

Accuracy of Masimo SET pulse oximetry in black and white volunteer subjects: a retrospective review

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Introduction: A recent letter to the editor¹ and more recent paper² purported to find a “racial bias” in pulse oximeter measurements based upon a comparison of data obtained from black and white patients. We questioned the validity of these reports, which were compiled from previously collected health record data using unspecified pulse oximeters and controls. Therefore, we performed a retrospective review of laboratory data obtained from black and white volunteer subjects undergoing induced hypoxia studies using Masimo SET pulse oximeters to identify any differences in pulse oximeter accuracy and bias between these ethnic groups.

Methods: Volunteer desaturation data collected between October 2015 and July 2021 was retrospectively evaluated. The data included 7,183 paired samples (3,201 black and 3,982 white) obtained from 75 subjects (39 black and 36 white). SpO₂ values obtained from Masimo SET pulse oximeters with RD SET sensors (Masimo, Irvine, California) were time-matched (within 5 seconds) with arterial blood gas (ABG) samples obtained from a radial arterial line and analyzed on ABL-835 Flex CO-oximeter blood gas analyzers (Radiometer, Brea, California). The ABG samples were collected and handled in accordance with the guidelines provided by the blood gas analyzer manufacturer.^{3,4} Subjects from each ethnic group were screened using the same criteria to remove potentially biasing health conditions. These subjects were exposed to the same hypoxia protocol that varied the arterial saturation of hemoglobin (SaO₂) between 70% and 100% while non-invasive pulse oximeter (SpO₂) values were obtained for comparison using a standard protocol aligned with the ISO 80601-2-61 standard.

Statistical calculations include bias (mean difference of SpO₂-SaO₂), precision (standard deviation [SD] of the difference), and accuracy (root mean square error [A_{RMS}]).

Results: The bias for black subjects was -0.20, compared to -0.05 for white. The precision for black subjects was 1.40, compared to 1.35 for white subjects. The accuracy (A_{RMS}) for black subjects was 1.42, compared to 1.35 for white. The bias difference between the white and black subgroups was found to be 0.15 (p-value < 0.001). This difference is not clinically significant because the SpO₂ display resolution on pulse oximeters is 1%.

| Masimo SET | Bias | Precision | A _{RMS} | N _{Pairs} | N _{Subj} |
|------------|-------|-----------|------------------|--------------------|-------------------|
| Black | -0.20 | 1.40 | 1.42 | 3,201 | 39 |
| White | -0.05 | 1.35 | 1.35 | 3,982 | 36 |
| All | -0.12 | 1.37 | 1.38 | 7,183 | 75 |

Conclusion: There was no clinically significant difference in the accuracy or bias between black and white subjects monitored with Masimo SET pulse oximetry and RD SET sensors.

References:

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