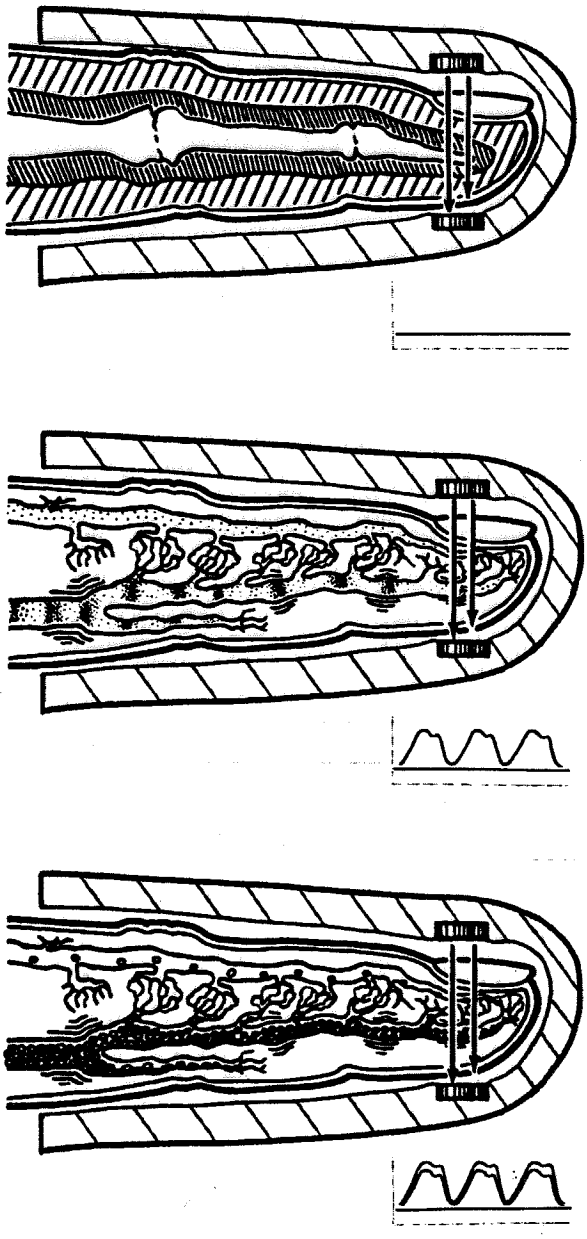
HEWLETT PACKARD

Application Note

PULSE OXIMETRY - A PRIMER

Introduction

The body's need for O_2 is unquestioned. Its availability at a tissue level is sometimes in doubt. For some years now, blood gas measurements have been the cornerstone of respiratory care and have provided critical information regarding oxygenation, ventilation and acid-base status. The problem is these measurements are discontinuous - providing only a snapshot of the patient's condition taken at the time that the blood was drawn. It is well known that oxygenation can change very quickly - hazardous levels reached in less than one minute when anoxic gas mixtures are inhaled or in slightly longer periods when ventilation is reduced or when apnea is present. In the absence of continuous oxygenation monitoring, these changes may go undetected until it too late.



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Operating Room

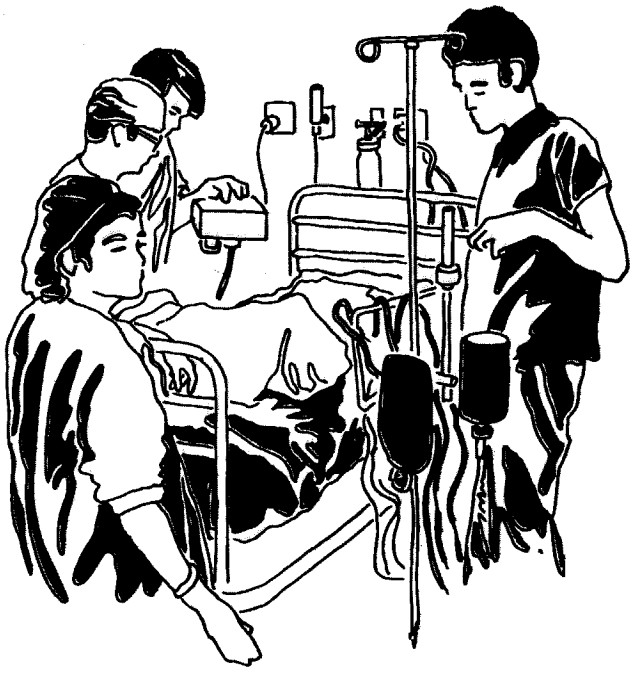
Important studies by Taylor et al (1) have shown that cardiac arrest in the operating room is often associated with hypoxia. Hypoxia is also related to many of the critical incidents studied by Cooper, et al (2) in their analysis of anesthesia mishaps. Time and again it is reported as an important factor in studies of anesthesia morbidity and mortality (3), (4), (5). In many cases, this consequence of human error—a major contributor to anesthesia mishaps—can be detected early with some form of continuous oxygenation monitoring. This is recognized in the monitoring standard adopted by the American Society of Anesthesiolgists in October of 1986, which states that continuous monitoring for oxygenation is encouraged.

PACU, ICU and ER

In other clinical areas where patients are mechanically ventilated, receive supplemental O_2 or are being treated for respiratory insufficiency, a frequent assessment of oxygenation is critical, and a continuous assessment would be very helpful. Disconnects occur, gas concentrations are changed, a ventilator may fail, or a patient's condition may deteriorate. Often exertion or even mild activity can produce significant desaturation that may go unnoticed.

It is also well known that hyperventilation resulting from pain and apprehension associated with arterial sampling may produce falsely high PaO_2 readings. This might complicate O_2 administration which should be carefully administered as with any drug.

In summary, a monitor providing continuous oxygenation assessment is useful in any circumstance where a patient's O_2 status is in question or where supplemental oxygen needs to be administered or controlled.



Existing Solutions

Technology has responded to the clinician's need for continuous, noninvasive O_2 monitoring. Progress has been evolutionary with identifiable milestones marking technical progress and a better understanding of the problem. Gas phase O_2 (FIO_2) monitoring has become commonplace. This insures that the breathing gas contains O_2 and that its concentration is at the desired therapeutic level. However, it does not insure the concentration *in the patient.* The first noninvasive, continuous O_2 monitors were transcutaneous sensors which evolved from blood gas technology. These electrochemical sensors have been well accepted in the care of neonates because they work best on the thin skin of the baby and because of the baby's critical need for continuous measurements. Their use on adults is more problematic. The O_2 gradients are larger and more variable because of a more complex skin structure. In all cases, heating is required to produce a stable arterialized vascular bed. This requires moving the sensor periodically to minimize skin irritation. Also, stabilization periods of 10–15 minutes are required to promote and get stable readings. In addition, careful skin preparation is required to eliminate the influence of ambient air.

This technique has been adopted by some clinicians in adult care because it gives valuable trend information on O_2 status and will provide an alert when significant changes have occurred.

Oximetry

It was necessary to turn from electrochemical to optical measurements in order to gain significant improvements in ease of use, accuracy, and stability. The newest devices are based on the old observation that well oxygenated blood appears red and deoxygenated blood looks blue (cyanotic)—or at least not so red. This is confirmed by spectrophotometric evidence (Figure 1) where oxyhemoglobin is shown transmitting more light in the red part of the spectrum (660 nm) than reduced hemoglobin. Cyanosis, then, provides some indication of oxygenation, but it is not a very sensitive indicator. Ten to twenty percent of the hemoglobin must be in the reduced form to produce a visible change. Also the clinician's ability to detect it is subjective. There are complicating factors such as body surface exposure, adequate lighting, and skin pigmentation.

Noninvasive instruments have been of interest for some time. Continuing progress has been made since Kramer & Matthes (1935) first published information on body surface oximeters. Their findings were based on measurements made at one wavelength in the red part of the spectrum (R). The measurement was influenced not only by the level of oxygenation, but also by the quantity of blood which changes in a pulsatile way. Later, Matthes added a second measurement in the infrared part (IR) of the spectrum which made it possible to compensate for this pulsatile activity. There are several ways of describing this correction, but the simplest is to recognize that at the isobestic wavelength, the absorbing power of oxyhemoglobin and reduced hemoglobin is the same (Figure 1). Therefore, the total absorbance depends only on the sum of the two and not on the state of oxygenation. In other words, it depends only on the total amount of blood present. Two wavelengths, then, provide information which makes possible the correction of the oxygenation-dependent wavelength for the pulsatile blood flow.

There are two remaining problems: first, how to correct for the venous blood which will be present in some portion of the vasculature, and second, how to correct for the absorbance of the skin pigments, tissue, and cartilage, which will be different for each subject.

The first question was answered by imposing the requirement of "arterializing" blood flow—usually by heating or rubbing the vascular bed. This stimulation results in a dramatic increase in blood flow. Venous saturation becomes only slightly less than arterial. Only a small amount of O_2 is extracted per unit of blood flow to meet local metabolic demands.

The second problem was answered by Goldie and successfully implemented by Wood & Geraci (1948) in a commercial device introduced in the 1950s. They suggested compressing the ear with an inflatable cuff. A bloodless ear enabled additional measurements which made it possible to correct for patient related variables: skin pigments, ear thickness, tissue, etc. These techniques solved the problem of making noninvasive measurements on subjects using somewhat elaborate procedures. It did not solve the problem of long-term monitoring using simple procedures without requiring the involvement of the subject in the calibration process.

The next significant technical contribution came from Shaw and Hewlett-Packard (6). Their empirically calibrated eight-wavelength oximeter stored sufficient information (18 coefficients) to calculate oxygen saturation corrected for skin pigments, tissue, and elevated levels of COHb and METHb. It was also possible to monitor for long periods of time. Measurements at eight wavelengths provide a great deal of information, which makes it possible to account for eight unknowns. This was sufficient to take into consideration the patient to patient variables and to account for the various forms and hemoglobin. The procedure was simple, requiring only the storage of initial light intensities at each of the eight wavelengths. However, it was still necessary to arterialize blood flow by warming the ear, and a large earprobe incorporating fibre optics was necessary to make the system work.

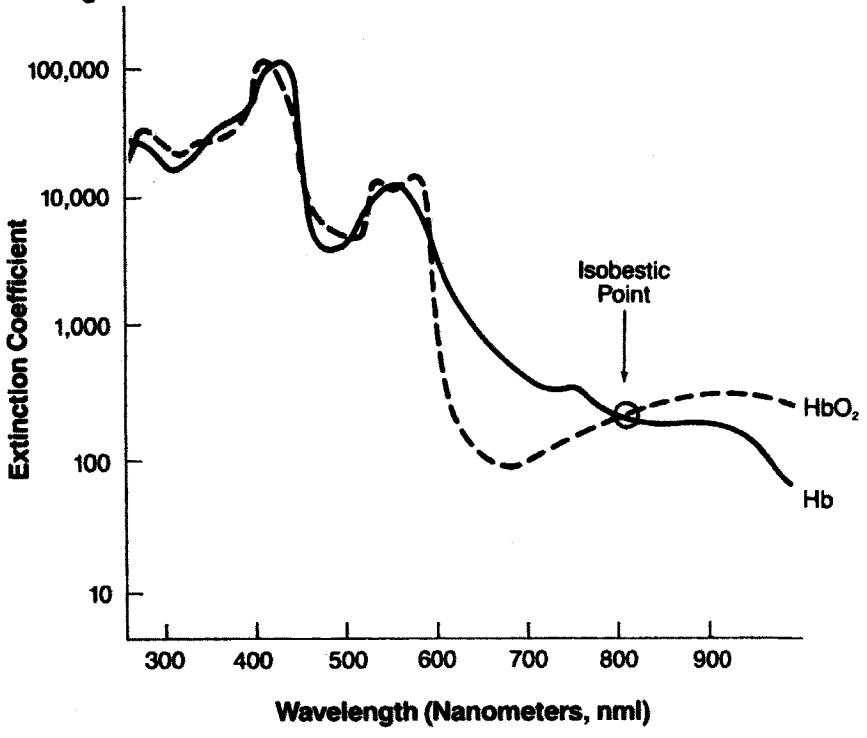


Figure 1. Absorption characteristics of blood in the visible and near infrared part of the spectrum. HbO_2 is oxyhemoglobin. Hb is reduced hemoglobin. At the isobestic wavelength, HbO_2 and Hb have the same extinction coefficients.

Pulse Oximetry

Pulse oximetry was the brainchild of Takuo Aoyogi (7), a Japanese bioengineer who suspected that arterial oxygen saturation determinations could be made using two wavelengths, providing the measurements were made on the pulsatile part of the waveform. The two wavelengths assume that only two absorbers are present; namely, oxyhemoglobin (HbO_2) and reduced hemoglobin (Hb). His observation, proven by clinical experience, was based on the following:

1. Light passing through the ear (or finger) will be absorbed by skin pigments, tissue, cartilage, bone, arterial blood, venous blood and blood whose composition is somewhere in between (Figure 2).

2. These absorbances are additive and obey the Beer-Lambert law:

$$A = -\log T = \log Io/I = \epsilon DC$$

where Io and I are incident and transmitted light intensities, ϵ is the extinction coefficient, D is the depth of the absorbing layer, and ,C is concentration.

3. Most of the absorbances are fixed and do not change with time. Even blood in the capillaries and veins under steady state metabolic circumstances is constant in composition and flow, at least over short periods of time.

4. Only the blood flow in the arteries and arterioles is pulsatile.

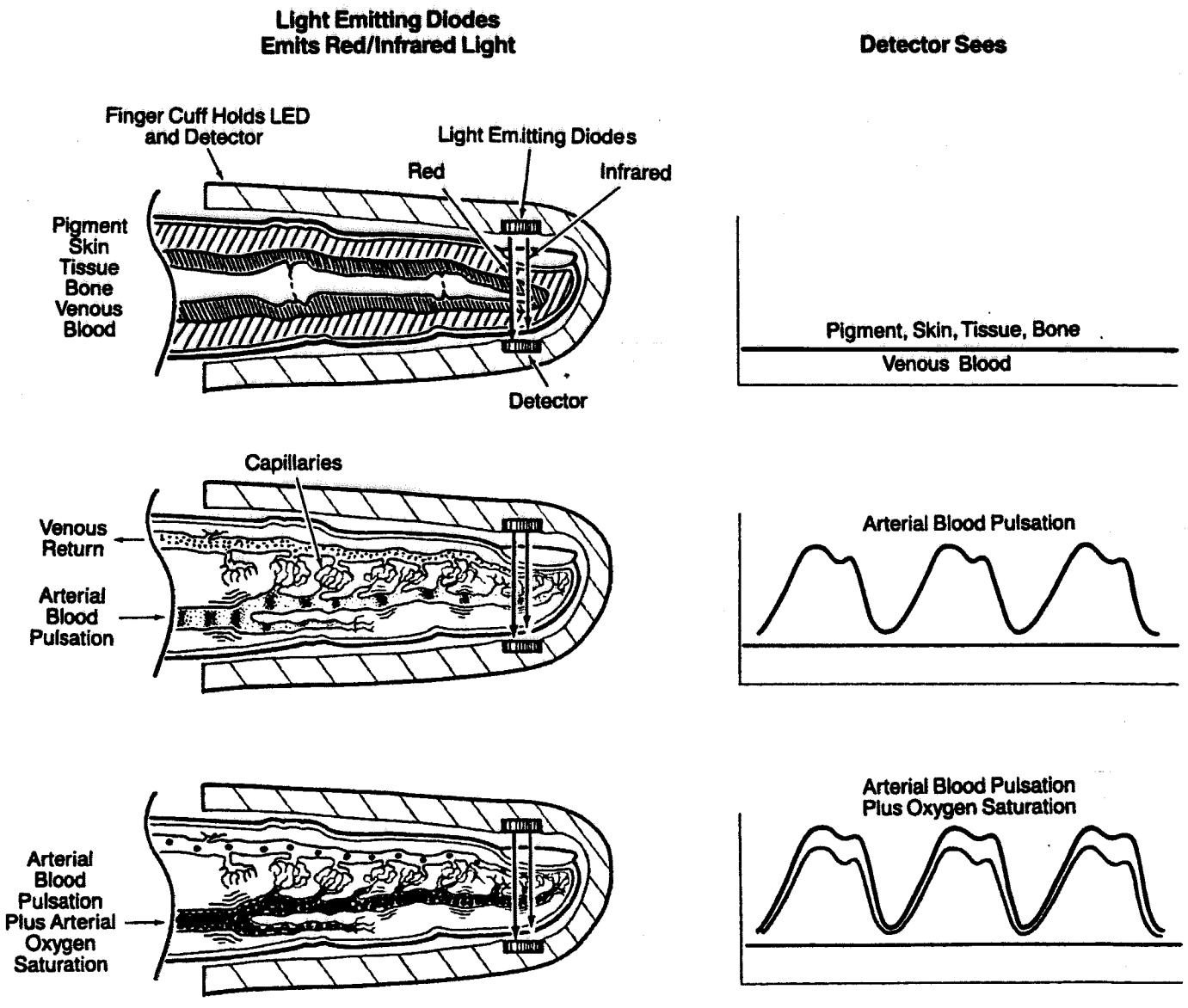


Figure 2. Pulse Oximetry. Skin pigments, tissue, venous blood, etc. produce a fixed signal. Arterial blood adds pulsatile activity. Measurements at two wavelengths make it possible to determine HbO_2 and Hb and therefore calculate oxygen saturation.

Therefore, measuring *only* the changing signal, measures *only* the absorbance due to arterial blood and makes possible the determination of arterial oxygen saturation (SaO_2)—this uninfluenced by all the other absorbers which are simply part of the constant background signal.

This insightful observation really solved a number of problems:

First, it removed the requirement of arterializing blood flow. No heating or rubbing is necessary. The measurement requires that pulsatile activity be present but the level is not critical. When that activity falls below a threshold—due to such influences as hypothermia, shock, vasoactive drugs, and inflating blood pressure cuffs—the display is blanked and the user alerted.

Second, Because a change in signal is measured, it is not necessary to store any initial light intensity values, simplifying operational procedures.

Third, The instrument can be empirically calibrated and be absolute in reading. Today's Pulse Oximeters make transmission measurements at two wavelengths, usually 660 nm and 940 nm—the first is in the red part of the spectrum and the second is in the infrared. Assuming that the only added absorbers present during pulsatile arterial flow are HbO_2 and Hb; then measurements at two wavelengths should be sufficient to compute oxygen saturation:

$$SaO_2 = \frac{100 \times HbO_2}{HbO_2 + Hb}$$

Oxyhemoglobin Dissociation Curve

For over twenty-five years, adequacy of oxygenation has been judged by the patient's PaO_2 and hemoglobin concentration. The relationship between SaO_2 and PaO_2 is best described by the oxyhemoglobin dissociation curve (Figure 3).

This curve tells us several things. At high saturations, SaO_2 is an insensitive indicator of PaO_2. At high FIO_2's modest changes in PaO_2 produced by atelectasis and/or shunting resulting in modest changes in PaO_2 will be difficult to detect with O_2 saturation measurements. On the other hand, decreases in PaO_2 which can be hazardous will be easily detected. It's also important to note that the position of the curve depends on many variables. Decreasing hydrogen ion and 2,3 DPG concentrations, as well as decreased $PaCO_2$ and temperature, will increase O_2 affinity and shift the curve to the left. Conversely, increasing all of the above will decrease affinity and shift the curve to the right. Therefore, interpolation at SaO_2 measurements to equivalent PaO_2 should be done only when the curve can be well qualified.

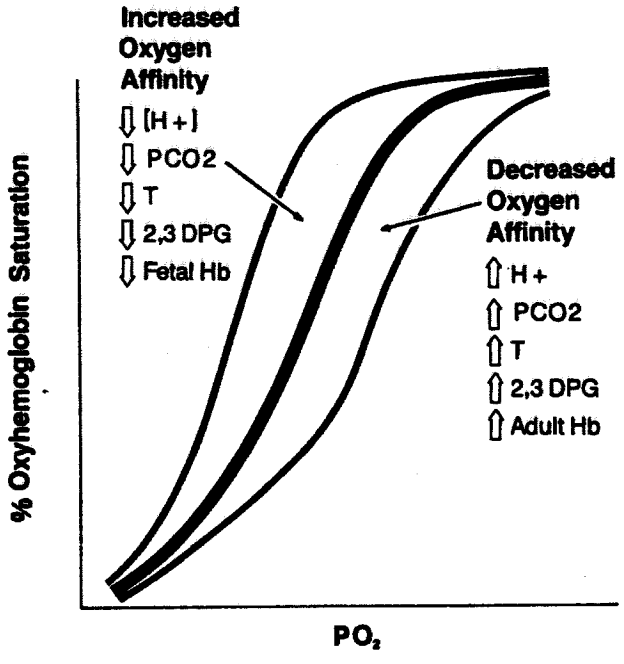


Figure 3. The oxyhemoglobin dissociation curve and parameters which influence oxygen affinity.

Oxygen Saturation—Definitions

Over the years several definitions of oxygen saturation have come into use. The oldest—based on oxygen content and oxygen capacity measurements—is called "functional" oxygen saturation:

$$\% SO_2 = \frac{100\ Hb\ O_2}{Hb + HbO_2}$$

It tells us the fraction of functional hemoglobin that is actually carrying O_2. The numerator answers the question "How much oxygen is there in the patient's blood (O_2 content)?" The denominator tells us how much could be there if all the functional hemoglobin carried oxygen (O_2 capacity). Both content and capacity can be corrected for the small amount of O_2 dissolved in the blood by knowing the PaO_2.

When colormetric instruments came into use for the determination of oxygen saturation, another definition was introduced—namely fractional O_2 saturation:

$$HbO_2\% = \frac{100 \times HbO_2}{Hb + HbO_2 + HbCO + METHb}$$

This tells us the fraction of total hemoglobin (functional and nonfunctional) combined with oxygen.

It's characteristic of optical measurements that the absorbance (A) at each wavelength is the sum of the absorbances of each pigment ($AHb + AHbO_2 + AHbCO + AMETHb$). If measurements are made at sufficient wavelengths, then the contributions of each can be calculated. This is worth remembering because pulse oximeters generally use only two wavelengths and therefore can measure only two species. In reality then

$$S\ O_2 = \frac{100 \times HbO_2 + HbCO + METHb}{Hb + HbO_2 + HbCO + METHb}$$

where SpO_2 is Oxygen Saturation determined using pulse oximetry.

In most clinical circumstances, the concentrations of HbCO and METHb are low—but when present in significant concentrations will cause the saturation to be falsely high.

Clinical Conditions with Altered Oxyhemoglobin Equilibrium

- Hypophosphatemia
  - Transfusion of stored blood
  - Hyperalimentation
  - Hemodialysis
  - Chronic antacid use
- Rare hematologic conditions
  - Hemoglobinopathies
  - Hexokinase deficiency anemia
  - Increased fetal hemoglobin
  - Cyanate treatment for sickle-cell anemia
- Increased carboxyhemoglobin
  - Cigarettes
  - Auto pollution
- Septic Shock
- Acute Alkalosis
- Hypothyroidism
- Hyperphosphatemia
  - "Physiologic anemia of childhood"
  - Uremic anemia
- Other anemias and hemoglobinopathies
- Cardiac Diseases
  - Angina pectoris
  - Myocardial infarction
  - Cyanotic heart disease
  - Low output failure
- Hypoxia
  - High Altitude
  - Chronic lung disease
- Acute Acidosis
- Hyperthyroidism
- Acute stress or exercise

From: Nevins, M.A. Oxyhemoglobin equilibrium in ischemic heart disease. *JAMA* 229: 805 (1974).

Influence of Temperature

As indicated above, temperature can have a profound influence on the position of the oxyhemoglobin dissociation curve. However, this curve assumes that there can be a free exchange with the environment,as in the lungs or a tonometer. In a closed space,as with a finger or ear, the temperature response is different (Figure 4).

If blood with a saturation of A decreases in temperature from T1 to T2, a sustained partial pressure P1 would produce a new saturation B. However, in a closed system,such as the ear or finger, there is not a sufficient source of oxygen to produce the new,higher level of SaO_2. The only source is the dissolved O_2 in the blood itself. That PO_2 could drop from P1 to P2 without changing the saturation values significantly. The slight amount of oxygen available in the blood (the dissolved component) would increase the saturation by only a small amount. Conversely, an increase in temperature would reduce the saturation slightly—a small amount of O_2 leaving the bound state to become dissolved oxygen. This increases the PaO_2 to the new level required by the higher temperature.

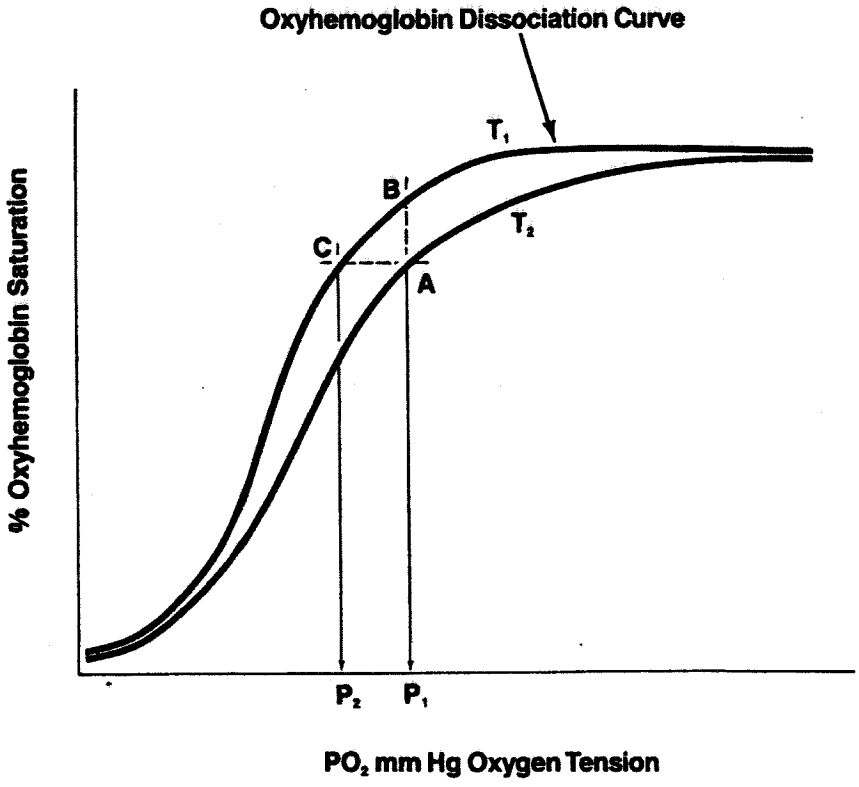


Figure 4. The influence of temperature on oxygen saturation under anaerobic conditions.

Limitations

Pulse oximeters have been well accepted. They have provided a noninvasive continuous view of the oxygenation status of the patient under a wide variety of clinical circumstances.

As with any technique, there are limitations—some of them fundamental. Let's deal first with those that affect pulsatile activity. Although full arterialization is not a requirement, there is a critical level below which accurate measurements are questionable. Under those circumstances, the instrument will blank the display. Patient circumstances contributing to such a condition are shock, hypothermia, the use of vasoactive drugs, and anemia. When encountered, these problems may be overcome by the application of heat or rubefacients, which may stimulate blood flow sufficiently for a measurement to be made.

There is another aspect of pulse activity which should be remembered. In some clinical circumstances venous flow can be pulsatile (right heart failure, obstructed venous return, high positive end expiratory pressure ventilation). This venous pulsatile activity will be added to the arterial and result in an erroneously low saturation.

The second area of concern is optical interference or crosstalk. Any material added to blood which has an absorption band near 660 nm or 940 nm will cause a problem. A number of clinically significant dyes which interfere have been identified. Methylene blue, indocyanine green and indigo carmine have been studied and found to decrease oximeter readings transiently—but possibly as long as 30 minutes (8).

Carboxyhemoglobin and methemoglobin are also absorbing species that will interfere. Because measurements are made at only two wavelengths, only two absorbing species can be accounted for—namely, oxyhemoglobin and reduced hemoglobin. Elevated levels of COHb have been shown to have an additive influence in dogs (9). Falsely high levels of SPO_2 may be displayed when COHb is elevated.

Ambient lights have been shown to interfere with the measurement (10)—with the sensor both on and off the patient. Sometimes covering the finger cuff with an opaque material is necessary to prevent such interference.

Motion artifact is also a potential problem. The information containing pulse activity is in the same frequency range as motion artifact.

These problems can be remedied by careful sensor design and specially designed signal processing algorithms.

Summary

Pulse oximeters serve the clinician well. They provide an accurate assessment of saturation noninvasively and continuously—useful in many clinical situations.

Specific advantages are:

1. Heating is not necessary; therefore, long term monitoring without site changes is practical.

2. Subject variability (skin pigmentation, for thickness, tissue, sensor location, etc.) has no significant influence on the measurement; therefore, accurate measurements are possible without involving the subject in any calibration procedure.

3. Instruments are calibrated in an absolute sense, and sensor application is simple, requiring no site preparation; therefore, no setup procedures are necessary, which adds significantly to ease of use.

4. True arterial saturation is measured because the pulsatile signal comes from the arterial blood.

5. Pulse rate is also determined and displayed. This confirms the heart's activity as a pump and guards against conditions such as electromechanical dissociation.

6. And lastly, only results that exceed a threshold pulse amplitude and are screened for artifact are displayed.

Inclusion of this parameter in routine patient monitoring will improve quality of care and contribute to the early detection of life-threatening mishaps.

a. *Sample Size* – number of data points used for data analysis.

b. *Identity Line* – if all device readings were the same as the Reference readings, then all data points would lie on this line. In a graph where the X and Y axis are both of the same scale, the Identity Line would have a slope of 45°

c. *Mean Difference (Mean Error)* – the mean of all individual differences between device reading and reference reading.

d. *Standard Deviation (SD)* – a statistical measure indicating the variety of all data points with respect to the identity line. 68% of the actual values can be expected to be within the range of +/- 2 times the standard deviation.

e. *Regression Line* – the best-fit line through all data points. Ideally, the regression line would match the identity line.

f. *Slope* – the slope of the regression line should be close to 1. The slope of the identity line equals 1.

g. *Intercept* – the point where the Regression Line intercepts with the Y axis. It should be close to 0. The intercept of the identity line is equal to 0. This is sometimes called the offsett.

h. *Confidence Level* – the degree of certainty that any reading will be within the specified accuracy. For instance, a confidence level of 95% (a typical figure) means that up to 5% of the results will outside to the specified accuracy.
The Confidence Level that readings will fall within the Standard Deviation (SD) is 68%. This means that for *any* parameter, 32% of readings will fall outside of the range of accuracy covered by the SD.

Specifications

These specifications record the accuracy of Hewlett-Packard SaO2 CMS and bedside monitors. They are quoted at 1 Standard Deviation.

Accuracy with HP M1190A transducer: 1 SD.

65% to 80%: +/- 2.5%

80% to 100%: +/- 1.5%

Accuracy with Nellcor® sensors: 1 SD (does not apply to M1025A).

80% to 100%: +/- 3%.

Unit 11. Performance & Specifications

The SaO2/Pleth parameter is an "empirically calibrated" parameter. This means that the derivation of the SaO2 numeric (from the ratio of Red to Infra-Red light passing through the finger) must be determined from empirical studies, and verified by clinical trials. (See Unit 4: "Algorithm & Implementation".)

This section is in two parts:

1. An explanation of the methods used to verify the performance of the SaO2/Pleth parameter.
2. Specification for M1190A and Nellcor sensors used with Hewlett-Packard monitors.

Explanation of Methods

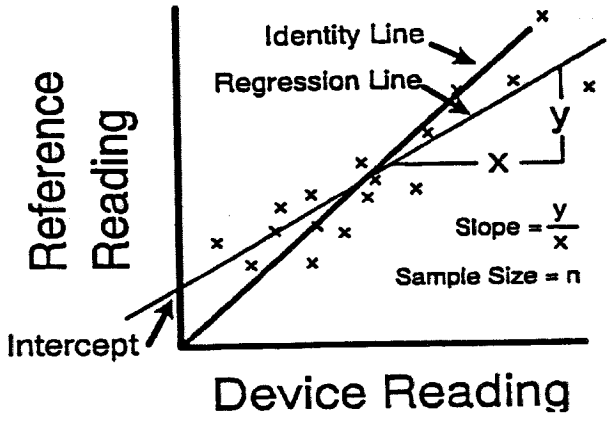
Because there is no reference standard device which can accurately model the bone, tissue, venous blood and arterial blood-flow of the application site, clinical studies are necessary to verify the performance of a Pulse Oximeter.

These studies must be performed on a representative population of patients of both sexes, and all weights, ages, and levels of oxygenation.

In the course of each study, readings from a Pulse Oximeter are compared to an accepted standard SaO2 reading, taken from the same patient. The standard device normally used is a Co-Oximeter (hem-oximeter), a device which requires arterial blood samples, and uses a number of wavelengths of light in order to perform the analysis.

Statistical Data Analysis

This section shows the kind of graph on which results are normally displayed, the main features of the graph, and explains what the results mean.



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