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SpO_2 Clinical Study Report

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SpO_2 Clinical Study Summary Information

Type: VM-2105 (0012105)

Sensor Tested: VM-2105 (integrated sensor)
Monitor Tested: VM-2105; S/N 30000323 (grey)

Test Date(s): 25 – 26 Aug 2009
Report Date: 28 Aug 2009

Data Analysis

SpO_2 and Co-oximeter data were inputted into Excel for analysis.
Functional SaO_2 (percent) was calculated as SaO_2 (%) = O_2Hb / [100 – (COHb + MetHb)].
Two co-oximeters were used: OSM3 for SaO_2 values; ABL520 to check validity by agreement.
Bland-Altman statistics; Bias, Standard Deviation of Difference (SpO_2 – SaO_2).
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	**Subject Demographics**	
Bias:	-0.177	**Male:**	60%
Std. Dev.:	1.513	**Female:**	40%
RMS Error:	**1.5194**	**Age Range:**	20-37
Slope:	1.041	**Dark Skin:**	30%
Intercept:	-3.725	**Light Skin:**	70%
Correlation (R^2)	0.967	**Excluded Points:**	None (see page 2)

Protocal 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 SpO_2 – SaO_2 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) (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} = **1.5** for the range 70% - 100% SaO_2. The accuracy is not specified below 70% SaO_2.

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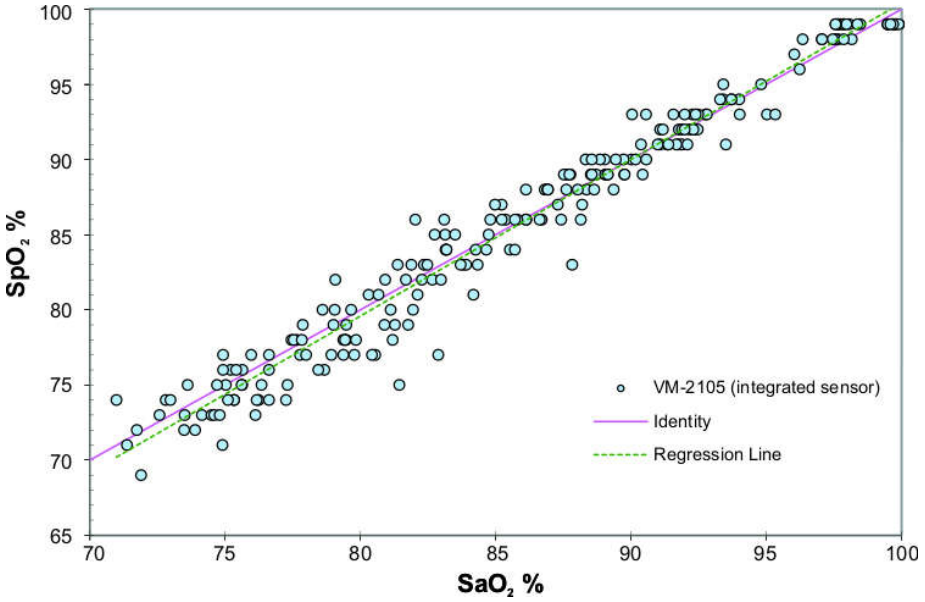
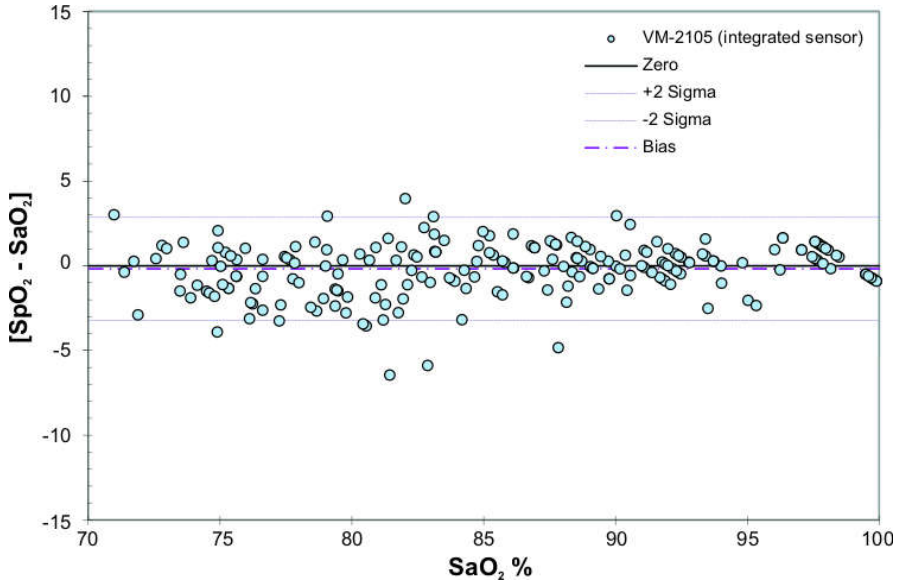
Graph: SpO_2 vs. SaO_2

Viamed VM-2105 SpO_2 Monitor vs. Co-oximetry (SaO_2)



Bland-Altman Plot (difference: SpO_2 – SaO_2)

Viamed VM-2105 SpO_2 Monitor: Difference vs. Co-oximetry (SaO_2)



Excluded Points(s):

(none)