Probe-Off Detection – A Common Limitation of Pulse Oximetry

Introduction

Pulse oximetry is widely adopted and considered to be a standard of care for determining the oxygen status of patients. However, all clinical monitors, including the pulse oximeter, are affected by specific circumstances that can impair accuracy and reliability. For example, pulse oximeter systems may erroneously display numbers when the sensor is detached from the patient. In most cases, when a sensor is accidentally dislodged from a patient and continues to display readings, the pulse oximeter readings will not be in the normal physiological range and therefore will trigger an alarm alerting the clinician of the problem. However, in rare circumstances the pulse oximeter can continue to give erroneous readings within the normal physiological range. Because the pulse oximeter is no longer reading the patient's actual oxygen saturation or issuing an alarm to alert the caregiver of the problem, this undetected, probe-off condition can potentially endanger the patient if desaturation occurs. For this reason, the undetected probe-off condition is a serious limitation of pulse oximetry. No pulse oximetry manufacturer appears to be immune from the undetected probe-off condition.[1]

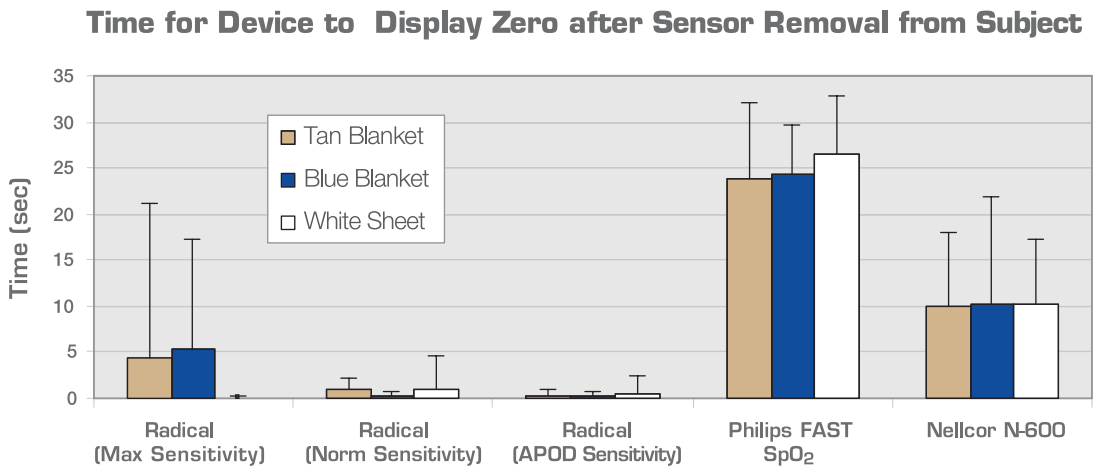

Figure 1 *(above) shows the results of a study conducted by the Masimo Quality Assurance Department on three of the leading pulse oximeter brands, (Masimo Radical with LNCS Neo sensors, Philips FAST SpO_2 with Oximax N sensors and Nellcor N-600, also with Oximax N sensors). The figure shows the time in seconds (+/- std) it took for each device to display a zero value after a normal reading was obtained when the sensor was removed from the subject and dropped onto the test blanket. Because different reflective backgrounds could produce different results, three colored backgrounds (tan, blue and white) were tested. The data represents the averages of 30 trials per background color.*

The results indicate that regardless of the background color used in the trial, the Masimo pulse oximeter with the APOD feature enabled had significantly better probe-off protection compared to the other devices.

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How the Undetected Probe-Off Condition Can Occur

To understand how the undetected probe-off condition can occur, one must first understand the general principles of how the pulse oximeter sensor functions. The typical pulse oximeter sensor is shaped so that two light emitting diodes (LEDs), which project wavelengths of light (red and infra-red) through a specific site on the patient (such as a finger or toe of an adult and the hand or foot in the neonate), is positioned opposite a photodiode detector which detects the transmitted light as it emerges from the tissue. The light absorbance of oxygenated hemoglobin is different from that of reduced hemoglobin at the two wavelengths used by pulse oximetry. Light absorbed by the photo detector can be used to calculate the oxygen saturation of the blood. Because the volume of arterial blood at the sensor site fluctuates with the pulsations of the cardiac cycle, the absorbencies at the two wavelengths also fluctuate, referred to as the AC component of the signal. Light attenuated by the non-pulsatile components at the sensor site, specifically skin, fingernail, soft tissue, bone and the non-pulsating arterial, venous and capillary blood, creates a stable component (DC component) of the signal. Because conventional pulse oximetry is sensitive to an oscillating signal from the sensor, any interference at the sensor that is pulsatile in nature has the potential to produce a false signal that could be interpreted by the pulse oximeter as a true physiological signal. As well, emitted light reflected by colored fabrics that are positioned in or near the photo emitter - detector path can also produce an SpO_2 reading that is artifactual.

Types of Signal Interference that Can Produce an Undetected Probe-Off Condition

Ambient Light or Light from the Emitter: The most common type of signal interference that can result in the undetected probe-off condition is ambient light. Surgical lights, bilirubin lights and infra-red radiant warmers are all potential sources of false signal that may be interpreted as the physiological signal if the sensor has come off the patient. The undetected probe-off condition can also occur when the detector receives light from the emitter diode without first passing through the patient's tissue. Small variations in the signal strength detected from the emitters, due perhaps to the breathing movements of the patient, can create an oscillating signal that could lead to the undetected probe-off condition.

Electrosurgical Units: Another external factor that can lead to an undetected probe-off condition is electrosurgical unit (ESU) interference. ESUs generate high-frequency currents which can radiate to the pulse oximetry sensor and interfere with the accuracy of readings when the sensor is correctly positioned on the patient or can result in an undetected probe-off condition if the sensor has become dislodged from the patient.[2]

Temperature Variation of the LED: Ambient temperature can affect the emission spectra of the pulse oximeter LEDs, which could potentially lead to an undetected probe-off condition. Although a temperature increase from 0 to 50°C was found to result in only a negligible increase of about 5.5 nm on the peak wavelength of a pulse oximeter emitting diode[3], a hazard report generated by ECRI[4] documents a case where a temperature dependent instability in the timing of a pulse oximeters digital signal led to phantom pulse oximetry readings within normal saturation ranges when the sensor was not attached to the patient.

Incompatible Sensor Type: ECRI MDSR[5] and FDA Medwatch[6] reports have documented occurrences of the undetected probe-off condition when a sensor type that is incompatible with the pulse oximeter is used on the patient. In this circumstance, the undetected probe-off condition may occur due to oscillations in the electrical current to the sensor resulting from a sensor/device mismatch. Incompatible sensors have also resulted in patient burns and so should be summarily avoided. The user should be cautioned that reprocessed sensors may be more prone to interference than new sensors.

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Solutions to the Undetected Probe-Off Condition

Masimo has employed various strategies to ameliorate the undetected probe-off problem. Some of these strategies are data processing solutions that impose signal quality based limits on the inputs that will be interpreted as physiological signals versus those that will be interpreted as noise. The strategies developed thus far impose a tradeoff between sensitivity to low perfusion and probe-off detection. Masimo pulse oximeters used in the maximum sensitivity mode are more susceptible to the undetected probe-off condition because the algorithms interpreting the incoming signals have been sensitized to seek a physiological signal from even small variations in the source. On the other hand, algorithms developed to enhance probe-off detection will result in lower sensitivity and therefore decrease pulse oximetry low perfusion performance.

Masimo Adaptive Probe-Off Detection Technology

Masimo has taken a multifaceted approach to addressing the probe-off problem including Adaptive Probe-Off Detection (APOD) algorithms and other, user selectable sensitivity modes. The Masimo APOD technology is a suite of sophisticated signal processing algorithms that evaluate the incoming signal with a signal quality analyzer that compares the sensor output to a physiological signal model. APOD consists of a probe-off output analyzer that indicates if the sensor is properly attached to the tissue site and a signal strength calculator in the detector portion of the sensor that defines a signal strength limit that is dependent on the input signal quality. The result of enabling APOD technology is a significant improvement in sensor off protection.

The APOD mode is useful for the majority of patients and especially those patients that are at particular risk for losing contact with the sensor as commonly occurs in pediatric patients or combative patients. In addition to APOD technology, Masimo pulse oximeters also provide other sensitivity levels (normal and max), adjustable by the clinician to allow for an unprecedented level of control. While APOD sensitivity is recommended for most patients, the clinician also has the option of Max Sensitivity for the sickest patients, when obtaining a strong patient signal is difficult and the clinician and patient are in continuous contact.

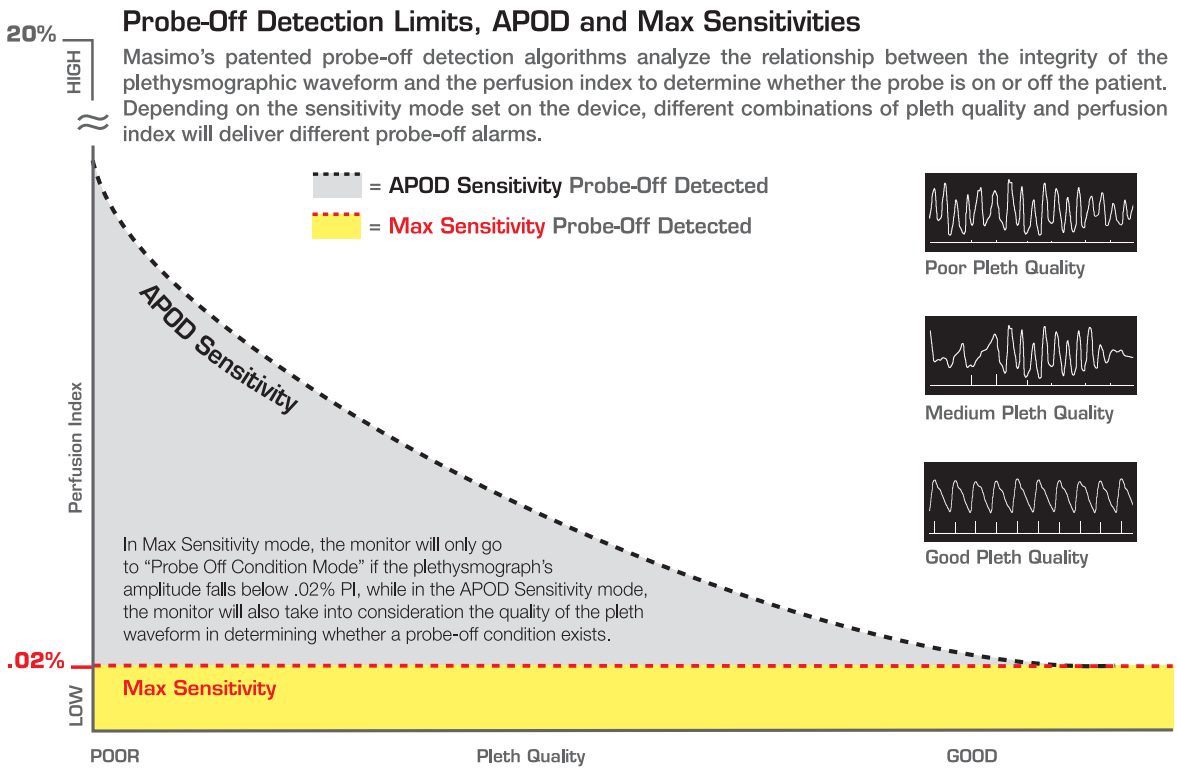

Figure 2 *- In most situations, the APOD Sensitivity mode is the most appropriate, except when the most critical patients with low perfusion are being directly observed by a qualified clinician.*

Clinical Solutions to the Undetected Probe-Off Condition

Besides utilizing the most advanced pulse oximetry technology and sensors, clinicians and other healthcare providers can take additional steps to protect their patients from the undetected probe-off condition. An obvious precaution is to always pay heed to low perfusion alarms or other technical alerts that may indicate a sensor problem. Caregivers should periodically verify the proper sensor placement on all patients but especially those with small, nonphysiologic plethysmographic waveforms, varying or weak pulse rates, or low perfusion values. Most importantly, caregivers need to be properly trained in correct sensor application and avoid incompatible sensor types.

Signal extraction pulse oximetry has become a highly valuable patient monitoring and diagnostic tool throughout the spectrum of healthcare. But as with any medical technology it has limitations for its effective and safe use with patients that must be understood by the healthcare provider. The undetected probe-off condition is one limitation of pulse oximetry that affects all brands of devices to some extent. Masimo has implemented specific design features in the Masimo SET pulse oximeters and sensors that, along with clinical precautions, can significantly limit the occurrences of the undetected probe-off conditions.

References

1. See Health Devices Alerts Action Item #A7784 and Philips Urgent Device Correction Letter at: http://www,medical.philips.com for examples of the Undetected Sensor Off condition occurring in a clinical situation.
2. Skin Integrity Issues Associated with Pulse Oximetry, *Patient Safety Authority.* 2005; 2(2): 25-29.
3. Reynolds KJ, DeKock JP, Tarassenko L, Moyle JTB. Temperature dependence of LED and its theoretical effect on pulse oximetry. *Brit J Anesth.* 1991; 67(5): 638-643.
4. Health Devices Alerts Action Item A7526 at http://members.ecri.org (ECRI is a non profit health services research agency that provides publication, information and consulting services internationally for healthcare technology).
5. ECRI Medical Device Safety Reports are available at http://www.mdsr.ecri.org/
6. Federal Drug Administration, Manufacturer and User Facility Device Experience Database Medwatch reports are available on the FDA website at http://www.fda.gov/cdrh/maude.html

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Instruments and sensors that contain Masimo SET and Masimo Rainbow SET technologies are identified with this logo. Always look for the Masimo designation for accurate monitoring when you need it most.

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