Lightman Case Studies

Case studies where inaccurate pulse oximeter sensors have increased the risk of an adverse incident.

THE ELECTRODE COMPANY LTD

Lightman®

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1.0 Introduction

Recent surveys conducted on pulse oximeter sensors in daily use have discovered that 1 in 3 sensors do not function as the manufacturers claim with implications for patient safety. During the surveys note was taken where inaccurate sensors might have been impacting on patient morbidity and mortality. These surveys have also highlighted that in many cases there is no effective planned maintenance schedule for pulse oximeter sensors, and in some cases a reluctance to recognise the problem.

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 is impacting on patient morbidity and mortality.

Currently the responsibility for sensor accuracy is not taken seriously. 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. This is because up to now there has been no way of checking sensor accuracy.

There is a dangerous gap in the testing of pulse oximeter sensors, and one that is increasing the risk of adverse incidents. Before the arrival of The Lightman it was not possible to check sensor accuracy. Now with The Lightman sensor accuracy can be tested where it is most needed, on the ward, in the operating theatre, or wherever.

A planned routine assessment of accuracy on every pulse oximeter sensor before being put into clinical use, and thereafter as part of a planned maintenance schedule would be a cost effective way of reducing potential litigation costs and improving patient safety.

The case studies in this document describe incidents where patient safety was compromised. These are all incidents which could have been prevented if the there had been a procedure in place to check the accuracy of pulse oximeter sensors.
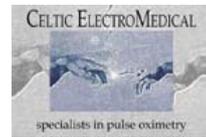
2.0 Clinical Implications of Sensor Accuracy

2.1 Sensors that read high

A sensor with positive error would cause a pulse oximeter to give a higher SpO$_2$ reading than were true.

High reading sensors will lead clinicians to consider that the patient is better oxygenated than is the case. This may lead to deferring instigation of oxygen therapy or lower levels being administered than would have been given if the data had been correct.

This can result in hypoxic damage to the patient, i.e. Neurological damage, strokes and death.

2.2 Sensors that read low

A sensor with negative error would cause a pulse oximeter to give a lower SpO$_2$ reading than were true.

Low reading Sensors will lead clinicians to consider that the patient has poorer oxygen levels than is the case. This may encourage the clinician to administer higher levels of oxygen than would have been given if the data had been correct.

This is a major causative factor in infant eye damage. Excessive oxygen application can also lead to metabolic disturbances.

3.0 Case Study - Misinformed Clinical Decision

Sleep apnoea studies – In Hospital A the paediatric ward nurses noticed that the children admitted for overnight sleep studies would sometimes look blue but that the pulseoximeter did not indicate low SpO$_2$ levels. The nurses did not have faith in the equipment and despite being told that it was new, the nurses wanted the equipment replaced.

The sensors involved were assessed using the Lightman; the results are shown in Graph 1.

When comparing sensor one and three in particular the lack of reliability of the data can be understood. The data would very much depend on which sensor was being used. The tendency for the patients to look blue whilst the SATs values were still in the 90s can be explained by sensors one and two tending to read high.

 When only the data and trends are looked at (as may happen when sleep studies are carried out) then a clinical decision is being misinformed and a different decision and management plan may be arrived at.
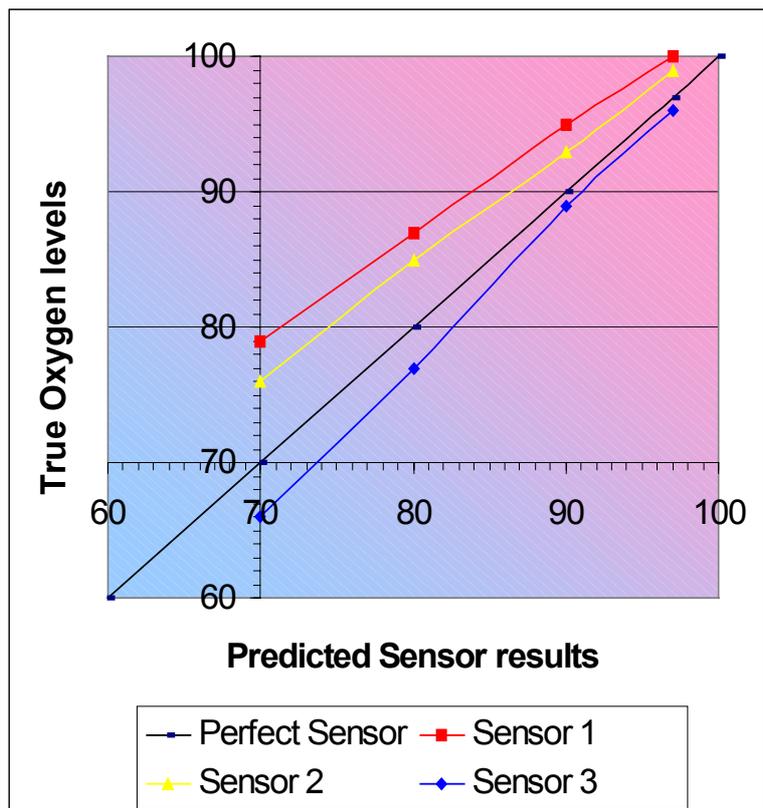
Graph 1

4.0 Case Study – Potential Neonatal Hypoxia

In Teaching Hospital B a baby on NICU (Neonatal Intensive Care Unit) was thought to have de-saturated, but the pulse oximeter alarms had not gone off. The nursing staff was blamed for turning off the alarms on the pulseoximeter system and not noticing that the baby was 'de-saturating' whilst the 'silent ' mode was operating.

Teaching Hospital SCBU

predicted error

individual sensors

■ 97% ■ 90% □ 80% □ 70%
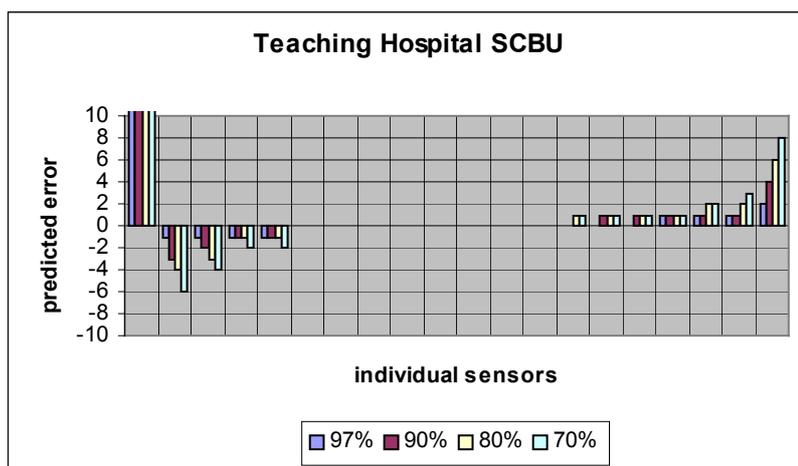
The Lightman was used on NICU to assess the sensors in use. The results of the assessment are shown in Graphs 2 and 3.

Graph 2

Graph 3 shows the effect of a high reading sensor (Sensor 4) such that the alarm would not have been triggered even when a baby had low blood oxygen levels.
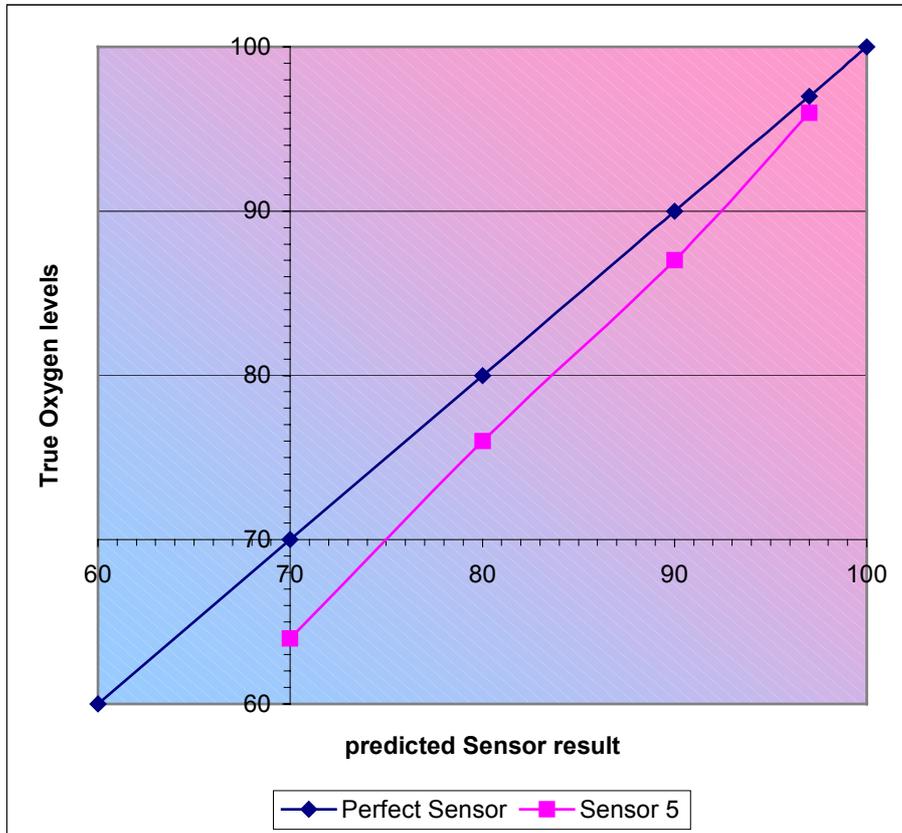
In this incident The Lightman proved that the nursing staff were not to blame. The incident was caused by an inaccurate sensor.

True Oxygen levels

Predicted Sensor results

—■— Perfect Sensor —■— Sensor 4 —▲—
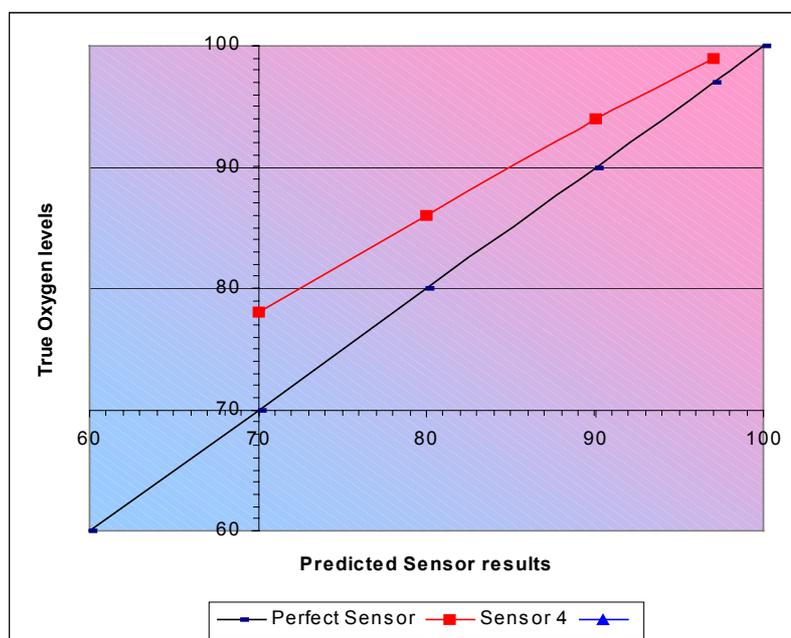
Graph 3

5.0 Case Study - Neonatal ROP risk

On testing sensors with the Lightman on the NICU in Hospital B a new unused sensor (Sensor 5) with low reading bias was found.
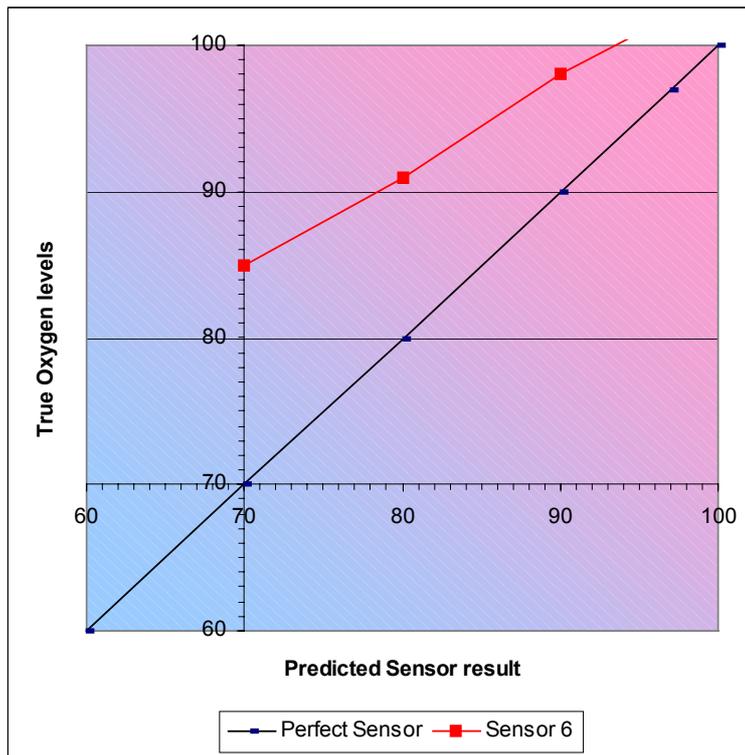

Graph 4

This would, if used, have led to excess oxygen being administered. This is a particular concern for clinicians working with premature babies where they are trying to maintain the SpO_2 within a very specific range in order to minimise morbidity risk factors.

Excessive oxygen is a major causative link in infant eye damage (ROP). There are still over 2000 cases of ROP every year in The USA. The large number of pulse oximeter sensors in use that read low must be impacting on this.

6.0 Case Study – Potential Adult Hypoxia

The medical staff at Hospital C noted that a patient was obviously low on oxygen but the SATS values displayed by the monitor did not fall. The clinical engineer traced the problem to the sensor and noted that when placed on his finger one sensor read 97% whilst the sensor under question read 100%.

Graph 5

The sensor (Graph 5 Sensor 6) was a new one. The Clinical Engineering Department reported this to the Pulseoximeter system manufacturer and was advised that this sort of variation is normal.

On testing with the Lightman the error associated with the sensor was found to be +5% at 97% SATs. When tested on the customer's finger this error was masked by the system display maximum of 100%, i.e. the system would have displayed 102% if the displayed had allowed this.

The most dangerous feature of this sensor was that it was capable of reading 90% whilst the true oxygen saturation value of the patient was in the high 70's, a value associated with anoxic damage of the brain. In other words the sensor was indicating that the patient was safe, whilst in reality the patient was at extreme risk from brain damage. A dramatic example of an inaccurate pulse oximeter sensor increasing the risk of an adverse incident.

The impact of such inaccurate sensors on morbidly and mortality is obvious and worrying.

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7.0 Case Study - Chronic Obstructive Pulmonary Disease

Low reading sensors can also increase morbidity (and potentially mortality rates) in the 'Blue Bloater' who has chronic respiratory problems and a reduced respiratory drive.

The sensor (Graph 6 - Sensor 7) found at Hospital D in Respiratory Support is obviously concerning for this type of patient.

Although as an Inpatient blood oxygen may be checked with blood sample analysis this takes time. Also many of these patients are managed at home on domicialary oxygen where blood samples is not an option. Ambulance staff when transporting patients, also do not have the opportunity to take blood samples, and rely totally on Pulse oximeters.
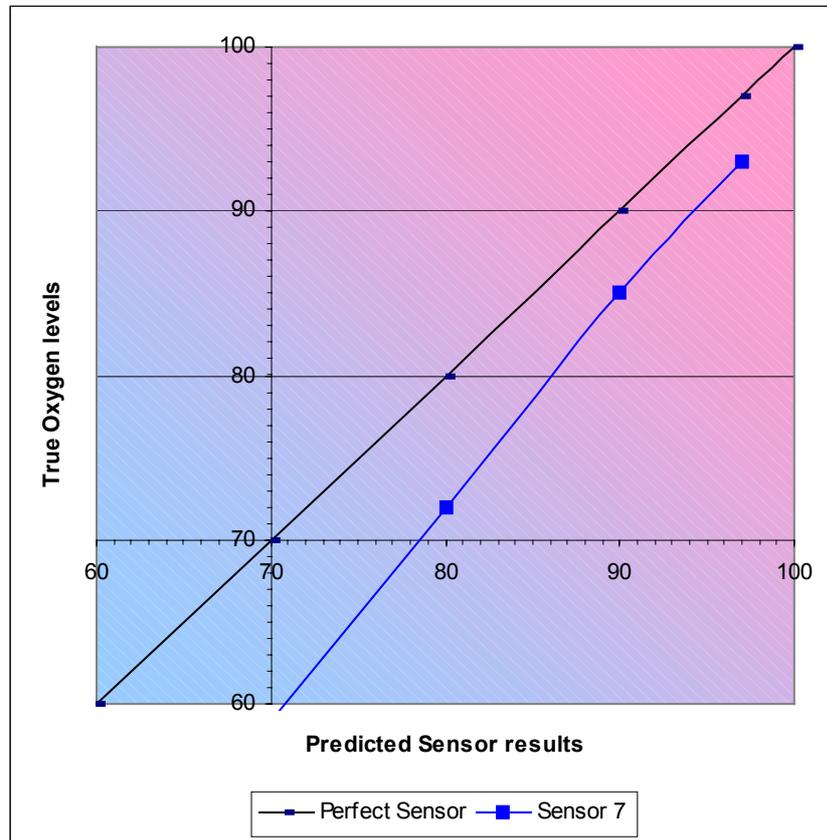
Graph 6

The sensor was removed from use and replaced with a sensor of minimal error.
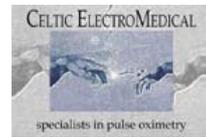
8.0 Case Study - Clinical Confusion

Recent surveys conducted on pulse oximeter sensors in daily use have discovered that 1 in 3 sensors do not function as the manufacturers claim with implications for patient safety. 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). With such variability between pulse oximeter sensors in daily use it is no surprise that at times clinicians do not always have confidence in the pulse oximeter systems that they are using.

During a routine operation, as is standard practice, the oxygen saturation of the patient was being monitored by means of pulse oximetry. During the operation the SATs value on the pulse oximeter monitor dropped. It was believed that the most likely explanation for this was that the sensor was not reading correctly.

The phenomenon of inaccurate sensors is well known in this trust. It is standard practice in operative procedure to use the same pulse oximeter sensor from the pre-operative stage (anaesthetic room), through the intra-operative stage (operating theatre), to the postoperative stage (recovery room). This procedure removes the problem associated with variability between sensors and allows trends in oxygen saturation to be noted. However this procedure does not reduce the risk of using pulse oximeter sensors with large errors.

After recovery the patient was suspected to have de-saturated during the operation. In other words it was suspected that the patient had not been given sufficient oxygen during the operation. The sensor used during the operation was later tested with a Lightman, and the sensor was found to be accurate.

Possibly if a Lightman had been available during the operation, the clinicians would have had more confidence in the data their pulse oximeter system was giving them, and the patient would have been given more oxygen. If the hospital involved had a policy of assessing the accuracy of every sensor before it was put into use, and thereafter as part of a planned maintenance schedule, clinicians would have more confidence in the pulse oximeter technology that they are provided with.

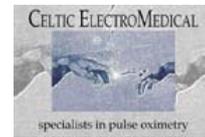## 9.0 Case Study - Clinical Engineering Confusion

After a number of incidents where patient safety was compromised by inaccurate sensors the Clinical Engineering Department at Hospital G bought a piece of test equipment known as a simulator believing that it could be used for testing sensor accuracy.

Whilst monitoring a patient on the ward the low oxygen alarm on a particular system kept on alarming, although the patient showed no clinical signs of hypoxia. The nursing staff swapped the pulse oximeter sensor for another sensor following which the pulse oximeter system indicated normal SATs values for that patient. The nursing staff were of the opinion that the pulse oximeter sensor was faulty.

The incident was reported to the Clinical Engineering Department who then tested the pulse oximeter sensor in question with their new simulator. They concluded that there was no fault with the sensor and recommended that it should be put back into use. Clinical Engineering did not realise that simulators only check functionality, i.e. check for broken wires and were unaware that simulators cannot and do not check pulse oximeter sensor accuracy.

After further communication with the nursing staff; who were not satisfied with the advice they had been given; the Clinical Engineering Department borrowed a Lightman to test the pulse oximeter sensor that caused the incident. The Lightman indicated the sensor was reading 11% low. This was entirely in agreement with the observations of the nursing staff. The sensor was removed from use.

The Clinical Engineering now says that there is a dangerous gap in the testing of pulse oximeter sensors, and one that is putting patients at risk every day. Before the arrival of The Lightman it was not possible to check sensor accuracy. Now with The Lightman sensor accuracy can be tested where it is most needed, on the ward, in the operating theatre, or wherever.

10.0 Case Study - Quality control

The Clinical Engineering Department in Hospital F uses the Lightman to assess all new and old sensors in use throughout the Trust. Sensors with the potential for patient harm are removed from use. Initially not all of parts of the trust appreciated the risk to patients that inaccurate pulse oximeter sensors can pose.

Another hospital within the trust bought a new batch of sensors and put them into use without consulting the Trust's Clinical Engineering Department. Clinical staff noticed a change in the data obtained from the pulse oximeter systems involved, and became concerned about accuracy. When tested by Clinical Engineering all the sensors in that batch were found to have errors that had potential for patient harm. These sensors were removed from use.

It is now appreciated that it is possible to assess pulse oximeter sensor accuracy easily without removing the sensors from use. The Lightman is used for routine commissioning of every new pulse oximeter sensor, and thereafter as part of a planned maintenance schedule. This trust considers that The Lightman should be The Gold Standard for the quality assurance of pulse oximeter sensors.