Lightman Scientific Pack

A literature review

Contents

1.0 Introduction

Pulse oximeters are used to monitor vital signs of patients. They provide important information about the Saturated Oxygen level of the blood of the patient (SpO_2). In addition they measure pulse rate. This information is usually displayed visually and alarm levels set to provide audible and visual warnings of a clinically unacceptable saturation level or pulse rate. They have made a substantial contribution to patient safety by better informing the clinical decision making process. They are widely used and now recommended as part of the minimum standards for monitoring by a number of Royal Colleges and Associations in many areas of medicine e.g. Anaesthesia, Critical Care (ICU), Paediatrics (SCBU / NICU) and Cardio-respiratory medicine. In many clinical areas 'spot checks' of SpO_2 are included as part of the routine recording of vital signs; blood pressure, pulse rate, respiration and temperature.

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 (Celtic ElectroMedical Newsletter Issue 5, 2004). In other words not all pulse oximeter sensors function as the manufacturers claim.

The **Lightman®** instrument contains a miniature spectrometer that calibrates itself using an internal highly stable emission source, prior to every sensor test. The Lightman tests circuit integrity and measures the LED colour spectrum and light output of the LEDs within the sensor. The Lightman is portable and can be taken to the wards and operating theatres, sensors can be tested quickly with minimum disruption to clinical services. The calculated accuracy of the sensor at critical patient SpO_2 levels is displayed on the Lightman screen. Thus enabling sensors that could be providing inaccurate data to be rapidly identified and withdrawn from clinical use.

2.0 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. The impact of this can be considered from the following examples.

Sleep apnoea studies - patient not considered to be hypoxic and a different clinical decision on management e.g. not eligible for Continuous Positive Airways Pressure (CPAP) respiratory support.

Hypoxia - Insufficient Oxygen administered contributing to oxygen starvation leading to hypoxic events with resultant damage to central nervous system and other tissue as evidenced by

- Confusion e.g. Post op confusion
- Strokes
- Cerebral palsy
- Death

Neonates – patient SpO_2 would actually be maintained at a lower level than prescribed resulting in significant physiological stress and associated increased morbidity.

3.0 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 will encourage the clinician to administer higher levels of oxygen than would have been given if the data had been correct. The impact of this can be considered from the following examples.

SCBU/NICU – A causative link exists between high levels of oxygen and Retinopathy of Prematurity (ROP). The clinician is therefore trying to maintain the SpO_2 within a very specific range. ROP occurs in over 16% of all premature births. In babies weighing less than 1,700 grams at birth, over 50% will develop ROP. In the United States, over 2,100 children annually experience the complications of ROP. Of those estimates of 500 to 1,200 cases of new blindness or severe complications are reported. Studies have found that about 30% of infants with advanced ROP have 20/200 or less in their better eye. (Understanding Retinopathy of Prematurity. Richard L. Windsor, O.D., F.A.A.O. Laura K. Windsor, O.D., F.A.A.O. Published in Vision Enhancement Journal).

Chronic Obstructive Pulmonary Disease – Excess oxygen may lead to a reduced respiratory drive leading to acid base imbalance (Price's Textbook of the Practice of Medicine, Section 9. Diseases of the respiratory system. The lungs and bronchi. Respiratory failure).

4.0 Manufacturer's Accuracy Claims

Manufacturers of pulse oximeters claim an accuracy of +/- 2 or 3% over the range 70 – 100% SpO_2. This allows for both measurement errors and individual patient variability (Tungjitkusolmun, S. Accuracy and Errors in pulse oximetry 2003,) (Design of Pulse Oximeters, Wouters, P. et al 2002)

5.0 Source of The Signal in Pulse Oximetry

Historically the origin of the pulsatile signal as used in pulse oximetry has been explained in terms of arterial pulsations. Conventionally this has been thought to be caused by the arteries expanding during systole and therefore containing more blood during systole than during diastole, leading to more light being absorbed when there is the maximum amount of blood in the light path during systole.

This absorption is then explained in terms of Beer's law that is only applicable to situations where there is no scattering of the light. However Beer's law alone cannot be used to explain pulse oximetry (Webster J G 2003, Steinke and Shepherd 1986, De Kock and Tarassenko 1993, Takuo Aoyagi 2002).

A model for the combination of absorption and scattering of light in pulse oximetry would be very useful as this then could be used to replace the empirical calibration curves used in pulse oximetry. Both Steinke and Shepherd, and De Kock and Tarassenko have concluded that Twersky's theory of radiation scattering and photon diffusion gives the best fit to measured data.

The outcome of this is that scattering greatly increases the sensitivity of pulse oximetry, in such a way that pulse oximetry would not work as we know it if it were not for the effect of scattering.

The effect of scattering is dependant of wavelength and the oxygenation state of the haemoglobin (Steinke and Shepherd 1986) in such a way that light scattering increases the sensitivity of whole blood oximetry.

Further work carried out by Nilsson, Alsholm, Karlsson and Anderson-Engels (1998) showed that the three-dimensional shape of the particles influences the scattering. Nilsson et al concluded that the assumption of independent scattering does not hold true for whole blood. Results obtained from diluted blood samples cannot be extrapolated to whole blood by a simple multiplication factor related to the concentration.

Random orientation of blood cells is not the case in flowing blood. The cells align in a preferred direction and their asymmetric disc like shape affects the scattering of light (Bitbol 1986,Lindburg et al). During their passage through the capillaries the red blood cells have to flex. They are also subjected to shear stresses and fluid dynamic interactions with other cells and blood vessel walls. These factors alter their shape and consequentially the scattering of the light, thus the assumption of the Lorentz-Mie theory, which assumes spheroidal blood cells, seems inappropriate to Nilsson et al.

Nilhson et al whilst accepting the proof for using the probability function of Henyey-Greenstein for a dense tissue such as skin dispute its use for whole blood. The absolute size of the scattering particle was less relevant than the size of the particle relative to the wavelength.

Blood cell orientation, size, shape and flow will all change the scattering of the light, which will be wavelength specific.

All these factors need to be allowed for in calculating the change in absorption of tissue with pulsatile blood at specific wavelengths as used in pulseoximetery calculations of Oxygen saturation levels.

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