

SpO₂ Accuracy of Fingertip Pulse Oximeter - The OxiCare® DB11



Summary

A study comparing SpO₂ accuracy of OxiCare DB11 Fingertip Pulse Oximeter to Masimo Rainbow Radical 7 pulse CO-Oximetry was conducted in December of 2011. Data was obtained from human subjects by using an induced hypoxia protocol that recorded saturation levels between 70%-100% SpO₂. The results showed good correlation of OxiCare DB11 SpO₂ data as compared to Masimo Radical 7. The A_{RMS} of OxiCare DB11 inner probe is 1.36 and the A_{RMS} of Adult finger glove sensor on OxiCare DB11 Pulse Oximeter is 1.33.

Purpose

The purpose of this study was to evaluate the SpO₂ accuracy performance of the OxiCare DB11 Fingertip Pulse Oximeter and its supporting SpO₂ sensor during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to Secondary-standard pulse oximeter equipment. The devices tested were OxiCare DB11 inner probe and Adult finger glove sensor on OxiCare DB11 Pulse Oximeter.

Method

The study was conducted in accordance to ISO9919, second edition 2005-03-15, also meet EN ISO9919:2009, applicable sections, Clause 50 and Annex EE.3. The reference SpO₂ data is obtained from Masimo Rainbow Radical 7 pulse CO-Oximetry under non-motion conditions. Subjects include eleven healthy adult males and females of

varying skin tones. The subjects must understand the study and consent to participation by signing the Informed Consent Form and satisfactorily completing a health assessment form. Subjects were given medical grade mixtures of oxygen and nitrogen to induce stable plateaus at various levels of hypoxia. At each stable plateau, reference SpO₂ data and SpO₂ data of OxiCare DB11 Pulse Oximeter were collected during non-motion conditions. Data collection requires a minimum of 250 points evenly distributed across the range of 70-100% SaO₂ for eleven subjects.

Results

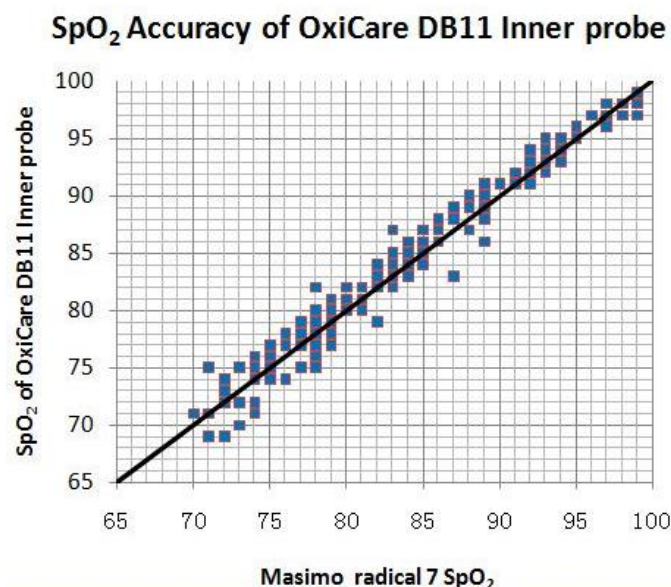
The Accuracy Root Mean Square (A_{RMS}) calculation is to be used for statistical analysis comparison of test device SpO₂ vs reference SpO₂ data.

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

SpO_{2i} : measured SpO₂ result of OxiCare DB11fingertip pulse oximeter;

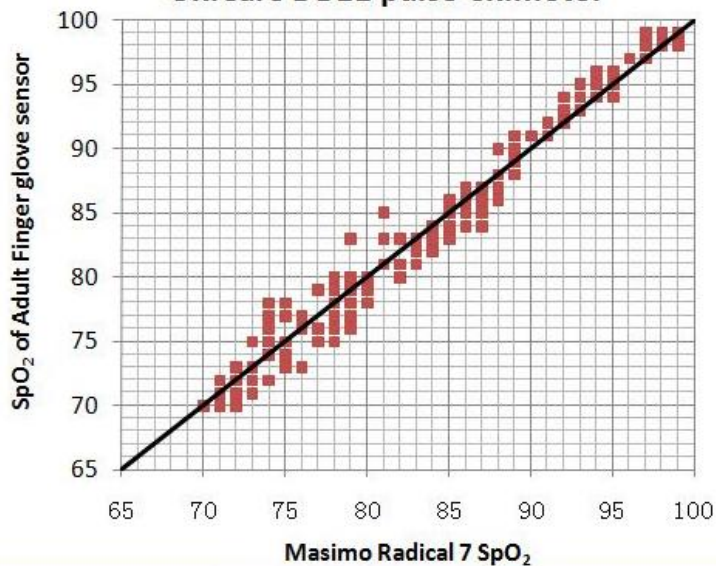
S_{Ri} : measured SpO₂ result of Masimo rainbow radical 7 Pulse CO-Oximetry;

n : Number of samples.



The blue dots are the SpO₂ value of OxiCare DB11 inner probe plotted against the SpO₂ value of Masimo radical 7. The results show that the data points align with the dark line, representing good correlation to Masimo radical 7.

SpO₂ Accuracy of Adult Finger glove sensor on OxiCare DB11 pulse oximeter



The red dots are the SpO₂ value of Adult Finger glove sensor on OxiCare DB11 pulse oximeter plotted against the SpO₂ value of Masimo radical 7. The results also show that the data points align with the dark line.

ARMS of OxiCare DB11 Pulse Oximeter

SpO ₂	OxiCare DB11 Inner Probe	Adult Finger Glove Sensor on OxiCare DB11 Pulse Oximeter	Samples
Entire Range	1.36	1.33	252
90-100%	0.89	0.96	89
80-89%	1.40	1.34	83
70-79%	1.69	1.65	80

According to above SpO₂ value and ARMS analysis, OxiCare DB11 fingertip pulse oximeter ensures excellent SpO₂ accuracy performance across 70-100% SpO₂ range.