Product Information

How Accurate are Your Sp02 Sensors?

Dr Geoff Mathews, B.Sc.(Hons), Ph.D.
Managing Director, The Electrode Company Ltd, specialists in non-invasive measurements.

Life Before Pulse Oximetry

Pulse oximetry has proved itself many times over during the last 20 years as a lifesaver. Before the advent of pulse oximetry a clinician wanting to know the oxygen content of a patients blood would have been guided by the colour of the patients lips or inside of the eyelids, a blue colour indicating a lack of oxygen. A sample of blood might have been taken for analysis in the laboratory, but the result would have probably taken twenty minutes to come back. Even then this would give no information on trends, and brain death occurs in about three minutes without oxygen. It has been estimated that when pulse oximetry was introduced, 91% of the accidental deaths and injuries during anaesthesia were eliminated (1).

Pulse Oximetry - An ever increasing Demand

Changes in users expectations are now putting greater demands on pulse oximetry where inaccurate sensors can compromise patient safety. For example, there are still 2000 cases of ROP (Retinopathy of Prematurity) in The USA each year; some claim that new generation pulse oximeters can help here (2). However this is only if the accuracy of the sensors can be guaranteed. More patients are being treated whilst in hypoxia. Sensors with large errors at low SATs values are dangerous here as any error associated with the sensor is magnified as the patient's SATs fall. The progress of many patients is monitored by recording trends in SATs values by spot checks. The value of this data depends on minimal variability between sensors.

Not all Sensors are the Same

Not all sensors are the same. Sensors vary due to manufacturing tolerances and ageing. The original clinical trials were done using a sensor(s) of a particular specification. Pulse oximeters do not function as the manufacturers claim when sensor specifications vary from the original clinical trials. This can lead to sensors that introduce a high reading bias and sensors that introduce a low reading bias.

Pulse oximeter accuracy is primarily dependent on knowing the LED wavelengths that arrive at the detector during measurement. In theory this is done during the manufacturing phase by selecting sensor LED wavelengths in a narrow enough band to meet a desired measurement accuracy requirement. In practice due to manufacturing and ageing errors, LED wavelengths arriving at the detector are not always what the manufacturer intends. A shift in the LED centre wavelength (from that for which the calibration curve was made) will cause a change in the absorption spectrum and result in an error in the measured arterial oxygen saturation (3). Thus it is not unusual to find pulse oximeter sensors with wavelength errors of sufficient magnitude to compromise patient safety. In other words not all pulse oximeter sensors function as the manufacturers claim.

Historically some of the early pioneers of pulse oximetry were faced with the problem of not being able to source LEDs in sufficiently tight wavelength band to ensure accuracy without wasting a large number of LEDs. This problem was overcome by matching LEDs of a particular wavelength to an identification resistor, which enabled the monitor to select the appropriate calibration data (R curve) for the LEDs. In recent times the patents protecting this technology have expired allowing generic manufacturers into the market. It seems that not all of the generic manufactures are capable of reproducing the specifications of the original manufacturers.

Manufacturers of pulse oximeters often claim a system accuracy of +/- 2 or 3% over the range 70 - 100% Sp02. This allows for both measurement errors and individual patient variability. A pulse oximeter sensor that results in a pulse oximeter system not functioning as the manufacturer claims increases the risk of an adverse incident.

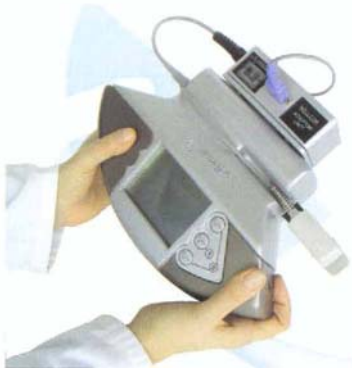
Clinical Implications of Inaccurate Sensors

Recent surveys involving more than 800 sensors from a number of leading UK hospitals have shown that approximately 30%, of the sensors tested have unacceptable faults and errors. The faults were either intermittent, or continuous cable faults. The errors ranged from a high of plus 15%, to a low of minus 17%. Cable faults are a clinical risk in that they can cause delays. Sensors that read high can result in insufficient oxygen being administered. Sensors that read low can result in excessive oxygen being administered. High reading sensors have been found capable of reading 90% SATs, whilst the true SATs are in the high 70's%. Such a sensor could delay the administration of oxygen, leading to neurological damage or death. Low reading sensors have been found capable of reading 85% when the true value is in excess of 90% SATs. This could lead to excessive oxygen being administered, a causative agent in ROP. The lack or accuracy in so many pulse oximeter sensors in daily use must be impacting on patient morbidity and mortality.

How do you Check Sensor Accuracy

Currently medical professionals have no convenient way or checking sensor accuracy. Some believe that CE marking is an assurance of sensor accuracy. This is not true. All the sensors in the above survey were CE marked. Some believe that simulators can be used to test sensor accuracy. Again this is not true, simulators at best can test sensor functionality, but they are incapable of providing the required data needed to properly evaluate the accuracy of Sp02 readings (4). Planned routine maintenance of pulse oximeter sensors, carried out on a similar basis to electrical safety would improve patient outcomes.

So the problem is this, if a pulse oximeter system is used with sensors of different wavelengths to those used in the original trials, then the system will not be accurate. Yet Clinicians continue to rely on pulse oximeters. In good faith, judgements are based on the data they give. The reliability of the data depends on the integrity of two very small low cost components - Light Emitting Diodes. If the spectral properties of the LEDs are not known to be correct, then every clinical decision made, that is based on the data, is without foundation.



Until now, there has been no convenient way to test the accuracy of pulse oximeter sensors. The Lightman is set to change all that. The Lightman is an elegant alliance of design and optics science specifically created to test sensors for accuracy and incipient failure. The Lightman is not a simulator, it is a miniaturised spectrometer, which calibrates itself against an internal argon/neon source immediately before each sensor test. It then goes on to measure the wavelengths emitted by the sensor LEDs, and give a clear read out of the result. Any sensor inaccuracies, positive or negative, will be picked up and indicated immediately. Over the Last 12 months users from across Europe and The USA report that The Lightman is in agreement with their clinical findings and experience, and is making a major contribution to patient safety.

For further information visit www.electro.co.uk or telephone +44(0) 1291 650279.