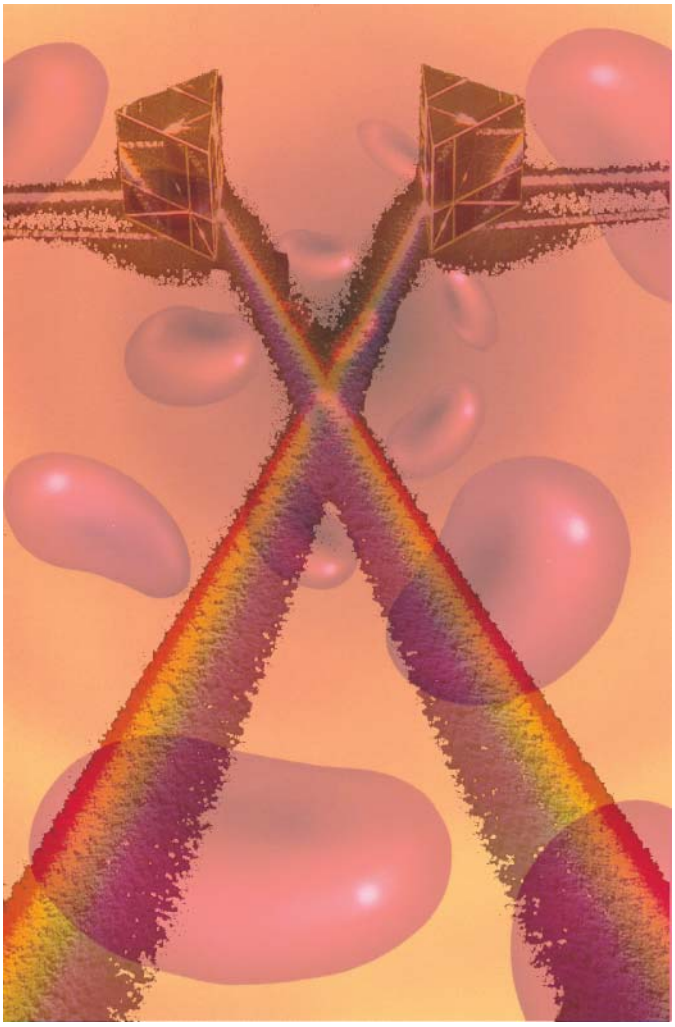
Lightman®

Clinical Impact of LED Performance in Pulse Oximetry



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1.0 Key Points

1. Surveys in The UK have revealed that in excess of 30% of pulse oximeter sensors in use do not function as the manufacturers claim.

2. Sensors that read high can lead to insufficient oxygen being given.

3. Sensors that read low can lead to excessive oxygen being given.

4. This is a problem that can lead to cataracts, retinopathy and strokes.

5. The accuracy of a pulse oximeter sensor is largely dependant on the spectral properties of the LEDs.

6. Manufacturing and aging errors impact on LED spectral properties, resulting in the LED wavelengths arriving at the detector not always being what the manufacturer intended.

7. If the spectral properties of the sensor in use are not known to be correct, then every clinical decision that is based on that data is without foundation.

2.0 Introduction

Currently medical professionals have no convenient way of checking sensor accuracy. Some believe that CE marking and FDA clearance are assurances of sensor accuracy. This is not true. Most of the inaccurate sensors in our surveys are CE marked and have FDA clearance (Electrode Co Ltd Newsletter Issue 6).

Sensors vary due to manufacturing tolerances and aging. The original clinical trials were done using a sensor 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. Any error introduced by a sensor is magnified as the oxygen saturation of the patient falls.

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 aging errors, LED wavelengths arriving at the detector are not always what the manufacturer intends. 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.

Manufacturers of pulse oximeters often claim a system accuracy of +/- 2 or 3% over the range 70 – 100% SpO_2. This allows for both measurement errors and individual patient variability. If for example a sensor is found to have an error of 10%, the accuracy of the system is then outside the manufacturers claim.

Drift in LED performance with age and incorrectly calibrated LEDs are the main source of inaccuracies in pulse oximeter sensors. LEDs are known to exhibit an infant mortality phenomena (nothing to do with patient), where a proportion of a batch ages very quickly (Tang 1993). Also manufacturing errors where sensors are fitted with the wrong LEDs are common.

Sensors that read high can result in insufficient oxygen being administered, which can lead to neurological damage, strokes, and death. Sensors that read low can result in excessive oxygen being administered, a causative link in infant eye damage (ROP). The lack of accuracy in so many pulse oximeter sensors in daily use must be impacting on patient morbidity and mortality.

3.0 Pulse Oximetry Explained

Oxygen is an essential requirement for the living tissue of the human body. One of the functions of the blood circulatory system is to carry oxygen from the lungs to all the corners of the body. Oxygen is carried in the blood in a specialised oxygen-carrying vehicle called haemoglobin. Haemoglobin, which is carrying oxygen, is red in colour, and haemoglobin, which has released its oxygen, is blue in colour. Red oxygen carrying haemoglobin is typically found in the arteries carrying its load of oxygen to where it is required, i.e. the brain, a toe, or any living cell. Blue haemoglobin is typically found in the veins returning to the lungs to pick up more oxygen. Any event that interferes with the flow of oxygen to the living tissues can be life threatening. Pulse oximetry is used to assess the state of the flow of oxygen to the living tissues, and of course any pulse oximeter must be accurate.

Twenty years ago 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 eye lids, 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. Pulse oximetry enables the oxygen content of the blood to be monitored continuously in a very convenient manner.

By the use of pulse oximetry the oxygen content of the blood can be measured by using specific wavelengths of light to determine the blueness or redness of the blood. If the light wavelengths are not known to be correct, then the pulse oximeter cannot be relied upon to be accurate.

During our activities as manufacturers of pulse oximetry equipment we have noticed that there are pulse oximeter sensors in use that are not accurate, because they have either not been calibrated properly or because the components within have deteriorated with age. A view that has been further confirmed by a nation wide survey of pulse oximeter sensors (Electrode Co Ltd Newsletter Issue 5, MDA Evaluation 303, ECRI, Compatibility of Alternative Source Pulse Oximeter Sensors).

4.0 Calibration for Pulse Oximetry

Pulse oximetry has proved itself many times over during the last 20 years as a lifesaver. When pulse oximetry was first introduced 90% of the accidental deaths during anaesthesia were eliminated. However there are now greater demands are being placed on pulse oximetry where inaccurate sensors can compromise patient safety.

The accuracy of a pulse oximeter system is largely dependant on the sensor in use having the correct wavelengths. If the wrong wavelengths are used, then the wrong measurement of blood oxygen is made and hence the displayed SATS values are not correct. The accuracy of the sensor is proportional to the wavelength error.

During the original clinical trials calibration was done with a sensor of particular wavelengths. Look up tables were compiled by comparing pulse oximeter readings with multi-wavelength measurements of oxygen saturation in arterial blood samples from a number of hypoxaemic volunteers (IS0 Pulse Oximetry Standard 9919, 2005).

Biological variability between individuals results in different SATs values being obtained with the same sensor when used on different people, even though the oxygen content of their blood is the same. It is important that when different sensors are tested on the same individual that the readings obtained are the same. If different sensors have wavelength errors then they will not read the same when tested on the same person.

The accuracy of an individual pulse oximeter sensor can be defined and measured precisely. If the sensitivity of the Photodiode is within specification, and the intensity of the signal emitted from the light emitting diodes (LED) is within specification, and that the sensor is assembled correctly, and not damaged, then the accuracy of an individual sensor pulse oximeter sensor is dependent on the wavelengths emitted from the LED's.

The relationship between wavelength and accuracy are highlighted in Design of Pulse Oximeters 2003, Pulse Oximetry Standard ISO 9919 2005. Thus 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. The purpose of The Lightman is to relate the magnitude of any wavelength errors to sensor accuracy.

5.0 Common Faults in Pulse Oximeter Sensors

There is three fault modes associated with pulse oximeter sensors:

1) Failure of the mechanical integrity (including cable faults).

2) Optical detection components.

3) Optical emission components.

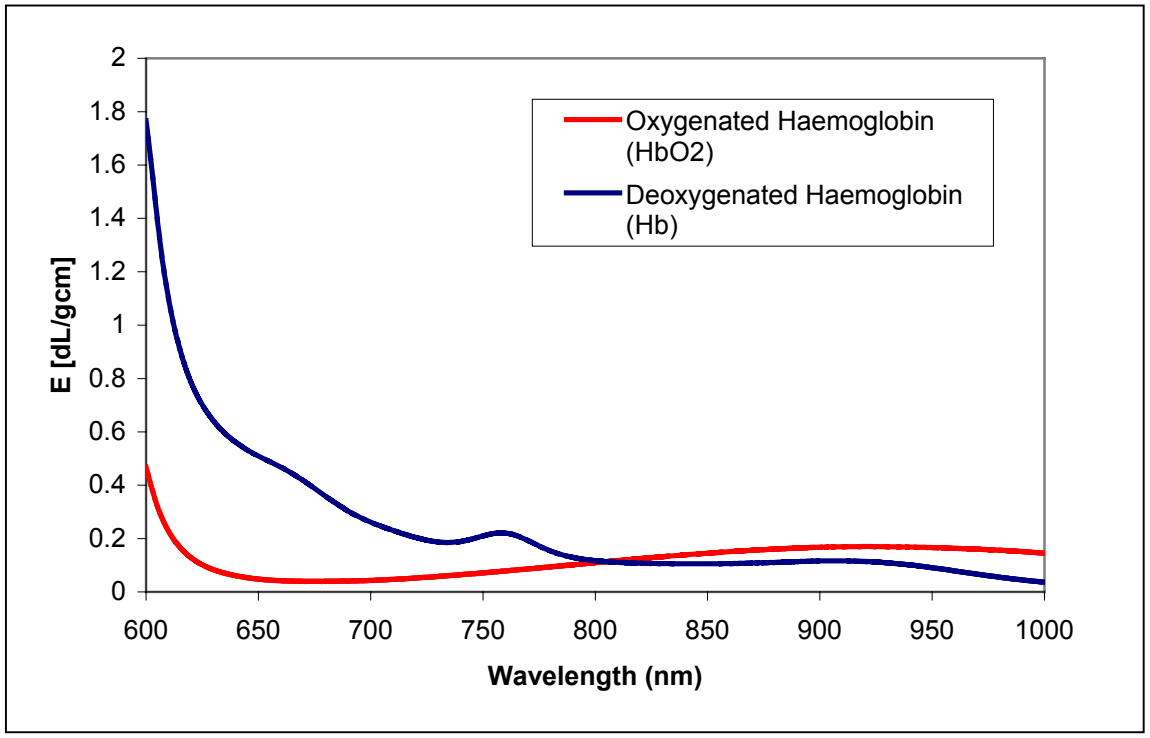
The first two faults are often easy to detect. Even if these are not obvious on visual inspection then such things as open circuits, short circuits, and weak signals are usually detected by the pulse oximeter monitor. However LED performance deterioration or incorrectly fitted LED's can lead to erroneous readings in an apparently functional pulse oximeter sensor. These faults would also not be identified by the use of a simulator.

LED performance is of great concern to us, and the focus of a great deal of research. In our experience drift in LED performance and incorrectly calibrated LED's, are the main source of inaccuracies in pulse oximeter sensors. LED performance in terms of deterioration is mainly material dominated, is of course influenced by subsequent use and abuse in the real world; and dependant on the manufacturer's processing specifications which, if are incorrect could lead to the device exhibiting arterial oxygen saturation measurement outside of the specified accuracy.

LED degradation was the reason for a product recall in 1998 (FDA Enforcement Report, 1998) where a recall for 1,969 pulse oximeter sensors was initiated. After some months of use the accuracy and reliability of the sensors deteriorated leading to intermittent and erroneous readings.

6.0 The Relationship Between LED Wavelength and Accuracy

Pulse oximetry is a method of calculating the percentage oxygenation of blood. It relies on determining the colour of the blood, which changes with oxygenation (as shown by the graph below).



The measurement is conducted by measuring the absorption of light at two wavelengths, where the optical characteristics are suitable e.g. 660 and 940nm. However, if LEDs with incorrect wavelengths are used within the sensor, the pulse oximeter monitor receives the wrong absorption characteristics and hence incorrect information is displayed. Due to the nature of the absorption characteristics of blood, the errors due to the sensor will increase as the patients saturation level decreases.

For example, as illustration only, if there is an inaccuracy of;

4 nm in red = approx 2.0% error at 97% SATS
4 nm in red = approx 4.0% error at 90% SATS
4 nm in red = approx 7.0% error at 80% SATS
4 nm in red = approx 9.0% error at 70% SATS

Different pulse oximeter manufactures use slightly different wavelengths for their measurements. Therefore it is vital to understand that changes in the wavelengths of the emission spectra of the LED's in a pulse oximeter will result in corresponding changes in the observed oxygen saturation reading (McGraw 1996).

It cannot be stressed too strongly that changes in the performance of an LED can affect the accuracy of an apparently functional pulse oximeter sensor. Furthermore pulse oximeter sensors are obviously less than accurate when they have been fitted with the wrong LED's.

7.0 Ageing & other Factors that Affect Accuracy

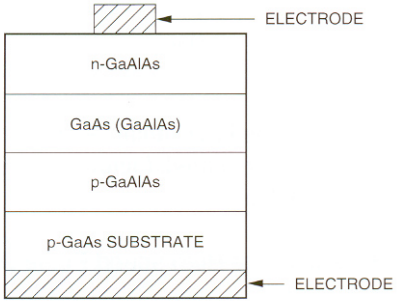
When a pulse oximeter sensor is used for long periods of time many aspects of the sensor deteriorate, including cables, plugs, shielding, and optical components. Physical damage such as cable damage that leads to weak or erroneous signals can affect accuracy. However the main source of inaccuracy is ageing effects on the LED's, which results in a change in the emission spectra (Carlin 1995). Increasingly we find sensors that have been fitted with LED's of the wrong type.

Therefore it is of vital importance that the emission spectra of the LED's in a pulse oximeter do not deviate from that specified. Performance deterioration of the LED's is particularly important when considering service intervals for pulse oximeter sensors.

Common LED deterioration phenomena include a decrease in the power output and variations in the forward voltage. It is thought that these deteriorations result from the crystal dislocation and shift caused by heat generation in the emission area. These can be observed as a dark line or dark spot in the emission pattern.

Deterioration can also be caused by external stress. If the LED is driven with stress applied to the LED chip, its performance may unduly deteriorate. This stress takes the form of mechanical distortion of the package containing the LED. Such stress may result from poor mounting of the LED during manufacture and may also result from damage to the pulse oximeter sensor during use.

8.0 Potential Mechanisms of Changes in Emission Spectra



LED deterioration is most prevalent in the infrared LED of the pulse oximeter sensor, whose composition includes Gallium (Ga), Aluminium (Al) and Arsenic (As), the exact proportions of these elements having a determining factor of the wavelength produced by the LED.

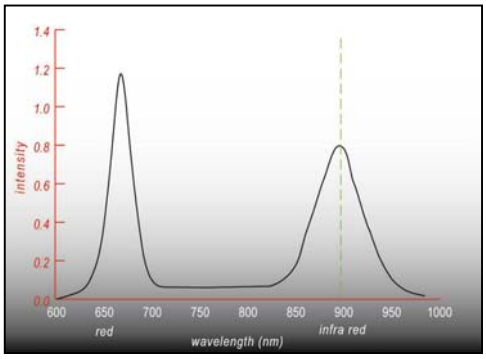
Figure 1: Basic structure of an infrared LED chip.

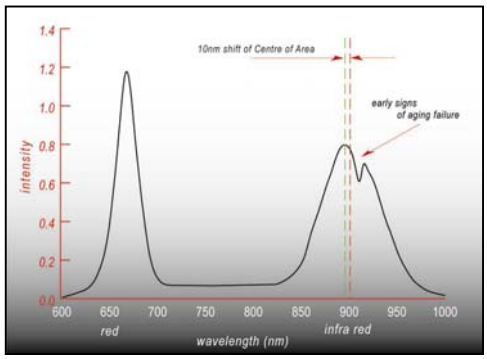
"The main degradation modes are: dislocations that affect the inner region, metal diffusion and alloy reaction that affect the electrode, solder instability (reaction and migration) that affect the bonding parts, separation of metals in the heat sink bond, and defects in buried heterostructure devices. These modes are enhanced by current during ambient temperature operations."(Ott, 1997)

The deterioration of LED's also occurs through the creation or the expansion of Dark Line defects. There are two potential sources of Dark Line Defects. Research shows that Dark Line defects are networks of elongated dislocation loops or half loops that originate in the quantum well during device operation. Current research shows that after degradation, the grown-in or pre-existing Frank-type stacking faults become tangles of dislocations. In contrast, the Shockley-type stacking faults remain unchanged for the photo degradation conditions recently studied, indicating they are more resistant to Photo degradation than the Frank-type stacking faults. It seems likely that the Frank-type stacking faults are the sources of Dark Line Defects. The mechanism for degradation probably starts by the emission of very small clusters of vacancies from the Frank type faults. Under a transmission electron microscope it can be seen that the dislocation loops found in the vacancies grow by gliding on (111) planes and become hairpin-like dislocation loops (Lacey 1997). This probably results in a change in the band gap with a consequential change in the wavelength of the emitted radiation.

9.0 Example of LED degradation

Red & Infra Red spectra are showing no evidence of faults. Wavelengths are correct. Minimal error associated with sensor.

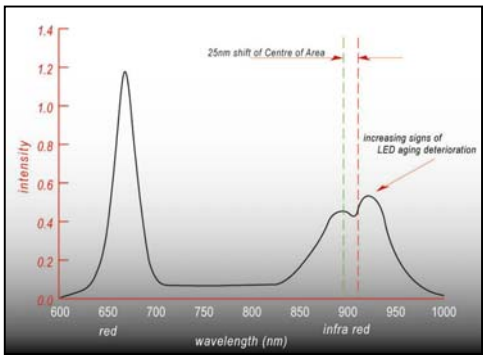


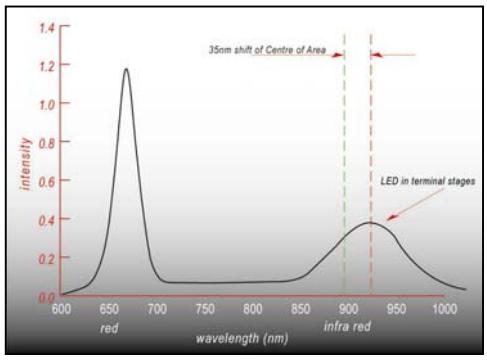


Spectra showing early signs of Infra Red LED failure. Centre of Area of IR Spectra has shifted 10nm. There will be no noticeable change in sensor performance.

Spectra showing increased signs of Infra Red LED aging deterioration. The initial IR peak has slumped most and the second IR peak begins to dominate. The Centre of Area of the IR Spectra has now shifted 25nm. At low patient SATS the sensor will begin to read bewteen 1 and 2% low.

Sensor is now compromising patient data





Spectra showing increased signs of Infra Red LED aging deterioration.

The intensity has dropped and although the sensor will still appear to function normally.

The centre of area of the IR spectra has shifted 35nm. At low patient SATs the sensor will read bewteen 4% and 5% low.

This error is of sufficient magnitude to increase the chance of an adverse incident.

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APPENDIX 1: STANDARDS USED FOR TESTING, MDA evaluation no 303, November –1996 (Latterly MHRA)

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