



SpO₂ Clinical Study Report

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SpO₂ Clinical Study Summary Information

Type: VM-2101 (0012101)

Sensor Tested: VM-2101

Test Date(s): 4 – 5 December 2007

Monitor Tested: VM-2101

Report Date: 7 January 2008

Data Analysis

SpO₂ and Co-oximeter data were inputted into Excel for analysis.

Functional SaO₂ (percent) was calculated as $SaO_2 (\%) = O_2Hb / [100 - (COHb + MetHb)]$.

Two co-oximeters were used: OSM3 for SaO₂ values; ABL520 to check validity by agreement.

Bland-Altman statistics; Bias, Standard Deviation of Difference (SpO₂ – SaO₂).

Regression Line: Slope, Intercept, and Correlation Coefficient.

RMS Error: Calculated per ISO 9919 as:

$$A_{RMS} = \sqrt{\frac{\sum_{i=1}^n (SpO_{2i} - S_{RI})^2}{n}}$$

Test Results

Refer to the graphs on the following page:

Samples (n)

220

Bias:

0.809

Std. Dev.:

1.861

RMS Error:

2.0

Slope:

0.864

Intercept:

12.507

Correlation (R²)

0.962

Subject Demographics

Male: 70%

Female: 30%

Age Range: 19 - 30

Dark Skin: 20%

Light Skin: 80%

Excluded Points: None (see page 2)

Protocol Information

Protocol: (title): Validation of Pulse Oximeters

Investigator: Dr. Philip S. Clifford, Ph.D.

Review Committee Approval: VA Project No: 1445-05 HRRC No.: 73-93

Facility: Medical College of Wisconsin, VA Medical Center, Milwaukee, WI 53295 USA

Subjects: 10 subjects per test series, minimum 20% dark skin

Number of samples: ≥ 20 SpO₂ – SaO₂ pairs/subject with co-oximetry in the range 70% - 100%

Blood Sample: via radial artery

Reference Method: Co-oximeter(s) – Radiometer OSM3 reference with ABL700 Co-oximeter check.

Subject Consent: Prior written informed consent was obtained for all subjects.

Subject Confidentiality: Confidentiality was maintained for all subjects per number system.

Protocol Execution: Performed in accordance with ISO 9919 Annex EE, analysed to (1), (2).

Technical References

- (1) ISO 9919:2005 (IEC 60601-2-54): Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
- (2) BLAND, J.M., ALTMAN, D.G. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. (8 Feb), (1986), pp. 307 – 310.

Conclusion

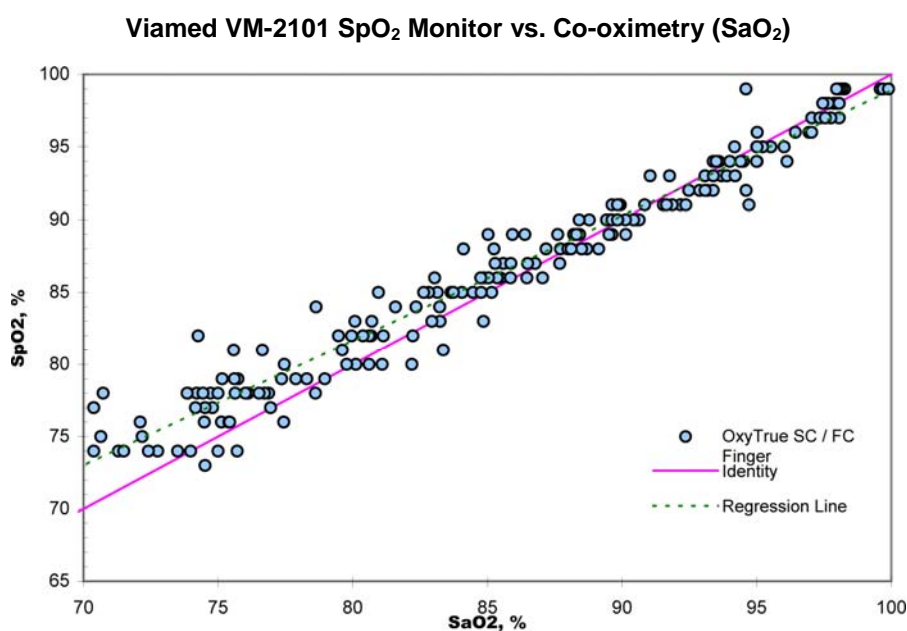
The tested device meets the stated accuracy specification for RMS Error $A_{RMS} = 2.0$ for the range 70% - 100% SaO₂. The accuracy is not specified below 70% SaO₂.



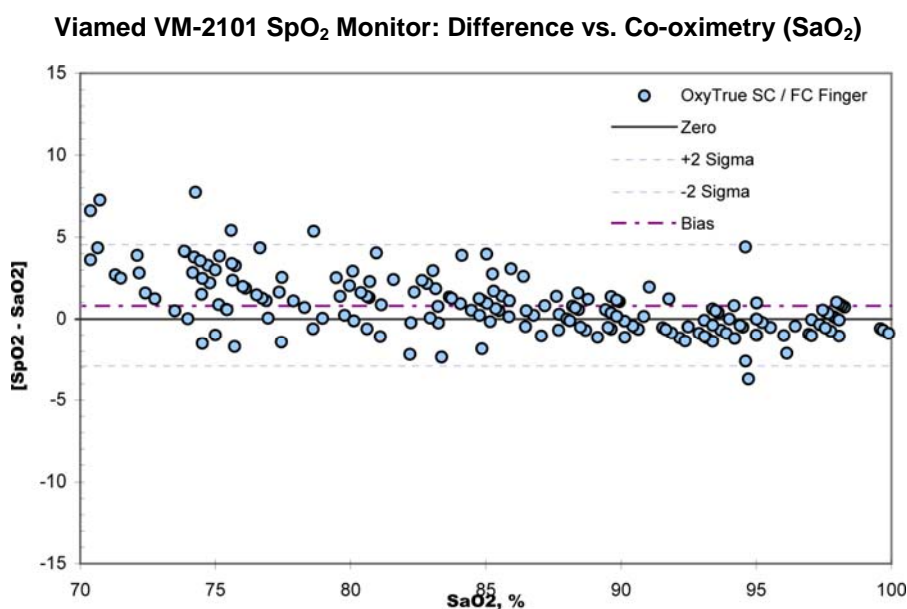
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Graph: SpO₂ vs. SaO₂



Bland-Altman Plot (difference: SpO₂ – SaO₂)



Excluded Points(s):

(none)