

Quantifying Pulse Oximeter Accuracy During Hypoxemia and Severe Anemia

Using an *In Vitro* Circulation System

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Introduction

- Pulse oximetry is essential for safe clinical care
- Pulse oximeter (SpO₂) accuracy can be compromised during profound hypoxemia
- The effect of anemia of the accuracy of pulse oximeters at varying levels of oxygen saturation (SaO₂) is less well understood
- This is especially relevant in low- and middle-income countries where severe anemia is prevalent as is the use of inexpensive pulse oximeters which may be more susceptible to inaccuracy
- In some settings in Sub-Saharan Africa, 12-29% of hospitalized children have a Hct less than 15%¹
- Accurate pulse oximeter measurements depend upon programming the empirical calibration curve into the device
- Currently, calibration and validation of accurate instrument readings is accomplished via desaturation studies in human test subjects
- These studies are expensive and limited

Specific Aims

- Study the performance of three modern pulse oximeters of varying cost during hypoxemia and severe anemia utilizing a novel *in vitro* circulation system
- Determine if pulse oximeter performance is impacted by severe anemia *in vitro*

Methods

- Three study oximeters of varying cost were selected
- Fresh, single donor human whole blood was mixed with normal saline to generate four desired hematocrit (Hct) levels: 40%, 30%, 20%, and 10%
- Oxygen or nitrogen was bubbled through the blood to generate various oxygen saturation levels, and the blood cycled through the IVC system using a peristaltic pump
- The emitter and detector from three study oximeters were attached to opposite sides of a pulsatile cuvette. SpO₂ readings were paired with simultaneously measured SaO₂ readings obtained by measurement on a reference laboratory CO-oximeter
- The standard error of the estimate (SEE) was calculated for each pulse oximeter at a given Hct level. A computed 2nd order equation was created at each Hct level for each device
- To account for the expected calibration difference between human and IVCS calibration, for each device, the curve fit at Hct 40% was subtracted from those at Hct of 30%, 20%, and 10%, and the bias (%) and average root mean square error (A_{RMS} %) calculated over the range of SaO₂ and Hct values

Methods (continued)

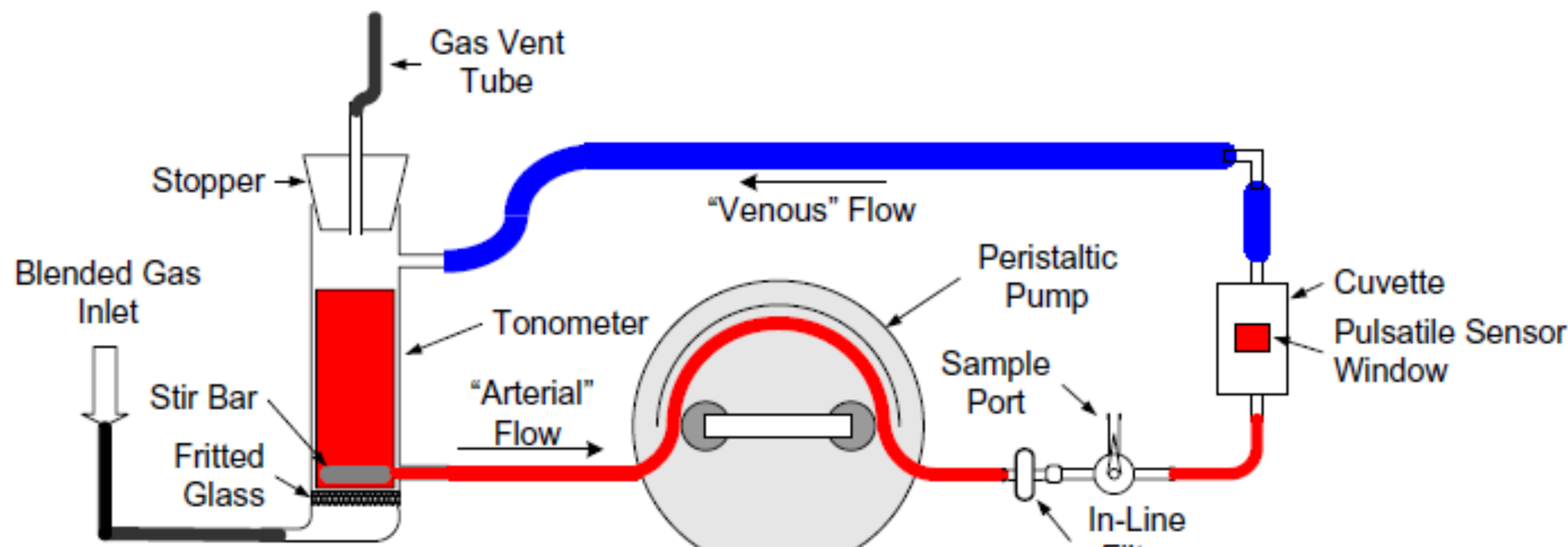


Figure 1: Diagram of In Vitro Circulation System ²



Masimo Radical
Approx cost \$1,000



**Acare AH-M1 or
"LifeBox"**
Approx cost \$250



Contec CMS 50 DL
Approx cost \$15

Results

SaO ₂ Range	Hct=30%		Hct=20%		Hct=10%	
	Bias (%)	A _{RMS} (%)	Bias (%)	A _{RMS} (%)	Bias (%)	A _{RMS} (%)
60 - 69.9%	0.04	0.04	0.27	0.28	3.76	3.83
70 - 79.9%	0.01	0.02	0.54	0.54	1.85	1.89
80 - 89.9%	-0.06	0.06	0.77	0.78	0.95	0.95
90 - 100%	-0.15	0.15	0.97	0.97	1.05	1.07
70 - 100%	-0.07	0.10	0.76	0.78	1.28	1.37

Table A.1: Masimo Radical SpO₂ Bias and A_{RMS} Statistics for differences from SpO₂ at Hct=40%

SaO ₂ Range	Hct=30%		Hct=20%		Hct=10%	
	Bias (%)	A _{RMS} (%)	Bias (%)	A _{RMS} (%)	Bias (%)	A _{RMS} (%)
60 - 69.9%	-0.82	0.83	-1.96	1.97	-5.97	5.98
70 - 79.9%	-0.97	0.97	-1.24	1.26	-4.56	4.59
80 - 89.9%	-0.59	0.62	-0.29	0.42	-2.25	2.39
90 - 100%	0.31	0.46	0.88	0.96	0.97	1.45
70 - 100%	-0.41	0.71	-0.21	0.95	-1.93	3.10

Table A.2: Lifebox v1.5 SpO₂ Bias and A_{RMS} Statistics for differences from SpO₂ at Hct=40%

SaO ₂ Range	Hct=30%		Hct=20%		Hct=10%	
	Bias (%)	A _{RMS} (%)	Bias (%)	A _{RMS} (%)	Bias (%)	A _{RMS} (%)
60 - 69.9%	-0.18	0.41	2.52	2.52	4.93	4.94
70 - 79.9%	0.69	0.70	2.10	2.10	3.50	3.53
80 - 89.9%	0.79	0.79	1.72	1.72	1.92	1.98
90 - 100%	0.10	0.33	1.37	1.37	0.18	0.56
70 - 100%	0.52	0.64	1.73	1.76	1.86	2.35

Table A.3: CMS 50DL SpO₂ Bias and A_{RMS} Statistics for differences from SpO₂ at Hct=40%

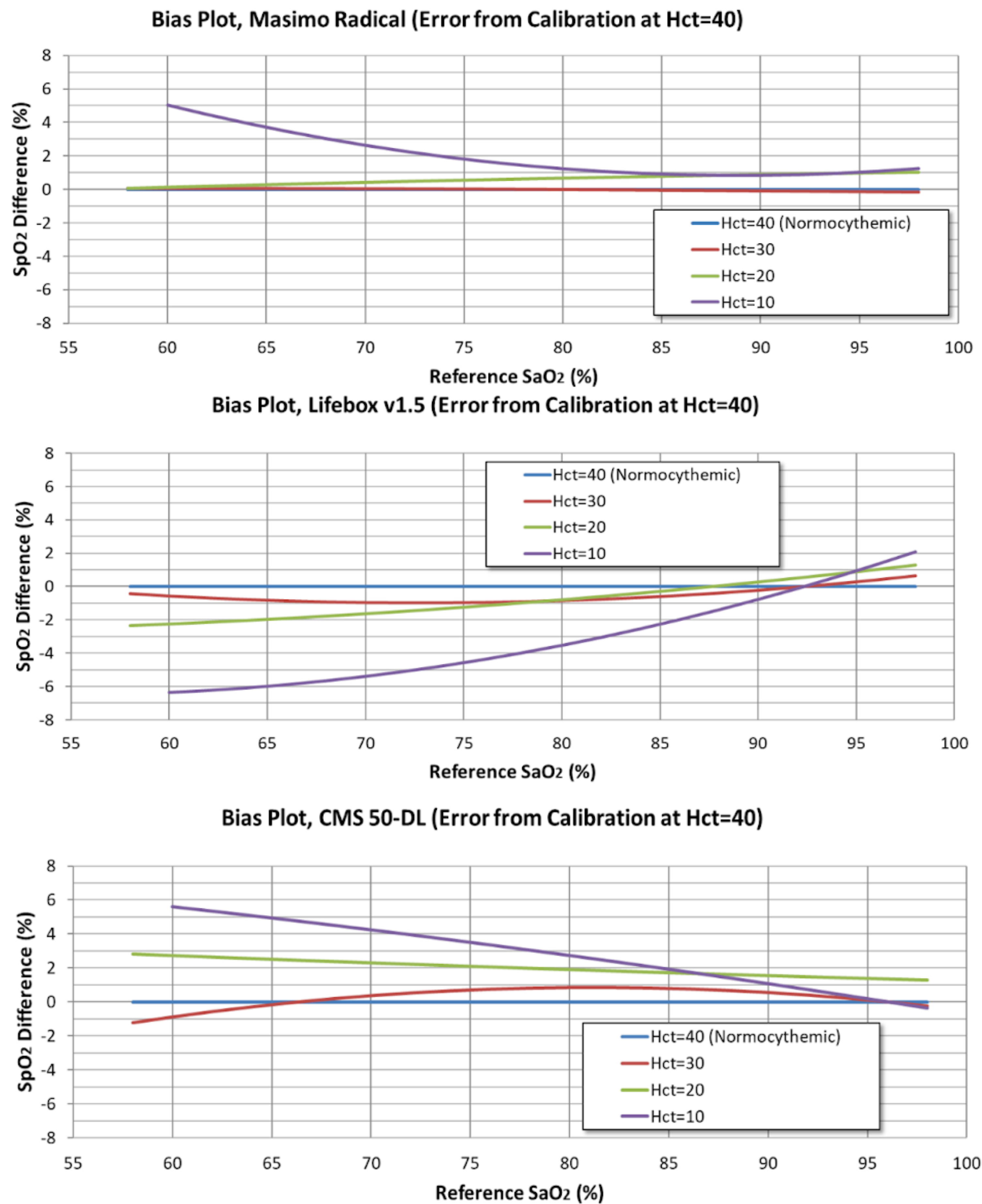


Figure 2: Bias Plots Showing Errors in SpO₂ Measurement as a Function of Reference Oxygen Saturation (SaO₂) and Hematocrit (Hct)
Errors shown are the differences in saturation measurement from those obtained for Hct=40; therefore, by definition, the zero-error line is the Hct=40 line. To obtain the curves shown in these plots, the curve fit for Hct=40 was subtracted from the curve fit at each of the other hematocrit levels. The Hct=10 and 20 curves for the CMS 50-DL oximeter were truncated below 58% SaO₂

- The Masimo device had an A_{RMS} less than 3% for all hematocrits tested between saturations of 70-100%, but the error was greater than 3% with severe anemia at low saturation
- The Acare device performed well at hematocrit levels greater than 20%, but with greater error than the Masimo device. At a Hct of 10%, the Acare was not accurate at saturation levels between 60-70%, 70-80%, and 70-100%
- The CMS 50DL showed greater bias and A_{RMS} than the two other devices starting at a Hct 20%. At a Hct of 10%, the 50DL similarly was not accurate at SaO₂ ranges less than 80%

Discussion

- The Masimo Radical maintained strong SaO₂-SpO₂ correlation at all but the most extreme anemic Hct level
- The handheld lower cost device (Acare AH-M1) had decreased SaO₂-SpO₂ correlation compared to Masimo. Correlation decreased at lower Hct levels
- The consumer grade fingertip device (CMS 50-DL) had the poorest SaO₂-SpO₂ correlation of the three oximeters
- The *in vitro* system may be a tool to rapidly assess oximeter performance and improve accuracy during severe anemia
- Clinical validation is required

Conclusions

- Pulse oximeter performance is impacted by severe anemia *in vitro*
- In vitro* studies may play an increasing role in augmenting expensive and time-consuming *in vivo* performance studies evaluating pulse oximeter performance in challenging conditions

Partners

Kestrel Labs, Inc.



HYPOXIA LAB
hypoxialab.org



Open Oximetry

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