

Pulse Oximeters

Jim Welch

Pulse oximetry is arguably the most clinically relevant non-invasive physiologic monitor. It is often called the fifth vital sign. In a single measure, a clinician obtains an indicator of both respiratory (oxygenation) and cardiac (pulse rate) condition. Lack of oxygenation to vital organs results in tissue ischemia and eventually tissue necrosis. Prior to the development and adoption of pulse oximetry in the early 1980s, clinicians had no reliable continuous evaluation of tissue oxygenation. Clinicians relied on skin coloration or periodic arterial blood gas measurements, each of which had limitations. The adoption of pulse oximetry in anesthesia, critical care, general acute care, and even the home has allowed clinicians to better diagnose and treat patients with compromised respiratory and circulatory function. Continuous pulse oximetry monitoring is considered a standard of care in anesthesia and respiratory care applications. It is essential for clinical engineers and biomedical technicians to understand the principles of measurement and limitation of available pulse oximeters to effectively support this technology.

Oxygen is the primary fuel for all metabolic activities. Oxygen is transported across the lungs and carried to tissues by the cardiovascular arterial system by binding to hemoglobin molecules contained in red blood cells. Tissues, such as the heart for example, draw oxygen off the hemoglobin molecules; exchange these molecules with CO₂ molecules, which then travel back to the lungs via the venous systems where the exchange reoccurs. Thus, oxygen content is high in arterial blood and low in venous blood. Oxygenated blood naturally absorbs light in the blue and green portion of the spectrum and minimally in the red, which gives typical arterial blood its characteristic bright red color. Deoxygenated blood, with a much stronger absorption of red light, is what gives venous blood a less rich red or bluish appearance.

James P. Welch is the chief technology officer at Welch Monitoring in Beaverton, OR, where he has worked since 1990. He holds two patents and has several patents pending. He is a member of the IEEE and AAMI and is a mentor for the Portland Area Saturday Technology.

Pulse oximetry takes advantage of these optical absorption characteristics.

Pulse oximetry measures the percentage of oxygenated hemoglobin (oxyhemoglobin) in the arterial vascular bed and expresses the value as SpO₂. Oxygen saturation for a healthy individual is normally above 97%. Measurements below 90% are of concern to clinicians because they indicate poor respiratory and / or cardiovascular function.

Technology

Pulse oximetry is a differential measurement based on the spectrophotometric absorption method using the Beer-Lambert Law for optical absorption. Two wavelengths of light—one in the red (660 nm) the other in the infrared (920 nm) spectrum—are directed across a vascular bed—usually the finger—and measured by a photo detector sensitive to these wavelengths. The ratio of absorption between these two spectrums cancels out the effects of optical path length (the distance between the LED emitters and detector) and is correlated to the relative concentration of oxygenated hemoglobin (oxyhemoglobin) and deoxygenated hemoglobin. The arterial component of the signal is separated from the venous, bone, and tissue component by analyzing the pulsatile component only; thus the term pulse oximetry. The resulting measurement is then adjusted according to a calibration curve embedded in the instrument to yield an arterial oxygen saturation measurement.

The first pulse oximeters became available in the early 1980s. These first-generation instruments were designed for use in anesthesia and pulmonary function applications where lack of oxygen (hypoxia) was a known clinical problem. Two companies dominated the early pulse oximetry market, Biox (later acquired by Ohmeda, then Datex, then GE) and Nellcor (acquired by Mallinckrodt, then Tyco International). The rapid adoption by anesthesiologists and soon afterwards intensive care specialists promoted bedside monitoring companies to develop or license pulse oximetry from the leading companies. All of the early devices shared the same common architecture; a patient worn sensor, connected to a microprocessor based instrument that

separated the pulsatile signal from the overall signal, detected a pulse, compared the relative amplitudes of the red and infrared pulse signals, and translated this value to a SpO₂ reading using an internal calibration curve.

Early LED manufacturing variances required special calibration matching between the sensor, and in particular the LED in the sensor, and the pulse oximeter (see Figure 1). Two methods were used—careful selection of the LED to match a specific manufacturer's device or a calibration resistor embedded in the probe to instruct the pulse oximeter to use a specific one of several

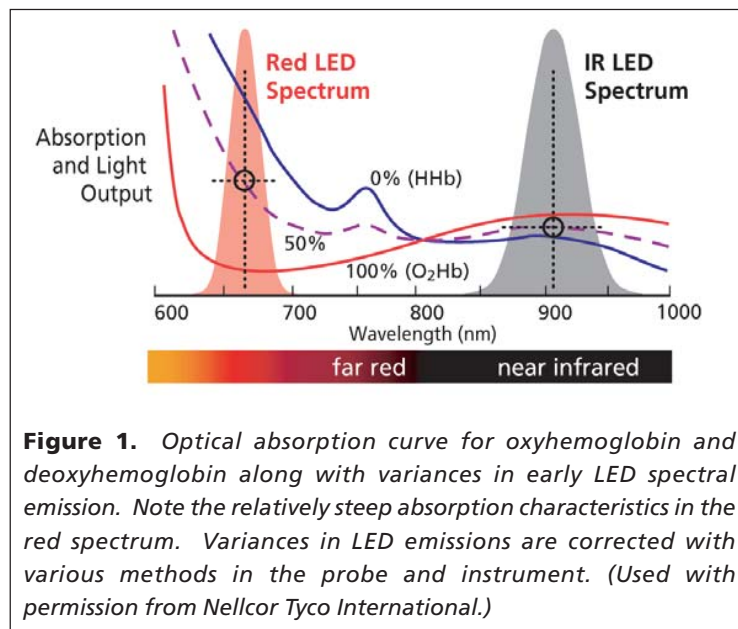
The primary limitation of these first-generation devices, many still in use today, is their sensitivity to motion artifact and low perfusion. This is less of a problem in anesthesia and intensive care where patients rarely move, but a much greater problem in other settings.

Second-generation pulse oximeters are distinguished by significant improved performance in the presence of motion artifact. The first second-generation pulse oximeter system was commercially introduced by Masimo in 1996 with the launch of Signal Extraction

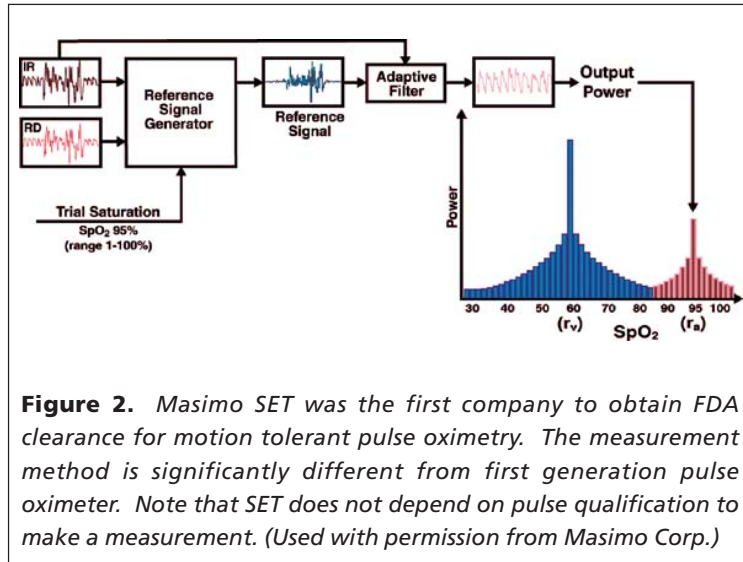
Technology (SET), which no longer required the detection of a pulse prior to the determination of an arterial pulse. Developers at Masimo hypothesized that the major contribution of motion artifact was pulsations in the venous vascular bed. The principal method employed in SET is to dynamically determine a noise reference signal associated primarily with venous pulsation through adaptive filters and then measure the instantaneous signal strength value at each potential saturation level (1% to 100%). The saturation value with the highest signal strength peak associated with the highest oxygen saturation value becomes the reported measurement (see Figure 2). The technologic claim of this approach is the ability to discriminate true oxygenation from noise artifact and to measure saturations at much lower perfusion levels than first-generation

pulse oximeters. The fact that SET does not rely on pulse detection prior to determining oxygen saturation values targets a potential weak link in the measurement chain. Masimo also claims probe improvements by recessing the detector to provide a mechanical cushion that reduces the effects of motion. In addition, Masimo identifies the sensor type (e.g. neonatal, adult, reusable, and disposable) by use of a resistor within the sensor. This allows the Masimo SET pulse oximeters to utilize specific algorithms designed for the type of patient and sensor.

The introduction of SET by Masimo stimulated other vendors to introduce their next generation platforms. In addition to advances in signal processing, innovations are taking place in the probes. Advances in the efficiency of LEDs, spectral output, and sensitivity are allowing developers to optimize probes for better



calibration curves embedded in the monitor. Failure to use the correct sensor with a specific pulse oximeter brand could result in erroneous measurements due to the mismatch of sensor and its light spectrum output and the monitor's internal calibration table. Nellcor was awarded a patent on the use of a calibration resistor embedded in the probe. This patent expired in 2003 leading the way to generic pulse oximeter probes for first-generation pulse oximeters. Furthermore, LED manufacturers have tightened the specifications on LEDs so calibration keys embedded in probes are not as necessary to ensure accurate pulse oximetry measurements. Nellcor recently introduced a new generation probe, OxiMax™, which digitally embeds the sensor's unique calibration curve in the probe itself to ensure accuracy and to open the opportunity to design specialized sensors.



overall performance and higher performance for specific applications. Nellcor has recently released the OxiMax™ family of probes. This design embeds the calibration curve of the sensor in a memory chip within each probe. Most of the new Nellcor probes are backward compatible with older Nellcor instruments. Nellcor's second-generation instruments offer additional probe features that take advantage of the probe's embedded memory. For example, the new forehead probe contains subtle differences in calibration because it contains a unique emitter that provides higher output for reflectance measurements. Masimo has also recently announced plans for new specialty sensors for resuscitation situations and cyanotic babies. We can expect continued advances in sensor designs from the technology leaders in the field in an effort to advance the performance of pulse oximetry in more challenging environments and potentially discriminate more species of hemoglobin.

Dominant market players can supply peer-reviewed evidence supporting their respective technologies. ECRI has issued several reports in *Health Devices* on the strengths and limitations of various brands that provide a reference in the selection process. These second-generation oximeters are much less prone to the limitations of first-generation pulse oximeters and should be strongly considered in clinical areas where patients are mobile or have diseases, such as Parkinson Syndrome, in which motion artifact is constantly present. In general, the same troubleshooting mechanisms apply for second-generation but the

occurrence of certain limitations, especially motion artifact, should be less frequent.

Next generation pulse oximeters will focus primarily on size and power consumption as clinicians expand the application of pulse oximetry to ambulating patients. Advances in low-power silicon chips and high-density batteries will allow pulse oximetry designers to shrink the packaging of the device to a more wearable form factor. Furthermore, advances in high output and high efficiency LEDs will lower the power requirements of the device and as a result will further drive ambulatory pulse oximeter applications. Researchers at MIT have demonstrated a working prototype of a ring pulse oximeter. Smaller size, lower power, and resulting lower

cost will make pulse oximetry available to greater numbers of patients, even beyond medical applications. Nonin is currently offering a self-contained finger pulse oximeter that is marketed to high-altitude climbers. Nonin has recently launched a wearable pulse oximeter with a Bluetooth™ wireless link. Advances in sensor technology can be expected as new LEDs become available for specialty applications. Sensor innovations will further push applications into new disease applications.

Managing and Troubleshooting

Pulse oximeters, because they are considered the fifth vital sign, are found throughout the hospital. Therefore, all the advantages of standardization apply. However, a low-cost solution for the typical patient application may not be acceptable for areas where high motion or low perfusion is encountered. A careful analysis of the needs of each clinical care area and the flow of these patients through the hospital should be considered when selecting a vendor. Also, the types of probes available and the compatibility of these probes with existing pulse oximeters must be evaluated. An aggressive upgrade program to second-generation pulse oximeters—especially in areas where high incidents of false alarms or clinician dissatisfaction—should be factored in an overall equipment management strategy.

As with all point-of-care devices, the common equipment repair problems encountered are cable and reusable probe failures. Lifecycle costs for these items favor the use of higher quality cables and reusable probes

in areas where use is high. Generic probes may offer cost savings if they can deliver the reliability and life cycle costs in the areas of intended use.

The greater challenge in the management of pulse oximetry is the cases where the instrument system (probe and device) fails to meet clinician expectations. The biomedical support request usually is to correct for high false alarm rates or suspected inaccurate readings. Any phenomena—either mechanical, physiologic, or optical—that causes artifact in the pulsatile signal can compromise some instruments, especially first-generation devices, from displaying accurate arterial oxygen saturations.

Motion artifact is the most common cause of unreliable readings resulting in a high incidence of false positive alarms. Movement of the extremity where the pulse oximeter probe is located can cause optical pulses to occur by inducing venous pulsations or by mechanically altering the distance between the LEDs and the detector. The later condition is more often associated with reusable probes. An unstable pulse rate

display is a clear indicator of motion artifact. Disposable probes have an advantage over reusable probes because the adhesive tends to stabilize the emitters and detector. The lower mass of the disposable probe favors less movement. Motion artifact can be lessened by exchanging reusable probes for disposable probes, using a second generation pulse oximeter designed specifically for motion tolerance, and choosing an alternate probe location.

Second generation pulse oximeters should be used in high-motion environments. Despite the order of magnitude improvement in minimizing false alarms, second-generation pulse oximeters can still report erroneous data during extremely challenging motion and low perfusion conditions. Minimizing motion and optimizing signal quality by using the most appropriate and properly applied sensor gives second-generation devices the best possible opportunity to display accurate measurements.

Venous pulsations, which can occur due to tricuspid valve failure, can cause low saturation readings since the

Origins and Evolution of Pulse Oximeters

The measurement of oxygen content in blood and vital organ tissues has long been to goal of biomedical innovators. Early demand for a portable measurement was driven by high altitude aviation prior to the development of pressurized cabins in military aircraft. The introduction of microprocessor and LED technologies allowed the creation of affordable and dependable instruments for broad clinical applications.

1935 Matthes: Developed first oximeter using two wavelengths of light to correct for optical path length and blood content. The device was too cumbersome.

1942 Millikan: First lightweight ear oximeter, developed for high altitude aviators for use during World War II. Required two point calibration. Accuracies of +/- 5% reported by Hemingway and Taylor in 1944.

1949 Wood: Adds inflatable bladder to ear oximeter to determine “bloodless” zero measurement.

1964 Shaw: Developed eight wavelength ear oximeters to identify multiple species of dyshemoglobins. Device marketed by Hewlett Packard to respirator function labs. Limited commercial success.

1974 Aoyagi: Developed first pulse oximeter by isolating the pulsatile component of an ear oximeter. Device developed and patented by Nihon Kohden. Minoruta Camera Company (Minolta) soon afterward introduced a competing device that used a fiber optic sensor.

1981 Nellcor / Biox: Two competing designs emerged based on Aoyagi early work. Nellcor focused on anesthesia market, Biox on the respiratory care market. Both realized sustainable clinical adoption.

1987 Nellcor: Nellcor introduces the N-200 pulse oximeters with C-lock designed to enhance signal quality under conditions of patient motion or a low-amplitude peripheral pulse.

1996 Masimo: First commercial launch of pulse oximetry using signal extraction technologies (SET) with FDA-cleared accuracy claims in controlled motion conditions.

Future: Further advances in signal process and power conservation to push pulse oximetry into new applications. New optical sensor technologies to extend tissue spectrophotometry to measure other blood components.

instrument is detecting both arterial and venous pulses (especially true for sensors placed on the ear or face). The presence of venous pulses is in itself an important finding. In addition, a tourniquet left in place (for venous blood drawing) will have the same effect. Pooled venous blood will begin to pulsate with each heartbeat. This venous signal is mixed with the arterial signal thus causing a lower reading. It is important to note that this interference with venous blood will cause a low saturation reading with a pulse rate that correlates with the electrocardiogram heart rate. Care should be taken to avoid applying the sensor too tightly as this can exacerbate venous pulsations.

Optical interference from nearby light sources or electromagnetic interference can also result in false readings. False high pulse rate readings, low perfusion alarms, or failure to measure are all indicators of high optical interference. Isolating the sensor from such sources by covering the sensor with an opaque material usually corrects this problem. Second-generation pulse oximeters do better under optical interference.

Electromagnetic interference (EMI) from nearby electrically operated equipment can cause false high reading through capacitive coupling to the probe or probe cable. EMI is often difficult to troubleshoot. If the source is known or suspected, removing it or creating a greater distance between the offending source and the probe can minimize the effect. Also, poor quality or partially failed cables and poor quality sensors can exacerbate the problem. Long extension cables increase susceptibility to EMI. Replacing cables and probes with a higher quality product may correct the problem in this case. Second-generation pulse oximeters do better under EMI due to advances in hardware and software design.

Dyshemoglobins in higher than normal concentrations in the arteries can cause either false high or false low readings. The presence of carboxyhemoglobin, such as those encountered in smoke inhalation, will cause a misleadingly high pulse oximeter reading, and therefore readings should be highly suspect on fire accident victims. Methemoglobin is normally found in extremely low blood concentrations. However, if present in high concentration may cause false low values or false high values, since it tends to drive the SpO_2 measurement to 80%. In any case where an abnormal mix of hemoglobin is found, a clinical laboratory test based on an arterial blood sample should be made to confirm the presents of

a dyshemoglobin so pulse oximeter readings can be relied upon for clinical decisions. In cases where high concentrations of dyshemoglobins are confirmed, changes in pulse oximetry readings can indicate a change in the relative amounts of these abnormal hemoglobins rather than saturated normal hemoglobin alone. For example, an increase of SpO_2 measurements in a smoke inhalation patient can indicate a lowering of carboxyhemoglobin in relation to oxyhemoglobin.

Low perfusion at the measurement extremity will cause a low signal at the detector. The normal amplitude of a pulse oximeter signal is typically 2% to 4% of the overall signal for a normally perfused measurement. Under low perfusion conditions there may be insufficient signal for the instrument to determine a measurement. This condition causes the instrument to continue to search for a pulse or to reenter the pulse search mode. A corrective action for this condition is to warm the extremity where the pulse oximeter probe is attached (often a blanket covering will work) or to reposition the probe to an alternative measurement site. Adhesive sensors should be used on patients with low perfusion. The reusable sensors stay on patients with force and can further diminish the perfusion at the monitoring site.

Misapplied Probes: Probes should only be used for their designed and labeled application site. All probes, including newer probes with embedded intelligence, are specifically designed and labeled for their intended use and therefore should not be used on alternative sites. For example, the use of a finger probe on the forehead can yield erroneous measurements. Specialty probes can often improve measurement performance when peripheral probes have difficulty in obtaining stable measurements. Forehead probes are a potential alternative site for low perfusion since the perfusion of

For More Information

Visit the following Web sites to learn more about pulse oximeters:

- www.rcjournal.com/online_resources/cpgs/pulsecp.html
- www.nellcor.com
- www.masimo.com
- www.findarticles.com/p/articles/mi_m0NUC/cpgs/pulsecp.html

the forehead is much less compromised when peripheral perfusion is poor.

Skin pigmentation / nail polish can diminish the optical signal. Removing dark nail polish should improve the signal strength. Close attention to probe attachment can also improve signal strength.

Regulatory and Risk Management

Pulse oximeters are considered a Class II device by the FDA. The FDA expects manufacturers to meet the internationally recognized performance standards in order to receive premarket 510(k) clearance. The most often cited performance standard is BS EN 865-1997. Conformance to these standards should be contained in the product labeling. Pulse oximetry is considered a standard of care in the operating room and intensive care where patients are dependent on supplemental oxygen support to sustain life.

The American Society of Anesthesia has adopted a minimum monitoring standard for anesthesia management that requires the use of pulse oximetry on all anesthetized patients. Failure to adopt this standard places the hospital and the anesthetist at a legal and

professional risk. Beyond anesthesia, any patient requiring oxygen therapy—or who is receiving medications that could result in respiratory compromise—could benefit from continuous pulse oximetry monitoring.

Clinicians are recognizing the benefits of continuous pulse oximetry monitoring and promoting its use throughout the continuum of care. As a result, monitoring vendors are offering pulse oximetry monitoring on most continuous and spot check devices, including traditional telemetry applications.

Implementation of pulse oximeters in telemetry applications requires larger batteries or shorter battery life due to the power requirements to support the measurement. Failure to monitor is recognized as one of the mitigations to prevent clinical incidents. Earlier detection of clinically reversible events provides clinicians with the tools to improve clinical outcomes.

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