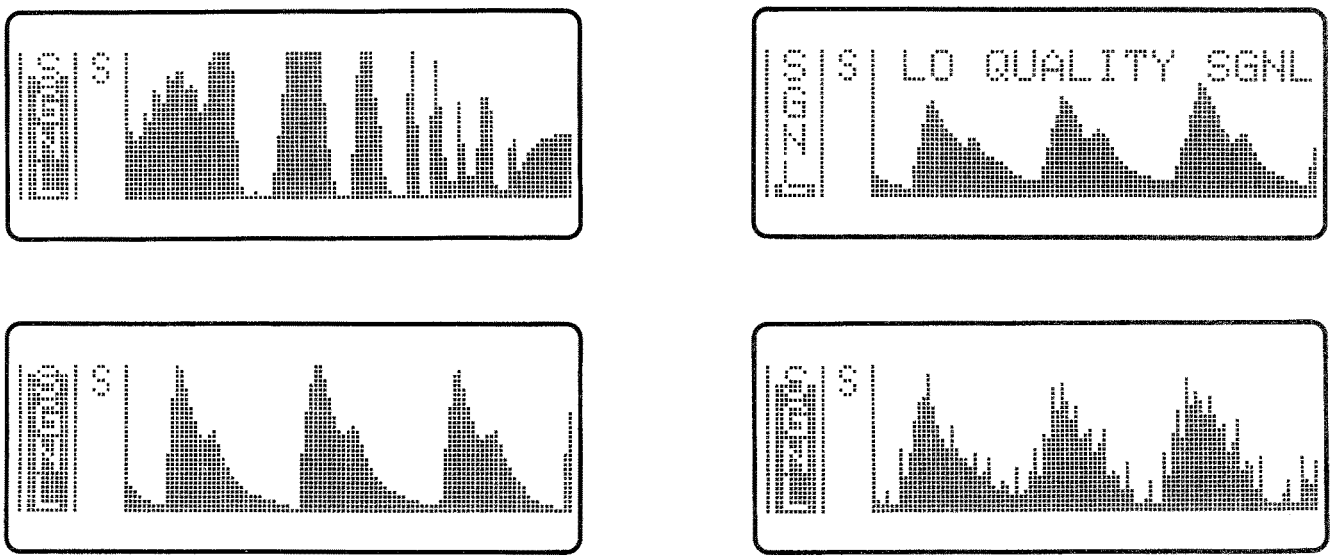


Fig 10. Waveform examples. S = *slow response;* SGNL = *signal strength indicator.*

URATION (SpO_2) values as compared with the red channel):

(AC/DC) × 100 > 0.2% = adequate pulsatile signal.

On the Ohmeda 3700 oximeter the signal strength indicator (SGNL) registers "full" when the value is 1%. We have chosen to show only this "bottom" 1% area (even though a 3% ratio can be considered normal and 10 to 11% high) because this factor becomes important in the low ranges. A message, "Low-Quality Signal," will be displayed if the signal strength indicator falls below 0.2% (Fig 10). Although SpO_2 values may still be valid, we believe clinicians should be warned of this low pulsatile level, which can result, for example, from shock, cold temperature, decreased cardiac function, or low hematocrit.

The system of weighting factors also can influence the signal strength display. Low weights can be assigned to SaO_{2i} values due to a low AC level or inconsistent SaO_{2i} calculations. When the weighting factors are summed in preparation to calculate the avg^P, this total, below a certain number, will also drive the signal strength indicator down. Therefore, the indicator will fall during low AC levels (poor perfusion) or low SaO_{2i} weights (artifact, etc), or both.

Plethysmographic Waveform

The Ohmeda 3700 pulse oximeter was the first to display a "plethysmographic" waveform, presenting a familiar picture to the clinician. With the plethysmographic waveform, problems related to probe placement or artifact that may not be recognized by the microprocessor and that may not be apparent from other types of displays (for example, amplitude only) can be observed by the clinician and acted on, satisfying the major requisite: that the pulse oximeter has pulsing arterial blood as the source of its signal [11,12].

The plethysmographic waveform display plus the signal strength indicator allows the clinician to use the pulse oximeter under the most difficult circumstances—for instance, vasoconstriction or heart massage—and to assess when displayed oxygenation levels are based on true arterial blood flow or on artifacts by observing the *shape* of the waves. Clinicians seasoned in the use of the pulse oximeter have used the rule of thumb that the SpO_2 value is valid when the oximeter pulse rate and electrocardiographic (ECG) heart rate are within one to two beats of each other. With the waveform display this observation is not necessary. Thus, the waveform display, now available on several models, makes the pulse oximeter a more useful and reliable device—particularly for monitoring the most compromised patients [13].

INTERFERING SUBSTANCES

Dyes

Because pulse oximetry works on the principle of light absorbance, dyes introduced into the blood stream

could interfere with the calculation of SaO_2. Dyes such as methylene blue, indocyanine green, indigo carmine, and fluorescein have been studied. Their effects range from significant to negligible, respectively [14,15]. Methylene blue has the highest peak absorbance of these dyes at 660 nm, and therefore has the greatest effect on pulse oximetry. The relationship is inversely proportional: the greater the amount of methylene blue, the lower the SpO_2 displayed. Of interest is the fact that methylene blue also depresses the readings measured by the CO-OXIMETER. Suffice it to say, the clinician should be aware that these dyes may interfere with light transmission at the red or infrared wavelengths used, causing errors in the displayed pulse oximetry readings.

HbCO and MetHb

Of perhaps greater importance (as previously mentioned) are the effects of HbCO and MetHb on the pulse oximeter. HbCO is a problem of urban life and, of course, is a consequence of smoking. In most nonsmokers, HbCO levels are below 2% but can be higher depending on the local environment [16]. MetHb levels are routinely less than 1%. However, methemoglobinemia does occur, and its effect on pulse oximetry is a source of controversy.

We studied the effects of both HbCO and MetHb on pulse oximetry with an in-house computer simulation. Both HbCO and MetHb tend to elevate the SpO_2 value displayed to greater than the actual SaO_2. HbCO has a larger effect than MetHb on the displayed number. For example, with an actual SaO_2 of 90% and an HbCO level of 10%, the SpO_2 value would be approximately 97 to 98%. The effect is less at lower SaO_2 values. At an actual SaO_2 of 60% and 10% HbCO, the displayed SpO_2 value would be approximately 64%. Barker et al [17] recently demonstrated this effect in a canine model.

For MetHb, at an actual SaO_2 of 90% and an actual MetHb level of 10%, the SpO_2 value would be approximately 91.5%. However, at an SaO_2 of 60% and 10% MetHb, the SpO_2 value would be approximately 66.5%. This effect also was demonstrated recently in a canine model [17].

Clinically, the errors produced by HbCO and MetHb usually are not significant. These substances (as long as their concentrations remain relatively constant) have no effect on the pulse oximeter's ability to trend. When the accuracy of pulse oximetry is being tested, subjects or patients with HbCO greater than 3% and MetHb greater than 1.5% are best excluded. The calibration of the Ohmeda Biox 3700 was performed on healthy nonsmokers with an average HbCO level of 1.6% and an MetHb level of 0.4% to limit false results.

Fetal Hemoglobin

High levels of bilirubin and fetal hemoglobin (HbF) have always been presented as possible problems for pulse oximetry. Bilirubin was known to have an effect on the Hewlett-Packard ear oximeter [18]. However, the two wavelengths used by current pulse oximeters are, in theory, relatively immune to the influence of bilirubin. A recent clinical report confirms this [19].

It is well known that HbF shifts the oxyhemoglobin dissociation curve to the left. Thus, the question has arisen, is the pulse oximeter (which was calibrated for adult Hb) actually reflecting true SaO_2? A theoretical model generated in-house, as well as experimental data recently published [20], demonstrate that HbF has no clinically significant effect on pulse oximetry. The degree of HbF of course affects the correlation of SaO_2 to arterial oxygen tension (PaO_2). Clinicians concerned with the PaO_2 value must have an understanding of the HbF level when interpreting the SpO_2 reading.

ACCURACY

Pulse oximeters are adjusted for accuracy by the use of empirically observed data from human subjects. Early testing showed that this technique produced a clinically acceptable device [21]. However, in a recent interbrand comparison, the actual level of pulse oximeter accuracy "differed widely between instruments" [22], even though manufacturers specify the same relative accuracy.

In vivo experiments make available data in the region of 80 to 100% SaO_2, enabling manufacturers to ensure good predictability in this range. It is typically difficult to get sufficient numbers in the 60 to 75% SaO_2 range to ensure accuracy within this range, thus manufacturers are forced to extrapolate their 80 to 100% results downward. This fact caused some surprises and a few red faces when Severinghaus and Naifeh [22] gave manufacturers accuracy test results at the 50% SaO_2 level.

Accuracy at 50% SaO_2 initially was not consistent among the models tested. Whether accuracy at 50% SpO_2 is required is arguable, as clinicians generally strive to keep patients at SaO_2 levels above 90%. Nevertheless, manufacturers seized this opportunity to improve performance in the low ranges.

The question of pulse oximeter accuracy, particularly at or near the limits of its capabilities, still surfaces occasionally. Pulse oximeter performance has been well studied; a computer search of the literature on pulse oximetry recently turned up nearly 150 titles dealing with accuracy (from a total of more than 500 articles). These reported tests show that:

1. Accuracy results show fair consistency.
2. Test conditions vary, as does the subject population.
3. Pulse oximeters are compared with (a) SaO_2 calculated from blood oxygen tension, [SaO_2 (CALC)]; (b) SaO_2 determined spectrophotometrically by a CO-Oximeter [HbO_2 or SaO_2 (FRAC)]; and (c) other noninvasive oximeters.
4. Performance is acceptable for most clinical settings.
5. Accuracy results many times fall outside of manufacturers' specifications.

It should be noted that past reports suggesting that the pulse oximeter measures "FUNCTIONAL" ARTERIAL OXYGEN SATURATION [SaO_2 (FUNC)] appear to have been recently disproven [17].

Most researchers understand that the device best suited for establishing pulse oximeter accuracy—a standard, if you will—is the CO-Oximeter.

Typically, these spectrophotometric devices determine HbO_2, HbCO, and MetHb. Although the CO-Oximeter value may not equal an SpO_2 value, an understanding of the HbCO and MetHb components can assist in the interpretation of the SpO_2 value.

SaO_2 calculated from arterial oxygen tension [SaO_2 (calc)] may be different from actual SaO_2. In order to calculate SaO_2 from arterial oxygen tension, correction factors for temperature, arterial carbon dioxide tension ($PaCO_2$), 2,3-diphosphoglycerate, and hematocrit must be inserted. Most often, arterial blood gases (ABGs) are analyzed with standard correction factors; seldom are all variables measured and inserted into the calculation. These factors can alter the shape and position of the oxyhemoglobin dissociation curve and, therefore, the derived SaO_2. SaO_2 (calc) from ABG is also "blind" to HbCO, although for a different reason and to a different degree than the pulse oximeter. The most appropriate "standard" to use as a gauge to pulse oximeter performance, then, is the CO-Oximeter [23].

Statistical analysis provides the tools necessary to compare the SpO_2 value to the "standard" of laboratory-derived results. When properly used, the various calculations, such as standard deviation, regression line, and standard error of estimate, can lead to an exact understanding of the data. These analytic devices plus an understanding or selective screening of the subject population can lead to a tightly controlled assessment of performance that is of fundamental importance to both the clinician and the manufacturer. Expecting that results of a meticulously controlled study will be viable in everyday clinical usage can be misleading, however.

Extensive use of pulse oximetry over a wide range of situations and conditions has shown that readings can vary over a relatively wide band—certainly beyond the manufacturers' specifications. The problems of small signal, susceptibility to artifact, skin and tissue factors, patency of arterial flow, venous pulsations, and dyshemoglobins in combination can contribute to SpO_2 inaccuracies approaching five or more percentage points from true SaO_2.

The terms *tolerance interval* and *prediction limits* are useful in qualifying the pulse oximetry reading. These represent boundaries within which the pulse oximeter is correctly indicating, as a function of time: "It appears that, . . . the 99% prediction limits are within ± 8% of the calculated regression line" [24]. This means that the pulse oximeter reading is within 8% of actual SaO_2 99% of the time (assuming the calculated regression line equals the line of identity). Lowering or tightening the variation also lowers the confidence (that is, ±95% prediction limit within ±4%). The tolerance interval [25] and prediction limit both are useful. For example, with a 99% prediction limit of ±8%, when SaO_2 is 90%, SpO_2 will be 82 to 98% 99% of the time; with a 95% tolerance interval of −4.5 to +5.5, when SaO_2 is 90%, SpO_2 will be 85.5 to 95.5% 95% of the time.

Even though many factors can affect the accuracy of the SpO_2 reading, the pulse oximeter's value is its ability to provide precise—if not 100% accurate—oxygenation data on a continuous basis. Several recommendations can be made to increase the likelihood that SpO_2 readings will be within or close to manufacturers' specifications:

First, patient probes must be used according to manufacturers' recommendations. Second, the pulse oximeter must be "focused" on pulsing, arterial blood. A pulsatile display is mandatory; a display that shows the arterial waveform is best. Third, an acceptable signal size or strength must be verified (adequate perfusion). Fourth, it is advantageous to observe close correlation between pulse rate (pulse oximeter) and heart rate (ECG), particularly with nonwaveform oximeters. (This gauge of quality control, unfortunately, is lost when the ECG heart rate takes the place of pulse rate on oximeters relying on ECG for validity.)

Although the "standard" for pulse oximeter accuracy is somewhat nebulous, the weight of the literature points to acceptable clinical performance in a wide and growing variety of applications.

SUMMARY

In pulse oximetry, we have technology that is simple to understand—deceptively simple. The concepts involving light absorption are straightforward. The use of pulsing arterial blood as a first-line filter is clear. At first glance, the oximeter appears to be no great problem to

design or, for that matter, to use. Years of experience have taught us that this is not the case. Producing a device that works on all patients and in all clinical circumstances has taxed the technologic capabilities of device manufacturers. The investment necessary for a proper range of patient probes, for instance, is extremely high. Pressure for increased performance has all manufacturers searching for improvements in function, features, and hardware and software in the attempt to satisfy all the clinical requirements. These demands have led to added complexity, not only in the equipment, but also as concerns the users' appreciation and interpretation of the pulse oximeter measurement. As with all patient monitors the value of the pulse oximeter must be properly interpreted for a given patient.

Ultimately, the value of oxygenation data, the relative ease of use of the pulse oximeter, and the impact this device has made on clinical practice combine to justify the claim that pulse oximetry is the most important new monitor of this era.

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GLOSSARY

CLASSIC OXIMETRY Multiwavelength noninvasive oximetry that does not use the cardiac cycle (that is, arterial pulsations) as the basis for its calculation of arterial oxygen saturation.

CO-OXIMETER A laboratory device that spectrophotometrically measures hemoglobin, oxyhemoglobin, carboxyhemoglobin, and methemoglobin.

EXTINCTION COEFFICIENT A numeric measure of opaqueness; the greater the number, the greater the opaqueness.

Hb In this text often used to express reduced hemoglobin or hemoglobin unbound to oxygen.

INSTANTANEOUS ARTERIAL OXYGEN SATURATION CALCULATION See SaO_{2i}.

INSTANTANEOUS WEIGHTING FACTOR (wt_i) A weighting factor assigned to each INSTANTANEOUS ARTERIAL OXYGEN SATURATION value in the Ohmeda Biox pulse oximetry system.

PROCESSED AVERAGE (Avg^P) The pulse oximeter arterial oxygen saturation value derived from the sum of the product of the INSTANTANEOUS ARTERIAL OXYGEN SATURATION and the INSTANTANEOUS WEIGHTING FACTOR divided by the sum of the weighting factors on Ohmeda pulse oximeters.

PULSE OXIMETER ARTERIAL OXYGEN SATURATION See SpO_2.

PULSE OXIMETRY Two-wavelength noninvasive oximetry that uses the cardiac cycle, that is, arterial pulsations, as the basis for its calculation of arterial oxygen saturation.

FUNCTIONAL ARTERIAL OXYGEN SATURATION See SaO_2 (func).

SaO_2 (calc) Arterial oxygen saturation calculated from pH and arterial oxygen tension at 37°C according to a standard dissociation curve.

SaO_2 (frac) Arterial oxygen saturation measured spectrophotometrically by a CO-Oximeter: $HbO_2/(HbO_2 + Hb + MetHb + HbCO) \times 100$.

SaO_2 (func) Arterial oxygen saturation calculated from measurements of variables derived from a CO-Oximeter: $\%HbO_2/100\% - (\%HbCO + \%MetHb) \times 100$.

SaO_{2i} Value of arterial oxygen saturation derived every 1/30 second by Ohmeda Biox pulse oximeters.

SpO_2 Arterial oxygen saturation as measured by pulse oximetry.

WEIGHTED AVERAGE The sum of a number of PROCESSED AVERAGES divided by that number, which yields the displayed arterial oxygen saturation value on Ohmeda Biox pulse oximeters. (The number may be 9, 18, or 36, depending on which operating mode is selected [fast, normal, or slow]).

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