

Clinical Trials.

Extensive Clinical Trials have been carried out in a number of UK Hospitals, to assess the accuracy and compatibility of Viamed SpO₂ probes. Trials were carried out, collating information on SpO₂ levels against blood gas analysis, in patients undergoing a variety of treatments including administered drugs, arterial lines and %oxygen inhalation.

Dr A Cohen, Director of I.T.U, oversaw a major project, recording 588 readings at St James's University Hospital, Leeds. St James's is one of Europe's largest hospitals, having a substantial Intensive Care Unit.

Trials were also carried out at the University of Florida, an institution currently evaluating pulse oximetry techniques and the University College of Los Angeles.

It was felt that an 'Operational' trial was required, to effectively highlight a correlation between potential errors in SpO₂ measurement to patient treatment ongoing at the time. Data was taken from patients undergoing a variety of treatments, in the normal, 'day to day' hospital environment. The trial was **not** carried out on volunteers using artificial SpO₂ manipulation.

In all, hundreds of readings were taken, on which statistical and trend analysis was carried out. Tables of data are included overleaf. Graphical and statistical analysis of the data collated for the two probe types is shown overleaf.

The data should be interpreted with an understanding of the inherent inaccuracies of pulse oximetry. Pulse oximetry measures 'functional' SpO₂. Co-oximetry measures 'fractional' SpO₂ and blood gas analysis derives SaO₂ values. There may be a difference of $\pm(1 - 2)\%$ between pulse oximetry derived oxygen concentrations to that of co-oximetry and blood gas analysis.

Nellcor probes are quoted as having a SpO₂ accuracy of (± 1 SD), 70 – 100% ± 2 digits.

The cumulative difference between pulse oximetry and other methods of oxygen concentration derivation is a combination of the original specification of the probe, differences between SpO₂ and SaO₂ and also errors induced due to the clinical condition of patients.

Published papers, which the reader may find relevant, are as follows:

1. **“Precision and Accuracy of Pulse Oxymetry”.**

Authors: P. Ahlburd M.D.,
J. Norreslet M.D.,
K. Knage M.D.,
T. Nielson M.D.,
J. B. Rasmussen M.D.,
I. Brandsland M.D., DMSC.

Department of Anaesthesia and Intensive Care and Department of Chemistry,
Vejle Hospital,
Denmark.

2. **“Potential Errors in Pulse Oximetry”.**

Authors: R. K. Webb, MB, BS, FFARACS,
A. C. Ralston, BSc, BappSc,
W. B. Runciman, BSc (Med), PhD.

Department of Anaesthesia and Intensive Care,
Royal Adelaide Hospital,
Adelaide, Australia.

3. **“A Comparison of the Performance of 20 Pulse Oximeters under Conditions of Poor Perfusion”.**

Authors : D. G. Clayton, BSc, MB, BS, FFARCS,
R. K. Webb, MB, BS, FFARACS,
A. C. Ralston, BSc, BappSc,
D. Duthie, MB, BCh, FFARACS,
W. B. Runciman, BSc (Med), PhD.

Department of Anaesthesia and Intensive Care,
Royal Adelaide Hospital,
Adelaide, Australia.

4. **“Oximetry Sensors: Factors that Impact Accuracy”.**

Published by Nellcor Puritan Bennett.