SpO2 Accuracy Validation Report

July 8-9, 2015

Protocol Title:	Accuracy of pulse oximeters with profound hypoxia. Test program and protocol. Revision: Feb 2005
Test location:	Hypoxia Research Laboratory University of California, San Francisco (UCSF) Philip E. Bickler, Ph.D., M.D. John R. Feiner, M.D. 513 Parnassus Ave, Med Sci San Francisco CA 94143
Test date:	July 8 -9, 2015
Report date:	rev.0 (March 15, 2016), rev.1 (January 03, 2017)
Equipment under Test	OxyTrue® A (SMARTsat OEM III) CapnoTrue®(SMARTsat OEM II)
Commercial sponsor:	Bluepoint Medical GmbH&Co. KG, An der Trave 15, 23923 Selmsdorf, Germany

This study was conducted in accordance to CFR for Non-Significant Risk Medical Device Study.

Principal Investigators:
Philip Bickler, MD, PhD, Professor of Anesthesia, University of California ("UCSF")
John Feiner, MD, Professor of Clinical Anesthesia, University of California ("UCSF")

Philip Bickler

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Date: 2017.02.19 10:22:43 -08'00'

Philip Bickler Date

John Feiner 2/12/17
Date

Table of Content

1 SUMMARY

Purpose: Validating the clinical SpO_2 - accuracy of the bluepoint Medical OxyTrue® A and CapnoTrue® with SMARTsat® Pulse Oximeter Technology. SMARTsat® SpO2 sensors in combination with the SMARTsat® modules are validated under conditions of controlled hypoxia in an industry standard breath-down clinical test in healthy consented adult volunteers. Other sensor/monitor combinations were studied during this test but are outside the scope of this report.

Scope: **OxyTrue® A** (SMARTsat® OEM III module) and **CapnoTrue®** (SMARTsat® OEM II module) with SpO_2 sensors:

SoftCap (SC7500), SoftFlap (SF7500), SoftWrap (W7500), Ear Probe (EP7500), Disposable Adult (10-AP)

Applicable Standard: ISO 80601-2-61:2011, Sub-clause 201.12.1.101 SpO2 accuracy of pulse oximeter equipment *(including Annex EE: Guideline for evaluating and documenting SpO2 Accuracy in human subjects)*

Method: See Annex 12.5: CTA Master BLUE05_150708_FE_7.7.15_p8-p10: „ACCURACY OF PULSE OXIMETERS WITH PROFOUND HYPOXIA" Test program and protocol. Revision: Feb. 2005

Test Facility: University of California at San Francisco, Hypoxia Laboratory Prof. Philip E. Bickler

Medical Sciences Building, 513 Parnassus Ave.

San Francisco, CA 94143-0542

Period of test: 08. – 09. July 2015

Results:

Table 1.1: CapnoTrue® (SMARTsat®OEM II)– A_{RMS} in the SaO_2 ranges

Sensor type	60 - 100 %	70 - 100 %	90 - 100 %	80 - 90 %	70- 80 %	60 - 70 %
10-AP	2.1	2.1	2.2	1.9	2.0	2,2
EP7500	2.2	2.1	1.0	1.7	2.8	3,5
SC7500	1.6	1.6	1.1	1.7	1.8	1,9
SF7500	1.6	1.5	1.4	1.3	1.7	2,3
W7500	1.6	1.4	1.0	1.2	1.8	2,8

Table 1.2: OxyTrue® A (SMARTsat®OEM III) – A_{RMS} in the SaO_2 ranges

Sensor type	60 - 100 %	70 - 100 %	90 - 100 %	80 - 90 %	70- 80 %	60 - 70 %
10-AP	2.5	2.4	2.1	2.3	2.6	3.4
EP7500	2.4	2.3	1.4	1.6	3.2	3.3
SC7500	1.7	1.6	1.5	1.8	1.7	2.4
SF7500	1.6	1.5	1.4	1.4	1.7	2.0
W7500	1.7	1.6	1.3	1.5	1.9	2.4

also see attached detailed result plots

Observations: The study proceeded normally with no difficulties and no adverse events reported.

Conclusion: The results of the study demonstrate compliance of all tested monitor and sensor combinations listed under SCOPE with the specification requirement of 4 Arms (as defined in ISO 80601-2-61:2011, Sub-clause 201.12.1.101) in the range of 60 - 100% (steady state and non-motion condition).

Furthermore the SpO2 accuracy performance of both tested monitor systems, OxyTrue® A (SMARTsat® OEM III) and CapnoTrue® (SMARTsat® OEM II), meets an specification of Arms 2 for sensors SC7500, SF7500 and W7500 and Arms 2.5 for sensors 10-AP and EP7500 and may be labeled as such.

2 INTRODUCTION

Aim of this study was the validation of the clinical SpO2 - accuracy of the bluepoint Medical SMARTsat® Pulse Oximeter Technology under conditions of controlled hypoxia in an industry standard breath-down clinical test in healthy consenting subject volunteers.

3 DEFINITIONS

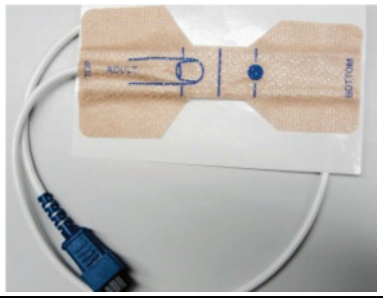
BGA	Blood gas analyzer
CapnoTrue®	Handheld CO2/SpO_2 Monitor manufactured by bluepoint Medical
EuT	Equipment under Test. Includes device, accessories, cables, PC-software etc.
IR	Infrared
N/A	Not applicable. Data does not apply to the configuration.
NaN	Not a number
OxyTrue® A	Handheld SpO_2 Monitor manufactured by bluepoint Medical
PR	Pulse rate
REF	Order number
SaO_2	Fraction of functional hemoglobin in arterial blood that is saturated with oxygen measured with the reference device (CO-Oximeter)
SMARTsat®	Registered trademark for bluepoint Medical developed high performance Pulse Oximeter Technology.
SN	Serial number
SpO_2	Estimate of SaO2 made by the pulse oximeter equipment (EuT)
UCSF	University of California at San Francisco

4 EQUIPMENT UNDER TEST (EUT)

The OxyTrue® A with SMARTsat® OEM III and CapnoTrue® with SMARTsat® OEM II were validated with each SMARTsat® sensor typ. Identification of all parts are listed below.

4.1 SMARTsat® SpO2-Sensors

Table 4.1: EUT – SpO_2-Sensor

SpO_2-Sensor	Photo	Type	REF	SN
SoftCap®		SC7500	6020132004	14B10044 130916-012
SoftFlap®		SF7500	3020132002	14A10017 130913-008 130913-007
SoftWrap®		W7500	6020132006	130914-004 14E10015
Disposable Adult		10-Ap	6020131194	LOT: 242312
Ear Probe		EP7500	6020132254	14F10003 130920-002

4.2 SMARTsat® Pulse Oximeter modules

Table 4.2: EuT – OxyTrue® A with SMARTsat® OEM III Module

Device	Device SN:	OEM III SN:	Sensor connected		Sensor SN:
OxyTrue® A	T90500201	15TT32028	SoftCap	(SC7500)	14B10044
	T90500202	15TT32023	SoftFlap	(SF7500)	14A10017
	T90500203	15TT32027	SoftWrap	(W7500)	130914-004
	T90500204	15TT32026	Disposable	(10-Ap)	LOT: 242312
	T90500206	15TT32022	Earprobe	(EP7500)	14F10003

Table 4.3: EuT – CapnoTrue® with SMARTsat® OEM II Module

Device	Device SN:	OEM II SN:	Sensor connected		Sensor SN:
CapnoTrue®	Sample #8	152333T06	SoftCap	(SC7500)	130916-012
	Sample #9	152333T09	SoftFlap	(SF7500)	130913-008 and 130913-007
	Sample #10	152333T08	SoftWrap	(W7500)	14E10015
	Sample #11	152333T05	Disposable	(10-Ap)	LOT: 242312
	Sample #12	152333T10	Earprobe	(EP7500)	130920-002

5 METHOD

5.1 Setup

The study included women and men. None of the subjects enrolled for hypoxy-studies should be anemic (Hemoglobin ≤ 10gm•dl-1) and only healthy non-smoking individuals of age 21-49 (Min. to Max.) are eligible to participate in the study.

For an overview on the equipment used in the Hypoxia Laboratory see Figure 5.1 - 5.5. For a detailed description on the procedure see section 6.2.

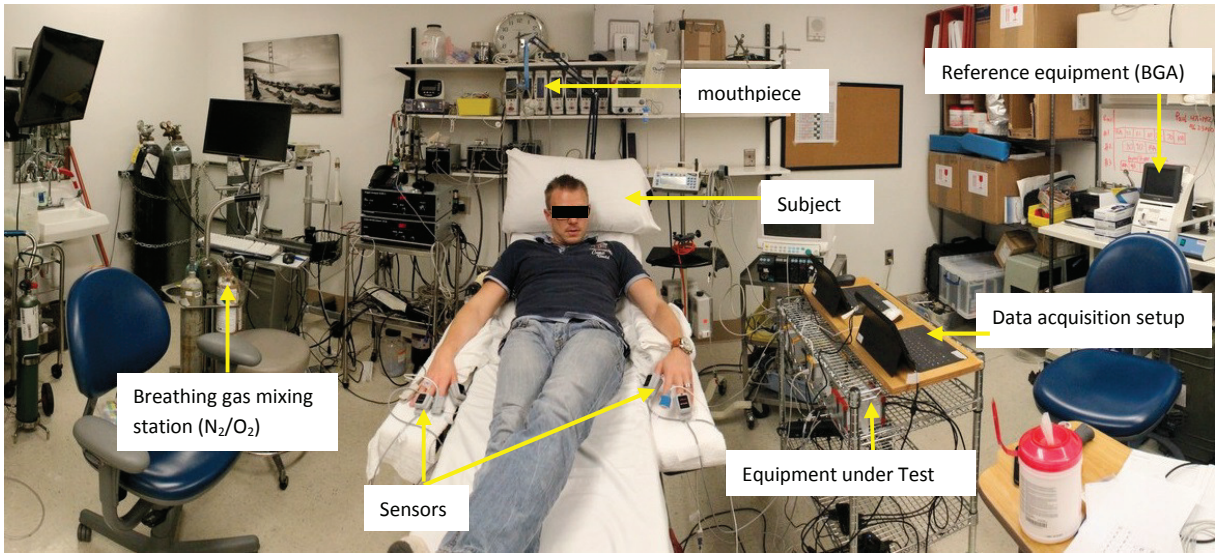


Figure 5.1: Hypoxia Laboratory (UCSF)

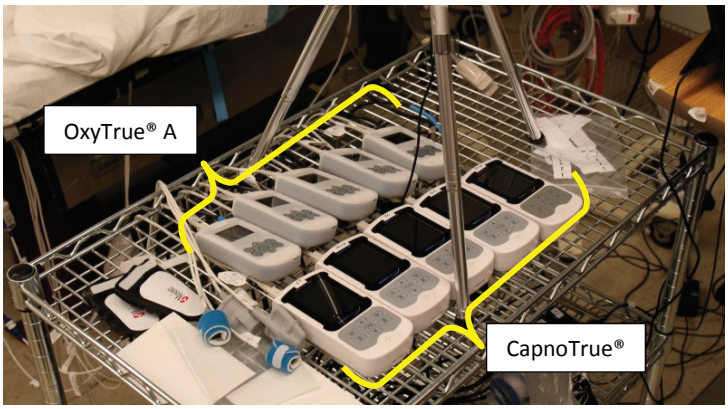


Figure 5.2: CapnoTrue® and OxyTrue® A setup / all devices are connected via USB hub for data storage on a PC (Windows Surface Pro)

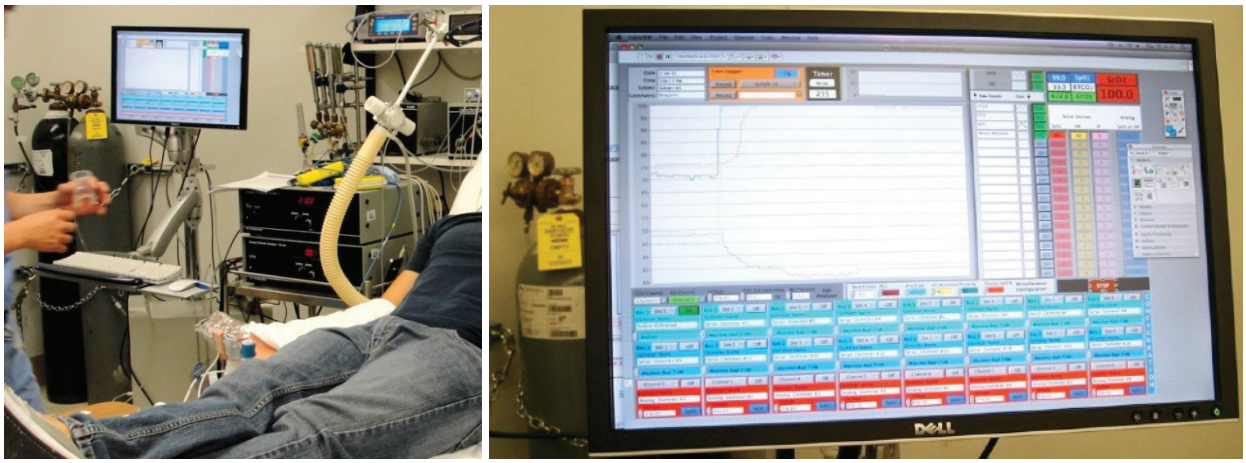


Figure 5.3: Setup to adjust and monitor the inspired gas mixture of nitrogen, carbon dioxide and room air (Breathing gas mixture station (N_2/O_2))

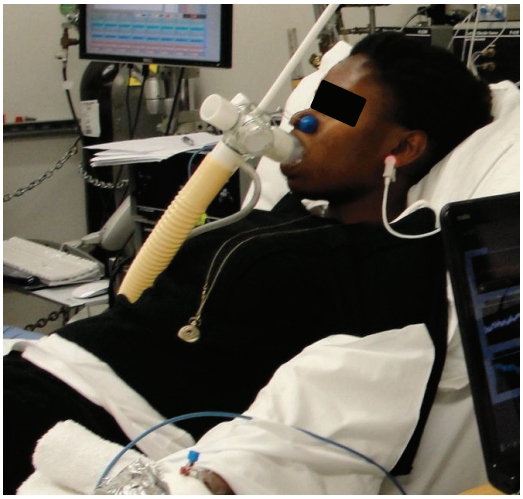


Figure 5.4: Mouthpiece and nose clip

5.2 Patient safety

The study was reviewed and approved by the University of California at San Francisco Committee on Human Research. The Approval number is 10-00437, expiring on April 21, 2016.
The approval letter is on file at UCSF.

5.3 Reference equipment

A blood gas analyzer (BGA) is used as comparison to determine the SpO2 accuracy of the EuT.

For this a radial arterial cannula was placed in either the left or right wrist of each subject (see Fig 5.5). The oxyhemoglobin saturation (SaO_2) at each plateau was determined by performing a blood gas analysis using an ABL-90 multi-wavelength oximeter (Hemoximeter, Radiometer, Copenhagen, serial 1393-090R0359N0002). This instrument contains factory certified calibration standards and quality control algorithms.

Figure 5.5: Reference equipment - "gold standard" ABL-90 multi-wavelength oximeter

6 DATA COLLECTION

6.1 Subjects and sensor placement

A pool of eight males and four females with skin tones ranging from light to dark were studied over two days, with 25 arterial blood samples each.

Table 6.1: Description of each volunteer subject

Subject #	Gender	Ethnicity	Skin pigment	Age	Date	did the subject complete the study
1	Female	Asian Hawaiin/Pacifi	Medium	29	07.08.2015	yes
2	Male	Caucasian	Light	28	07.08.2015	yes
3	Male	Asian Other/Mutiethnic	Dark-Medium	21	07.08.2015	yes
4	Male	Caucasian Light	Light-Medium	28	07.08.2015	yes
5	Female	Caucasian Light	Light-Medium	28	07.08.2015	yes
6	Female	Asian Light	Light-Medium	23	07.08.2015	yes
7	Male	Caucasian	Light	25	07.09.2015	yes
8	Male	Caucasian	Light-Medium	29	07.09.2015	yes
9	Female	Caucasian	Light	25	07.09.2015	yes
10	Male	Caucasian	Light-Medium	32	07.09.2015	yes
11	Male	Caucasian	Light-Medium	26	07.09.2015	yes
12	Male	African American	Dark	27	07.09.2015	yes

All subjects were in good health at the time of the study. The values for COHb and MetHb for all subjects were low. The COHb values were in the range of 0.5 % to 1.5 % and the MetHb are in the range of 0.1 % to 0.8 %. The ctHb values were in the range of 11.6 g/dl to 15.8 g/dl. Each subject was placed in a semi-supine position during the experiment.

For each subject the position of the sensors were changed on the hand. The detailed position of each sensor is listed in the table below.

Table 6.2: Sensor position

	OxyTrue® A (SMARTsat® OEM III)					CapnoTrue® (SMARTsat®OEM II)				
Subject #	**SC**	**SF**	**Disp**	**EP**	**Wrap**	**SC**	**SF**	**Disp**	**EP**	**Wrap**
1	LR	RM	RR	ER	LK	LZ	RK	RZ	EL	LM
2	LK	RR	RM	ER	LZ	LM	RZ	RK	EL	LR
3	LZ	Rk	RZ	ER	LM	LR	RM	RR	EL	LK
4	LM	RZ	RK	ER	LR	LK	RR	RM	EL	LZ
5	LR	RM	RR	ER	LK	LZ	RK	RZ	EL	LM
6	LK	RR	RM	ER	LZ	LM	RZ	RK	EL	lR
7	LZ	RK	RZ	ER	LM	LR	RM	RR	EL	LK
8	LM	RZ	Rk	ER	LR	LK	RR	RM	EL	LZ
9	LR	RM	RR	ER	LK	LZ	RK/RD*	RZ	EL	LM
10	LK	RR	RM	ER	LZ	LM	RZ	RK	EL	LR
11	LZ	RK	RZ	ER	LM	LR	RM	RR	EL	LK
12	LM	RZ	RK	ER	LR	LK	RR	RM	EL	LZ

First letter: ***R*** *– right hand* ***L*** *– left hand*
Second letter: ***D*** *– thumb;* ***Z*** *– fore finger;* ***M*** *– middle finger; R – annular finger;* ***K*** *– little;* ***E*** *– ear*

**sensor slipped off little finger, moved to thumb in second run*

6.2 Procedure

Each subject had two control blood samples taken at the beginning of each experiment, while breathing room air. After this the subject was allowed to breathe through a mouthpiece whereas the nose was blocked by a nose clip (refer to Figure 5.4)

Hypoxia was then induced to different and stable levels of oxyhemoglobin saturation (between 60-100%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide. Each plateau level of oxyhemoglobin saturation was maintained for at least 30 seconds or until reference pulse oximeters readings were stable. The operator observed a breath-by-breath display of the arterial saturation computed from tidal PO2 and PCO2 (refer to Figure 5.3 and Figure 6.1).

Two arterial blood samples were obtained for each plateau, approximately 30 seconds apart. Each stable plateau therefore was maintained for at least 60 seconds with SpO2 fluctuating by less than 2-3%. The plateaus were nominally at 100%, room air saturation, 93%, 90%, 87%, 85%, 82%, 80%, 77%, 75%, 70% and 60%. A total of 25 samples were obtained at the saturation plateaus across this span within 2 runs. Data were provided for analysis. At least 200 data points were collected for each type of oximeter and probe combination studied.

See figures below for typical records of the gases and data recorded by the EUT.

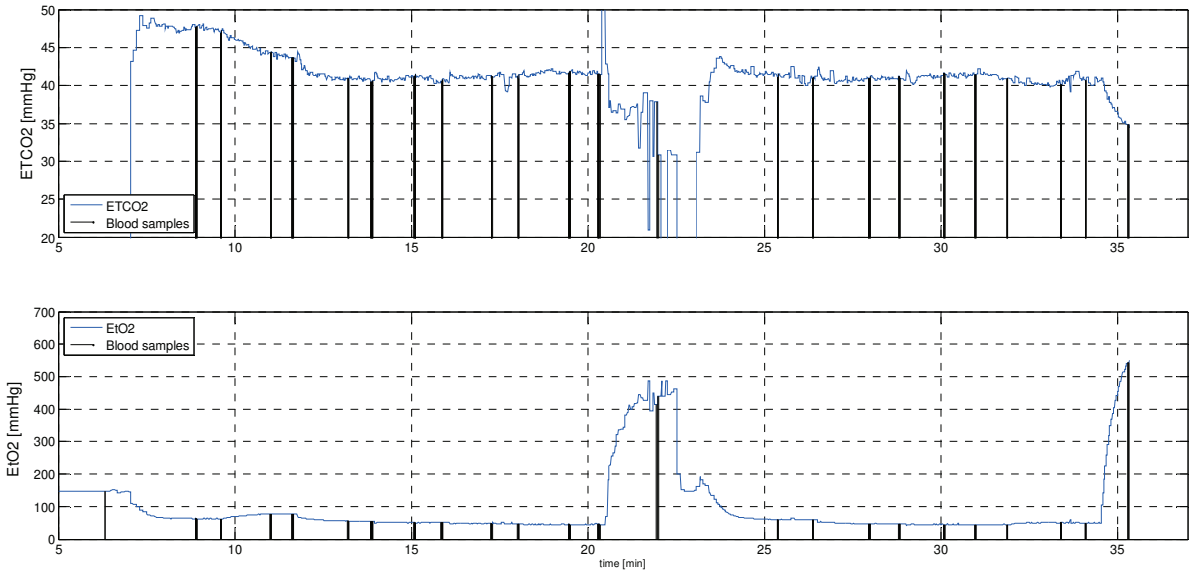


Figure 6.1: Typical recorded of the gases

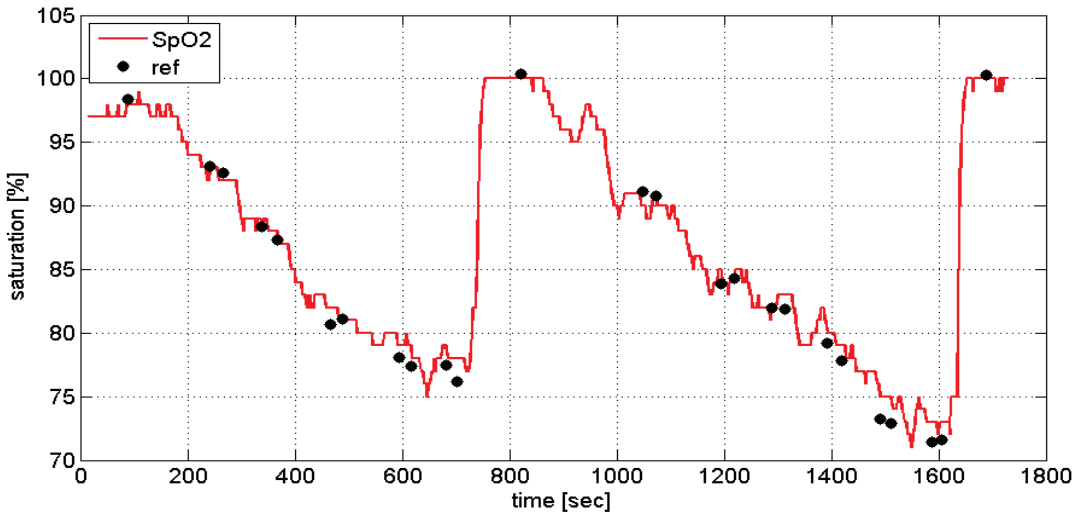


Figure 6.2: Typical data record with the oximeter (EUT)

7 DATA ANALYSIS

7.1 Method

Pulse oximeter data is taken as 5 second averages corresponding to the point of arterial blood analysis.

Individual data points may be missed or excluded for dropped signals or failure of the oximeter signal to achieve an appropriate plateau (see section 12.2 Data). Data is plotted as Hemoximeter data (SaO2) vs. pulse oximeter bias (SpO2 – SaO2).

A different marker is used for each study subject. Linear regression is shown for all subjects combined, and the equation with R^2 is shown on the plot.

Mean bias is displayed as a solid horizontal line, and the upper and lower limits of agreement (mean bias ± 1.96•SD [3]) are shown by dashed horizontal lines.

For the "pooled" plots, different markers are used for each pulse oximeter. Tables of mean, standard deviation, standard error, minimum, maximum, 95% confidence interval, count and root mean square are provided for each oximeter's bias, and all oximeters combined in the following ranges of SaO2 (Hemoximeter): 60 - 80%, 80 - 100%, 60 - 100%, 70 - 100%, 50 - 60%, 60 - 70%, 70 - 80%, 80 - 90%, and 90 - 100%.

7.2 Determination of accuracy

The determination of accuracy was performed according to the ISO 80601-2-61, Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment [1] and [2].

7.2.1 Accuracy (A_{RMS})

The accuracy is be stated in terms of the root-mean-square (A_{rms}) difference between measured values (SpO_{2i}) and reference values (S_{Ri}), as given by the following equation.

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

7.2.2 Bias

The bias is defined as the mean difference of the test and reference values, preserving sign as indicated in following Equation.

$$B_{\mathrm{s}} = \frac{\sum_{i=1}^{n}(\mathrm{SpO_{2i}} - \mathrm{S_{Ri}})^2}{n}$$

7.2.3 Precision

The precision (P_s) is defined as the "standard deviation of the bias".

$$P_{\mathrm{s}} = \sqrt{\frac{\sum_{i=1}^{n}(\mathrm{SpO_{2i}} - \mathrm{S_{Ri}} - B_{\mathrm{s}})^2}{n-1}}$$

8 SpO2 Accuracy Results

Table 8.1 - Table 8.10 plot the Arms accuracy results in the SaO2 ranges for each sensor and oximeter individually.

Detailed results including Bland-Altman-Plot for each table are listed in ANNEX 12.

Table 8.1: 10-AP - OxyTrue® A (SMARTsat®OEM III) – ARMS in the SaO2 ranges

OxyTrue® A with 10-Ap Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	298	1.38	1.28	0.67	2.19	**pass**
Bias	1.17	82	90	102	24	
Precision	2.17	1.54	1.94	2.54	2.61	
A_{RMS}	2.46	2.06	2.31	2.62	3.36	

Table 8.2: EP7500 - OxyTrue® A (SMARTsat®OEM III) – ARMS in the SaO2 ranges

OxyTrue® A with EP7500 Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	266	70	81	92	23	**pass**
Bias	-0.83	-0.68	-0.53	-1.22	1.21	
Precision	2.29	1.20	1.52	2.93	3.11	
A_{RMS}	2.38	1.37	1.60	3.16	3.27	

Table 8.3: SF7500 - OxyTrue® A (SMARTsat®OEM III) – ARMS in the SaO2 ranges

OxyTrue® A with SF7500 Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	299	83	90	102	24	**pass**
Bias	0.32	0.73	0.34	0.13	-0.39	
Precision	1.53	1.25	1.37	1.66	2.00	
A_{RMS}	1.56	1.44	1.41	1.66	1.99	

Table 8.4: SC7500 - OxyTrue® A (SMARTsat®OEM III) – ARMS in the SaO2 ranges

OxyTrue® A with SC7500 Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	298	82	90	102	24	**pass**
Bias	0.35	0.00	0.04	0.70	1.19	
Precision	1.68	1.51	1.75	1.51	2.09	
A_{RMS}	1.71	1.50	1.75	1.66	2.37	

Table 8.5: W7500 - OxyTrue® A (SMARTsat®OEM III) – ARMS in the SaO2 ranges

OxyTrue® A with W7500 Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	299	83	90	102	24	**pass**
Bias	-0.31	0.01	-.037	-0.46	-0.60	
Precision	1.65	1.30	1.49	1.82	2.38	
A_{RMS}	1.68	1.29	1.52	1.87	2.41	

Table 8.6: 10-Ap - CapnoTrue® (SMARTsat®OEM II) – ARMS in the SaO2 ranges

OxyTrue® A with 10-Ap Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	296	80	90	102	24	**pass**
Bias	0.96	0.96	1.09	0.66	1.78	
Precision	1.83	1.97	1.62	1.92	1.38	
A_{RMS}	2.06	2.18	1.94	2.02	2.23	

Table 8.7: EP7500 - CapnoTrue® (SMARTsat®OEM II) – ARMS in the SaO2 ranges

OxyTrue® A with EP7500 Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	272	0.00	82	92	23	**pass**
Bias	0.23	75	0.46	-0.19	1.86	
Precision	2.21	1.04	1.67	2.85	2.98	
A_{RMS}	2.22	1.03	1.73	2.84	3.46	

Table 8.8: SF7500 - CapnoTrue® (SMARTsat®OEM II) – ARMS in the SaO2 ranges

OxyTrue® A with SF7500 Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	282	72	86	100	24	**pass**
Bias	0.30	0.75	0.18	0.13	0.07	
Precision	1.58	1.24	1.34	1.73	2.30	
A_{RMS}	1.60	1.44	1.34	1.73	2.25	

Table 8.9: SC7500 - CapnoTrue® (SMARTsat®OEM II) – ARMS in the SaO2 ranges

OxyTrue® A with SC7500 Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	298	82	90	102	24	**pass**
Bias	-0.16	0.02	-0.54	-0.06	0.23	
Precision	1.62	1.15	1.59	1.85	1.90	
A_{RMS}	1.62	1.14	1.67	1.84	1.88	

Table 8.10: W7500 - CapnoTrue® (SMARTsat®OEM II) – ARMS in the SaO2 ranges

OxyTrue® A with W7500 Sensor	100 – 60 %	*100 – 90 %*	*90 - 80 %*	*80 - 70 %*	*70 - 60 %*	A_{RMS} Spec 4 % for range of 60 – 100 %
# pts	299	83	90	102	24	**pass**
Bias	-0.25	0.03	-0.45	-0.32	-0.14	
Precision	1.55	1.02	1.12	1.78	2.89	
A_{RMS}	1.57	1.02	1.20	1.80	2.84	

9 CONCLUSION

The clinical accuracy testing verify that the bluepoint Medical OxyTrue® A and CapnoTrue® with SMARTsat® Pulse Oximeter Technology in combination with the SMARTsat® SpO2 sensors: SoftCap® (SC7500), SoftFlap® (SF7500), SoftWrap® (W7500), Disposable Adult (10-AP) and Ear Probe (EP7500) demonstrated clinical accuracy performance consistent with the requirements of the applicable international standard (<= 4Arms) under steady state and non-motion condition.

Furthermore the SpO2 accuracy performance of both tested monitor systems, OxyTrue® A (SMARTsat® OEM III) and CapnoTrue® (SMARTsat® OEM II), meets an specification of Arms 2 for sensors SC7500, SF7500 and W7500 and Arms 2.5 for sensors 10-AP and EP7500 in the range of 60 - 100% and may be labeled as such.

10 REFERENCE

[1] ISO 80601-2-61:2011 : Medical electrical equipment -- Part 2-61: Particular and essential performance of pulse oximeter equipment

[2] BLAND, J. M., ALTMAN, D. G. Statistical methods for assessing agreement between clinical measurement. Lancet. (8 Feb), (1986), pp. 307-310

[3] Bland and Altman. Agreement between methods of measurement with multiple observations per individual. J Biopharm Stat (2007) vol. 17 (4) pp. 571-82

11 REVISION HISTORY

Rev.	Date	Description
0	March 15, 2015	Summary report of results , Doc.: Bluepoint Report.7-8-15.2_Final
1	January 03, 2017	Detailed Report including analysis of outliers

12 ANNEX

12.1 SpO2 Sensor vs Ref. CO-Oximeter

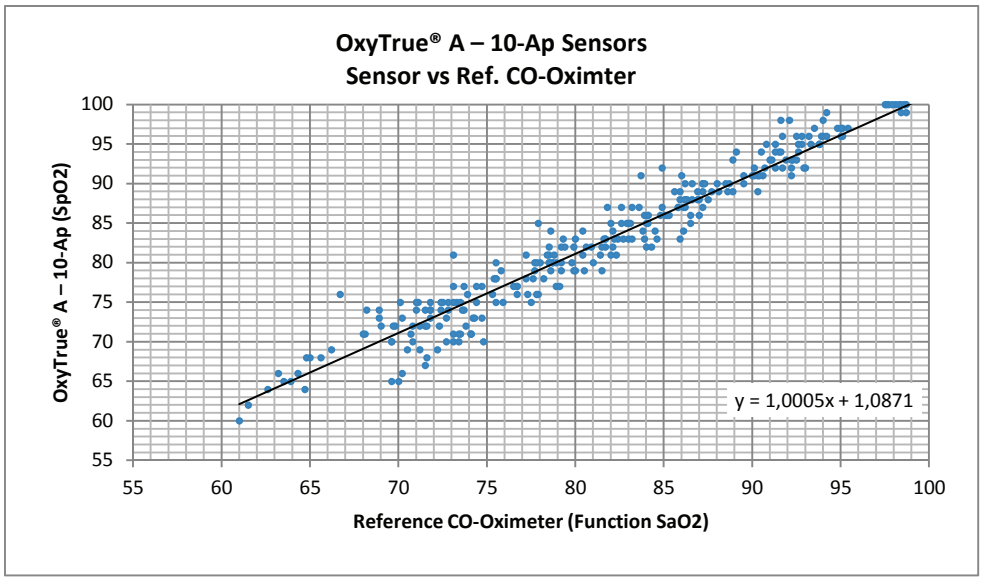


Figure 12.1: OxyTrue® A – 10-AP vs Ref. CO-Oximeter

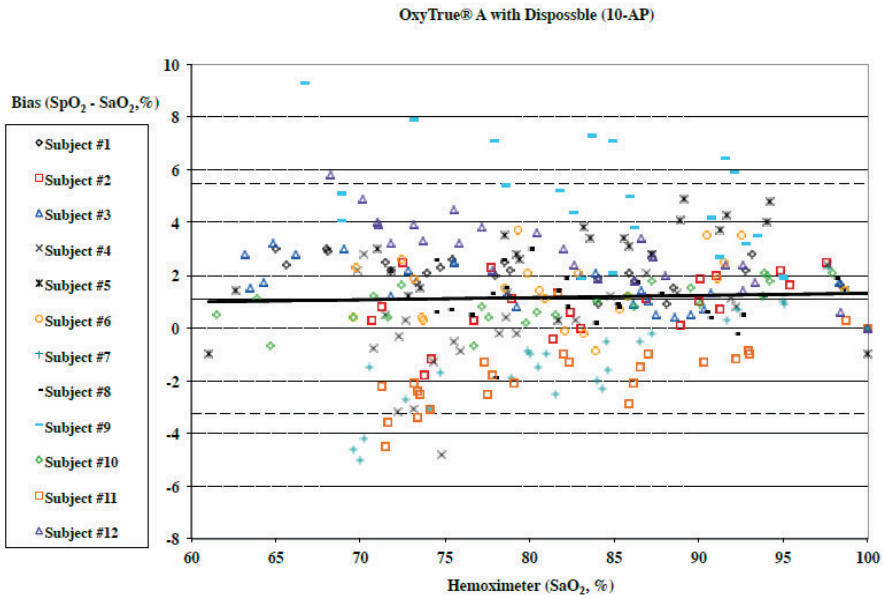


Figure 12.2: OxyTrue® A – 10-AP vs Ref. CO-Oximeter (Difference)

OxyTrue® A with 10-Ap Sensor	
Reference Bland-Altman Range	60 – 100%
# pts	298
Linear Regression (Bland-Altman)	$y = 0.01x + 0.49$
Bias	1.17
Precision	2.17
A_{RMS}	2.46
Upper 95% Limits of Agreement	5.52
Lower 95% Limits of Agreement	-3.18

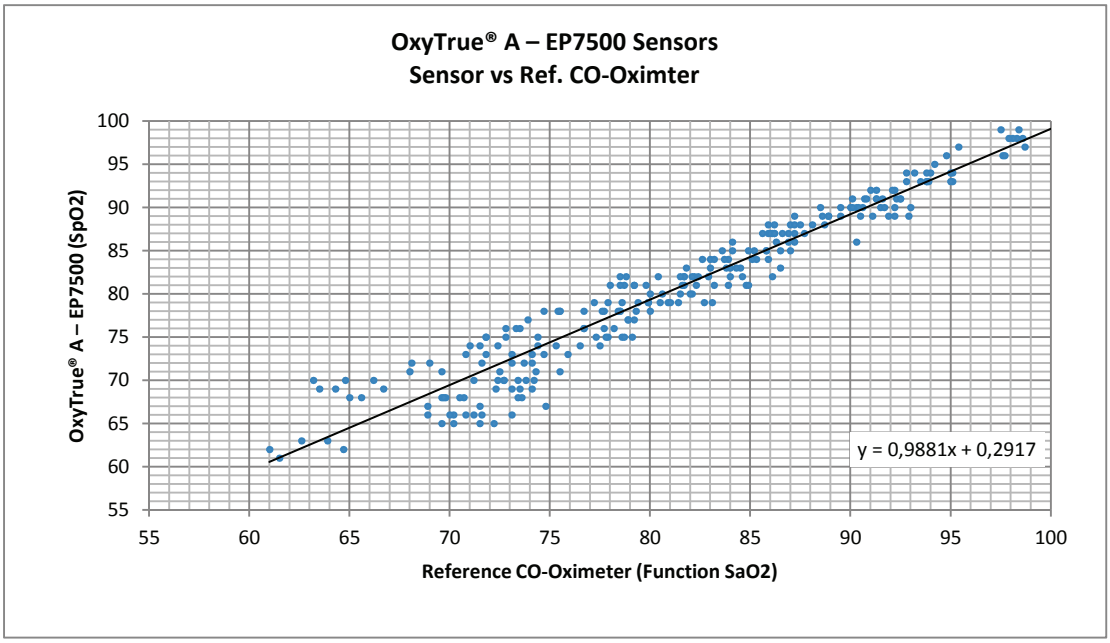


Figure 12.3: OxyTrue® A – EP7500 vs Ref. CO-Oximeter

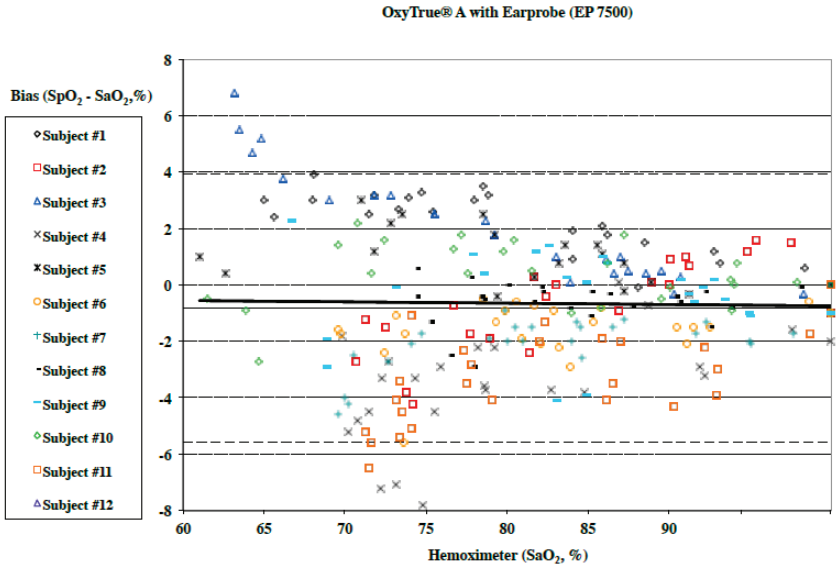


Figure 12.4: OxyTrue® A – EP7500 vs Ref. CO-Oximeter (Difference)

OxyTrue® A with EP7500 Sensor	
Reference Bland-Altman Range	60 – 100%
# pts	266
Linear Regression (Bland-Altman)	$y = -0.00x - 0.26$
Bias	-0.66
Precision	2.29
A_{RMS}	2.38
Upper 95% Limits of Agreement	4.10
Lower 95% Limits of Agreement	-5.41

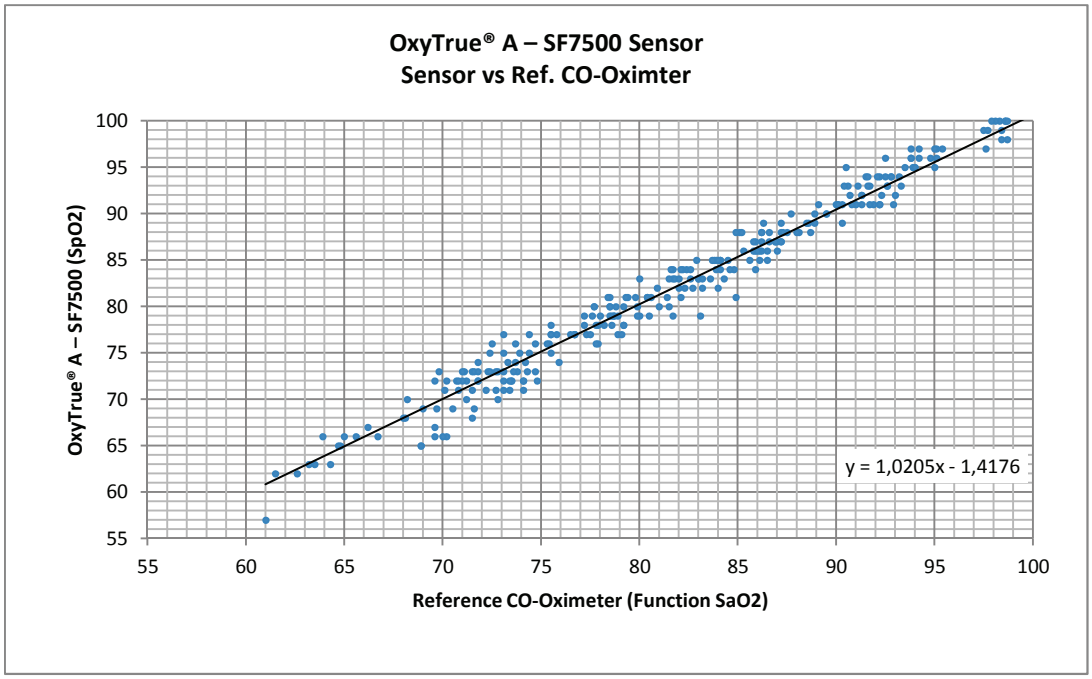


Figure 12.5: OxyTrue® A – SF7500 vs Ref. CO-Oximeter

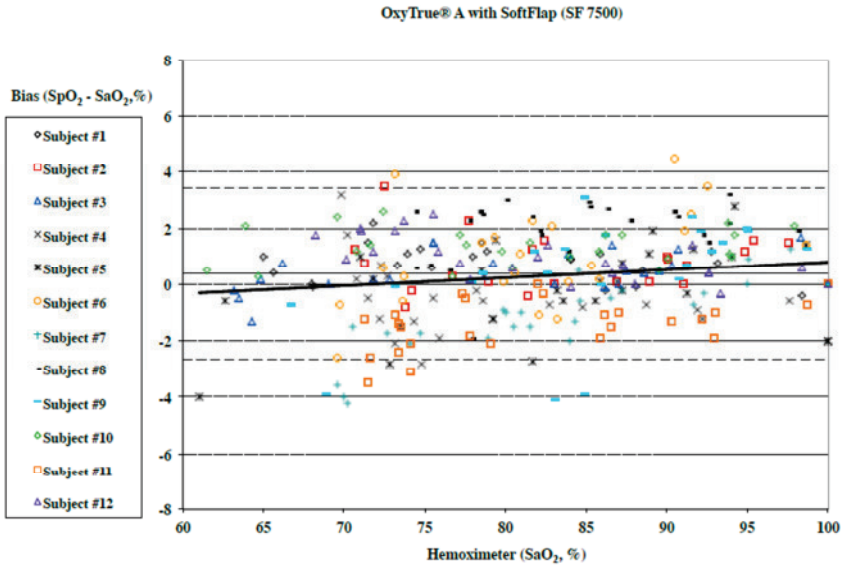


Figure 12.6: OxyTrue® A – SF7500 vs Ref. CO-Oximeter (Difference)

OxyTrue® A with SF7500 Sensor	
Reference Bland-Altman Range	60 – 100%
# pts	299
Linear Regression (Bland-Altman)	$y = 0.03x - 2.03$
Bias	0.32
Precision	1.53
A_{RMS}	1.56
Upper 95% Limits of Agreement	3.36
Lower 95% Limits of Agreement	-2.73

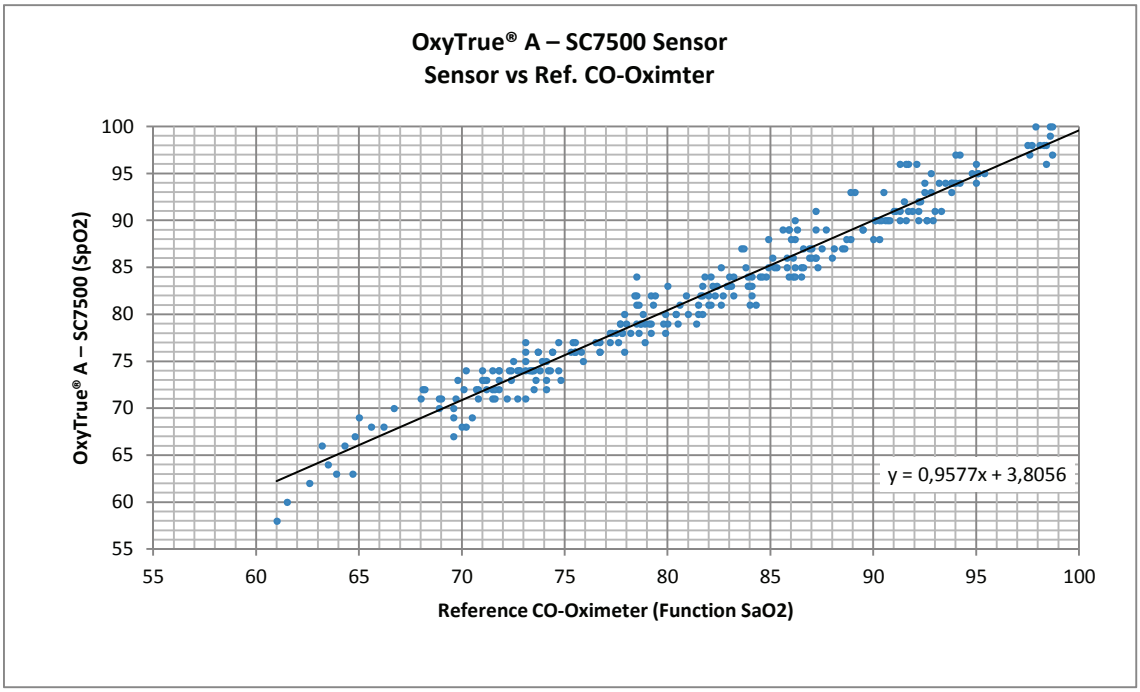


Figure 12.7: OxyTrue® A – SC7500 vs Ref. CO-Oximeter

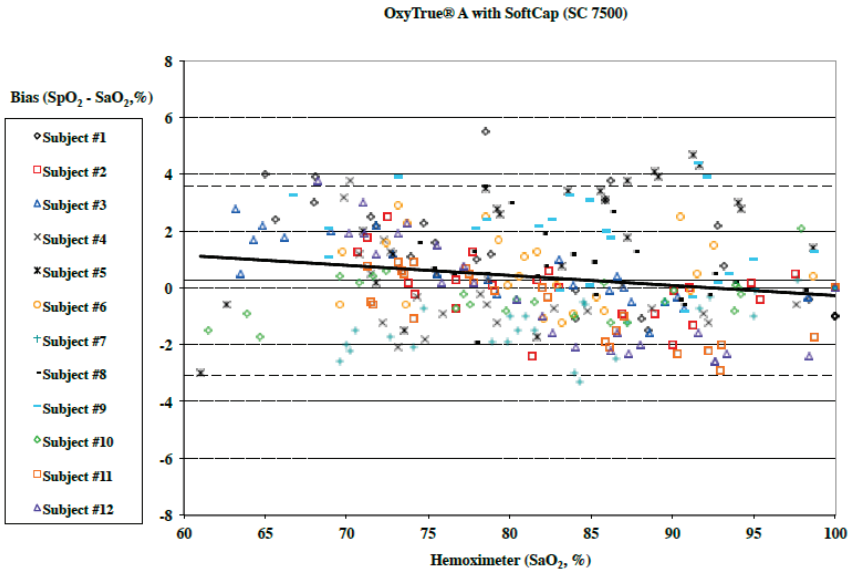


Figure 12.8: OxyTrue® A – SC7500 vs Ref. CO-Oximeter (Difference)

OxyTrue® A with SC7500 Sensor	
Reference Bland-Altman Range	60 – 100%
# pts	298
Linear Regression (Bland-Altman)	$y = -0.04x + 3.28$
Bias	0.35
Precision	1.68
A_{RMS}	1.71
Upper 95% Limits of Agreement	3.68
Lower 95% Limits of Agreement	-2.99

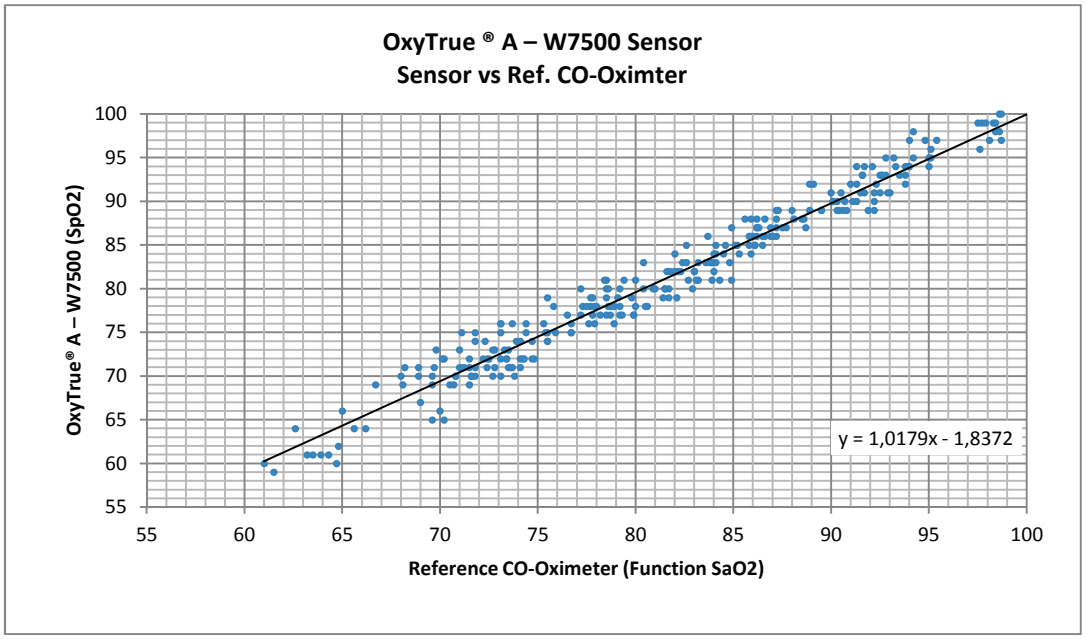


Figure 12.9: OxyTrue® A – W7500 vs Ref. CO-Oximeter

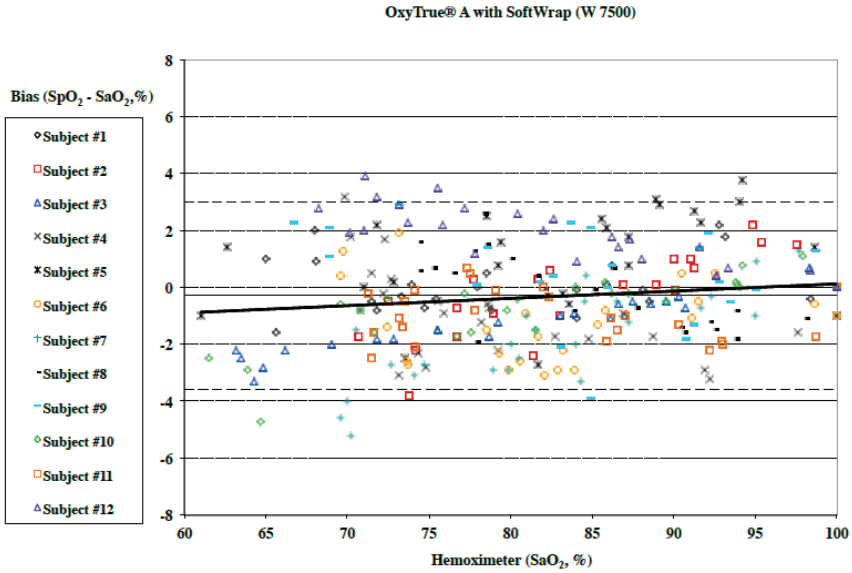


Figure 12.10: OxyTrue® A – W7500 vs Ref. CO-Oximeter (Difference)

OxyTrue® A with W7500 Sensor	
Reference Bland-Altman Range	60 – 100%
# pts	299
Linear Regression (Bland-Altman)	$y = 0.03x - 2.43$
Bias	-0.31
Precision	1.65
A_{RMS}	1.68
Upper 95% Limits of Agreement	2.97
Lower 95% Limits of Agreement	-3.60

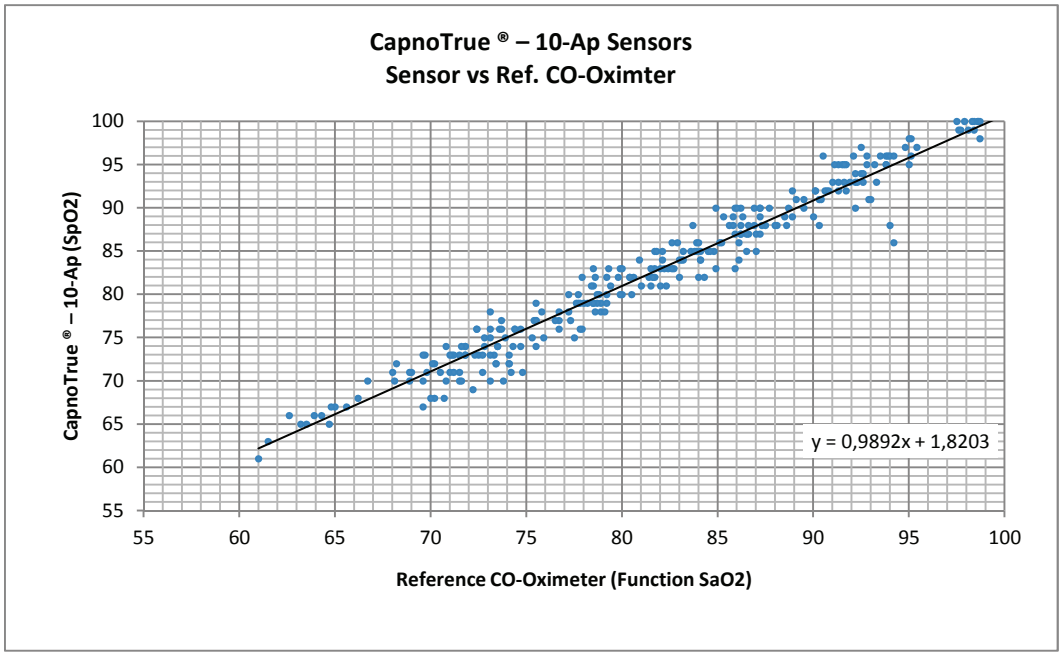


Figure 12.11: CapnoTrue® – 10-Ap vs Ref. CO-Oximeter

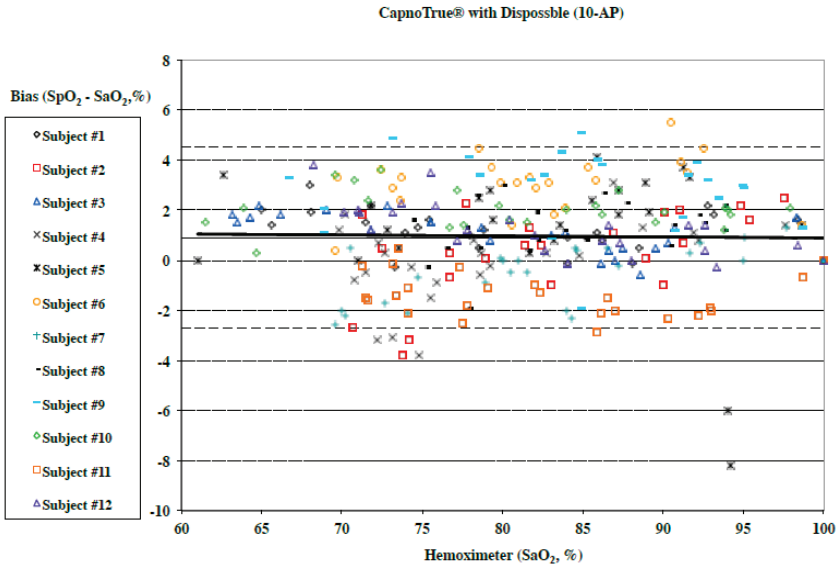


Figure 12.12: CapnoTrue® – 10-Ap vs Ref. CO-Oximeter (Difference)

CapnoTrue® with 10-Ap Sensor	
Reference Bland-Altman Range	60 – 100%
# pts	296
Linear Regression (Bland-Altman)	$y = -0.00x + 1.49$
Bias	0.96
Precision	1.83
A_{RMS}	2.06
Upper 95% Limits of Agreement	4.60
Lower 95% Limits of Agreement	-2.68

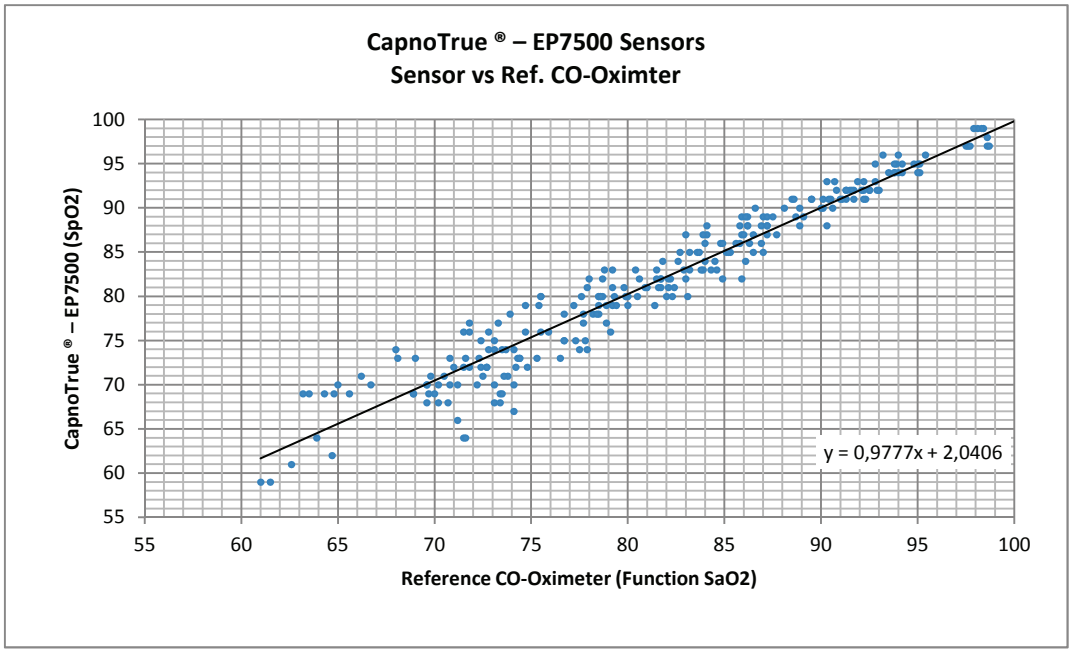


Figure 12.13: CapnoTrue® – EP7500 vs Ref. CO-Oximeter

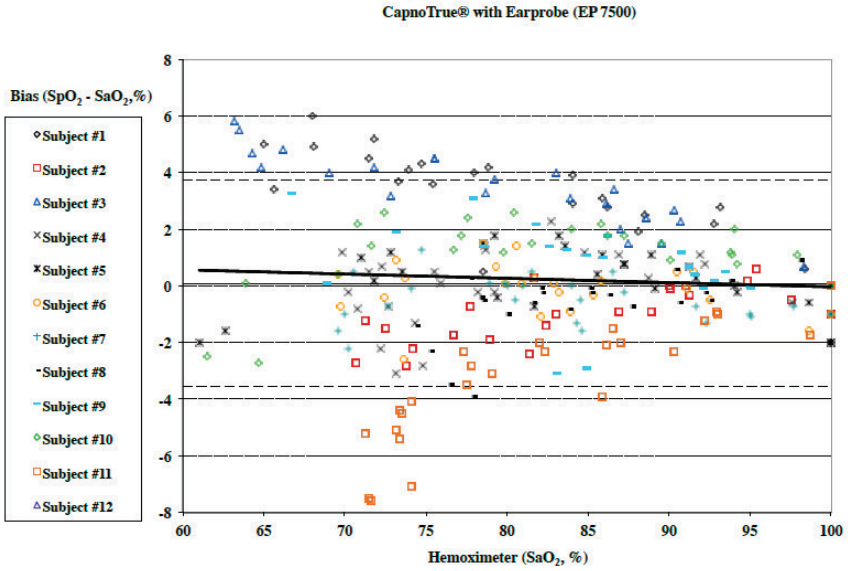


Figure 12.14: CapnoTrue® – EP7500 vs Ref. CO-Oximeter (Difference)

CapnoTrue® with EP7500 Sensor	
Reference Bland-Altman Range	60-100%
# pts	272
Linear Regression (Bland-Altman)	$y = -0.00x + 1.48$
Bias	0.23
Precision	2.21
A_{RMS}	2.22
Upper 95% Limits of Agreement	4.83
Lower 95% Limits of Agreement	-4.37

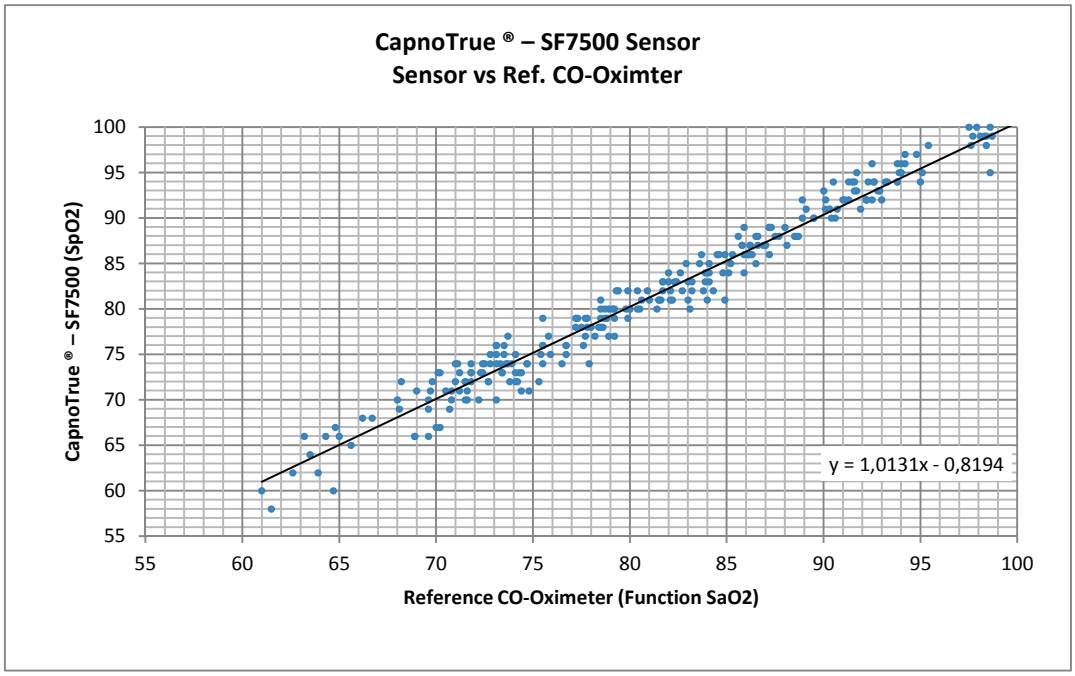


Figure 12.15: CapnoTrue® – SF7500 vs Ref. CO-Oximeter

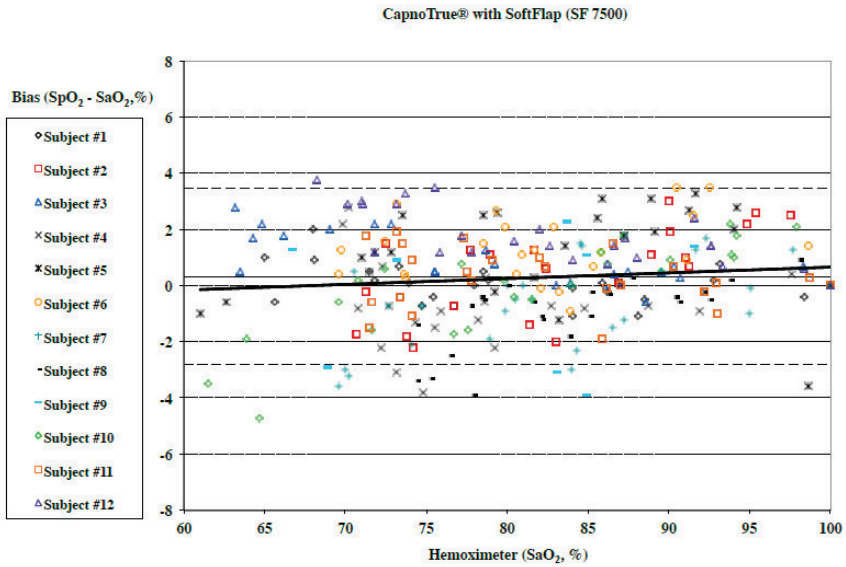


Figure 12.16: CapnoTrue® – SF7500 vs Ref. CO-Oximeter (Difference)

CapnoTrue® with SF7500 Sensor	
Reference Bland-Altman Range	60-100%
# pts	282
Linear Regression (Bland-Altman)	$y = 0.02x - 1.39$
Bias	0.30
Precision	1.58
A_{RMS}	1.60
Upper 95% Limits of Agreement	3.43
Lower 95% Limits of Agreement	-2.83

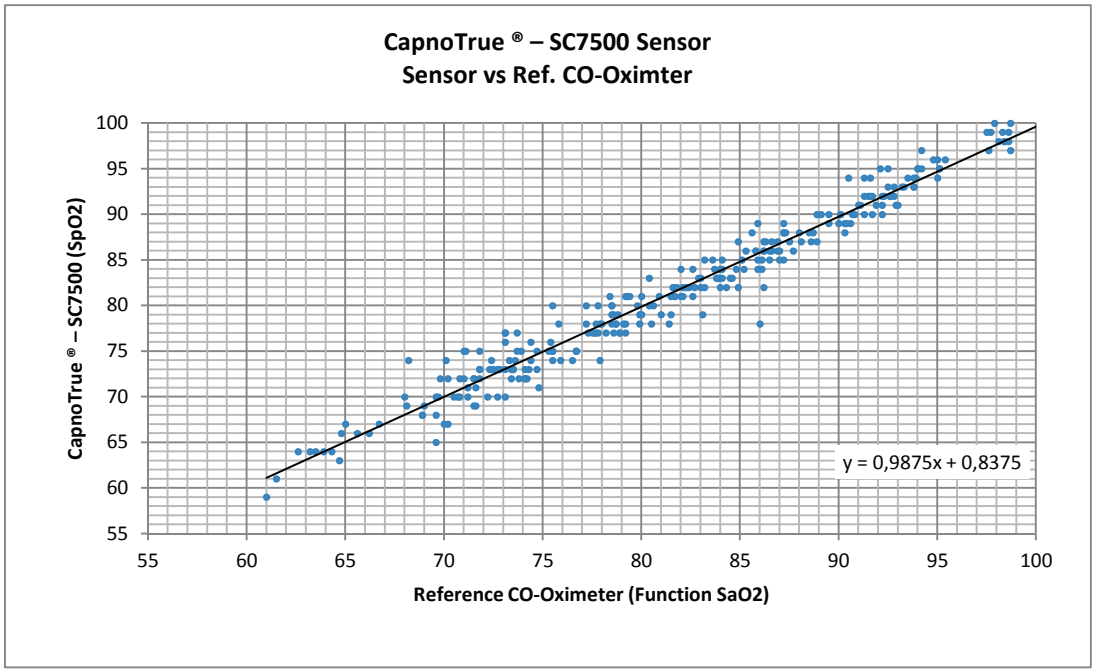


Figure 12.17: CapnoTrue® – SC7500 vs Ref. CO-Oximeter

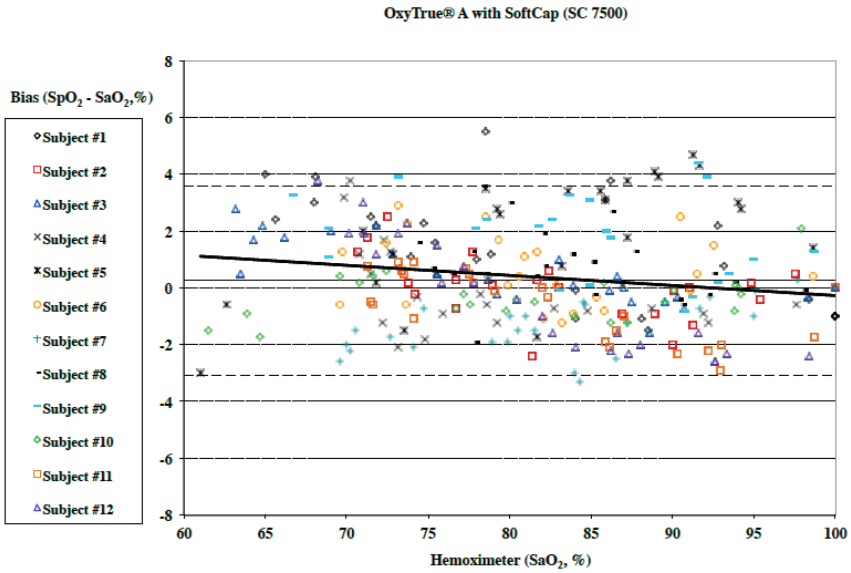


Figure 12.18: CapnoTrue® – SC7500 vs Ref. CO-Oximeter (difference)

CapnoTrue® with SC7500 Sensor	
Reference Bland-Altman Range	60-100%
# pts	298
Linear Regression (Bland-Altman)	$y = -0.01x + 0.30$
Bias	-0.16
Precision	1.62
A_{RMS}	1.62
Upper 95% Limits of Agreement	3.06
Lower 95% Limits of Agreement	-3.37

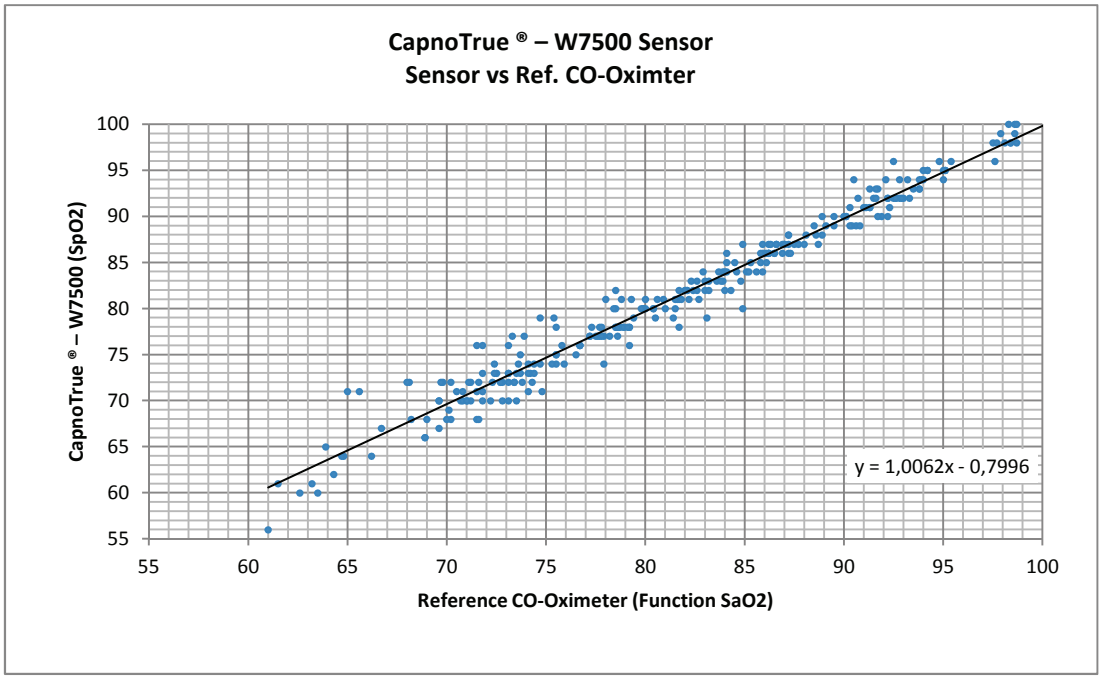


Figure 12.19: CapnoTrue® – W7500 vs Ref. CO-Oximeter

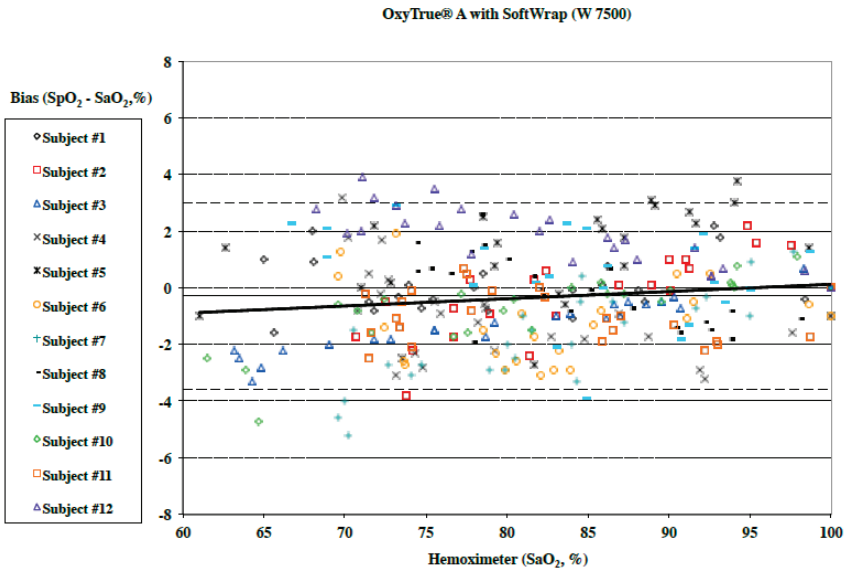


Figure 12.20: CapnoTrue® – W7500 vs Ref. CO-Oximeter (Difference)

CapnoTrue® with W7500 Sensor	
Reference Bland-Altman Range	60-100%
# pts	299
Linear Regression (Bland-Altman)	$y = -0.01x - 1.37$
Bias	-0.25
Precision	1.55
A_{RMS}	1.57
Upper 95% Limits of Agreement	2.84
Lower 95% Limits of Agreement	-3.33

12.2 Data

- Yellow highlighted cells indicates SpO2 monitors delivers no measurement values
- Orange highlighted cells indicates values >4 from Reference ABL 90 CO-Ox
- Red, data exclusion (refer to section 12.3)

12.2.1 OxyTrue® A (SMARTsat OEM III)

		Reference	OxyTrue® A					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P01	1	98,4	98	98	98	100	99	n/a
P01	2	93,2	94	94	95	96	94	n/a
P01	3	92,8	95	94	95	95	94	n/a
P01	4	86,2	90	86	87	88	88	n/a
P01	5	85,9	89	87	86	88	88	n/a
P01	6	78,5	84	80	79	81	82	n/a
P01	7	73,9	75	75	74	76	77	n/a
P01	8	73,3	74	74	73	75	76	n/a
P01	9	100,7	99	100	100	100	99	n/a
P01	10	100,6	99	100	100	100	99	n/a
P01	11	88,5	87	89	88	90	90	n/a
P01	12	88,1	87	88	88	89	88	n/a
P01	13	84,1	83	85	83	86	86	n/a
P01	14	84,1	84	85	84	85	85	n/a
P01	15	78,8	80	80	78	81	82	n/a
P01	16	78,0	79	79	78	80	81	n/a
P01	17	75,4	77	76	75	78	78	n/a
P01	18	74,7	77	76	74	77	78	n/a
P01	19	71,8	74	74	71	74	75	n/a
P01	20	71,5	74	73	71	74	74	n/a
P01	21	68,1	72	68	69	71	72	n/a
P01	22	68,0	71	68	70	71	71	n/a
P01	23	65,0	69	66	66	68	68	n/a
P01	24	65,6	68	66	64	68	68	n/a
P01	25	100,5	99	100	100	100	100	n/a
P02	1	97,5	98	99	99	100	99	n/a
P02	2	91,0	91	91	92	93	92	n/a
P02	3	90,1	90	91	90	92	91	n/a
P02	4	94,8	95	96	97	97	96	n/a
P02	5	95,4	95	97	97	97	97	n/a
P02	6	88,9	88	89	89	89	89	n/a
P02	7	86,9	86	87	87	88	86	n/a
P02	8	82,4	83	84	83	83	82	n/a
P02	9	81,7	82	83	82	83	82	n/a
P02	10	77,7	79	80	78	80	76	n/a
P02	11	76,7	76	77	75	77	76	n/a
P02	12	72,5	75	76	72	75	71	n/a
P02	13	71,2	73	72	71	72	70	n/a
P02	14	100,2	100	100	100	100	100	n/a
P02	15	100,3	100	100	100	100	100	n/a
P02	16	91,3	90	92	92	92	92	n/a
P02	17	90,0	88	91	91	91	90	n/a
P02	18	78,9	79	79	78	80	77	n/a
P02	19	76,7	77	77	76	77	76	n/a
P02	20	74,2	74	74	72	73	70	n/a
P02	21	70,7	72	72	69	71	68	n/a
P02	22	73,8	74	73	70	72	70	n/a
P02	23	83,0	83	83	82	83	83	n/a
P02	24	81,4	79	81	79	81	79	n/a
P02	25	100,4	100	100	100	100	99	n/a
P03	1	98,3	98	100	99	100	98	n/a
P03	2	90,7	90	92	90	92	91	n/a
P03	3	90,3	90	91	90	91	90	n/a
P03	4	86,6	87	88	86	88	87	n/a

		Reference	OxyTrue® A					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P03	5	86,1	86	86	85	87	87	n/a
P03	6	83,9	84	85	83	86	84	n/a
P03	7	83,0	84	83	82	85	84	n/a
P03	8	75,5	76	77	74	78	78	n/a
P03	9	75,5	76	77	74	78	78	n/a
P03	10	69,0	71	69	67	72	72	n/a
P03	11	66,2	68	67	64	69	70	n/a
P03	12	100,6	100	100	100	100	100	n/a
P03	13	100,7	100	100	100	100	100	n/a
P03	14	88,6	87	89	88	89	89	n/a
P03	15	89,5	89	90	89	90	90	n/a
P03	16	87,5	87	88	87	88	88	n/a
P03	17	87,0	87	87	86	88	88	n/a
P03	18	79,2	79	80	78	80	81	n/a
P03	19	78,7	79	79	77	80	81	n/a
P03	20	72,8	74	73	71	75	76	n/a
P03	21	71,8	74	72	70	73	75	n/a
P03	22	64,8	67	65	62	68	70	n/a
P03	23	63,2	66	63	61	66	70	n/a
P03	24	64,3	66	63	61	66	69	n/a
P03	25	63,5	64	63	61	65	69	n/a
P04	1	97,6	97	97	96	100	96	n/a
P04	2	91,9	91	91	89	93	89	n/a
P04	3	92,2	91	91	89	93	89	n/a
P04	4	84,8	84	84	83	86	81	n/a
P04	5	82,7	82	82	81	83	79	n/a
P04	6	78,6	78	78	78	79	75	n/a
P04	7	78,7	79	79	78	80	75	n/a
P04	8	75,9	75	74	75	75	73	n/a
P04	9	75,5	76	75	75	75	71	n/a
P04	10	71,5	72	71	72	72	67	n/a
P04	11	70,2	74	72	72	73	65	n/a
P04	12	100,7	100	100	99	100	98	n/a
P04	13	100,7	100	100	99	100	99	n/a
P04	14	88,7	88	88	87	90	88	n/a
P04	15	86,9	87	87	86	89	87	n/a
P04	16	79,2	78	78	77	79	77	n/a
P04	17	78,2	78	78	77	78	76	n/a
P04	18	72,7	74	73	73	73	70	n/a
P04	19	74,3	74	73	72	73	71	n/a
P04	20	72,3	74	73	74	72	69	n/a
P04	21	69,8	73	73	73	72	68	n/a
P04	22	73,1	71	71	70	70	66	n/a
P04	23	70,8	72	71	70	70	66	n/a
P04	24	74,8	73	72	72	70	67	n/a
P04	25	72,2	71	71	72	69	65	n/a
P05	1	98,6	100	100	100	100	NaN	EP7500 No value
P05	2	91,7	96	93	94	96	NaN	EP7500 No value
P05	3	91,3	96	91	94	95	91	n/a
P05	4	87,2	89	88	89	90	87	n/a
P05	5	87,2	91	87	88	90	88	n/a
P05	6	83,6	87	83	83	87	85	n/a
P05	7	83,2	84	83	83	87	84	n/a
P05	8	81,7	80	79	79	82	82	n/a
P05	9	79,2	82	78	80	82	81	n/a
P05	10	73,5	72	72	71	75	76	n/a
P05	11	72,8	74	70	73	74	75	n/a
P05	12	100,5	NaN	98	100	NaN	NaN	SC7500, 10-Ap, EP7500 No value
P05	13	100,5	100	98	100	99	NaN	EP7500 No value
P05	14	94,2	97	97	98	99	NaN	EP7500 No value
P05	15	94,0	97	95	97	98	NaN	EP7500 No value
P05	16	89,1	93	91	92	94	NaN	EP7500 No value
P05	17	88,9	93	90	92	93	89	n/a
P05	18	85,9	89	86	88	89	87	n/a
P05	19	85,6	89	85	88	89	87	n/a

		Reference	OxyTrue® A					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P05	20	79,4	82	81	81	82	79	n/a
P05	21	78,5	82	79	81	82	81	n/a
P05	22	71,8	72	72	74	74	73	n/a
P05	23	71,0	73	72	71	74	74	n/a
P05	24	62,6	62	62	64	64	63	n/a
P05	25	61,0	58	57	60	60	62	n/a
P06	1	98,6	99	100	98	100	98	n/a
P06	2	91,5	92	94	91	94	90	n/a
P06	3	91,1	91	93	90	93	89	n/a
P06	4	85,8	85	86	85	87	85	n/a
P06	5	85,3	85	86	84	86	84	n/a
P06	6	83,2	82	82	81	83	81	n/a
P06	7	83,9	83	84	81	83	81	n/a
P06	8	82,1	81	81	79	82	80	n/a
P06	9	80,9	82	82	80	82	79	n/a
P06	10	73,7	76	74	71	74	72	n/a
P06	11	73,6	73	73	71	74	68	n/a
P06	12	100,7	100	100	99	100	99	n/a
P06	13	100,6	100	100	100	100	99	n/a
P06	14	92,5	94	96	93	96	91	n/a
P06	15	90,5	93	95	91	94	89	n/a
P06	16	82,9	83	85	80	85	82	n/a
P06	17	81,7	83	84	80	83	81	n/a
P06	18	79,3	81	81	77	83	78	n/a
P06	19	78,5	81	80	77	80	78	n/a
P06	20	79,9	80	80	77	82	79	n/a
P06	21	80,6	81	81	78	82	80	n/a
P06	22	73,1	76	77	75	75	72	n/a
P06	23	72,4	74	73	71	75	70	n/a
P06	24	69,6	69	67	70	70	68	n/a
P06	25	69,7	71	69	71	72	68	n/a
P07	1	97,7	98	99	99	100	96	n/a
P07	2	92,3	92	92	92	93	91	n/a
P07	3	91,7	91	91	91	92	90	n/a
P07	4	84,5	84	85	84	84	83	n/a
P07	5	84,6	84	84	85	83	82	n/a
P07	6	81,5	80	80	80	79	80	n/a
P07	7	81,0	80	80	80	80	79	n/a
P07	8	80,5	79	79	78	79	79	n/a
P07	9	80,0	79	79	78	79	78	n/a
P07	10	72,7	71	71	70	70	70	n/a
P07	11	70,5	69	69	69	69	68	n/a
P07	12	100,6	100	100	100	100	99	n/a
P07	13	95,1	95	96	96	96	93	n/a
P07	14	95,0	94	95	94	96	93	n/a
P07	15	87,2	86	87	86	87	86	n/a
P07	16	86,5	84	86	86	86	85	n/a
P07	17	84,0	81	82	82	82	82	n/a
P07	18	84,3	81	83	81	82	83	n/a
P07	19	79,9	78	79	77	79	79	n/a
P07	20	78,9	77	77	76	77	77	n/a
P07	21	74,7	74	73	72	73	73	n/a
P07	22	74,1	72	72	71	71	72	n/a
P07	23	70,2	68	66	65	66	66	n/a
P07	24	70,0	68	66	66	65	66	n/a
P07	25	69,6	67	66	65	65	65	n/a
P08	1	98,1	98	100	97	100	98	n/a
P08	2	93,8	94	96	92	95	93	n/a
P08	3	93,8	94	97	93	95	93	n/a
P08	4	90,6	90	93	89	91	90	n/a
P08	5	90,4	90	93	89	91	90	n/a
P08	6	85,1	86	88	85	86	84	n/a
P08	7	85,2	85	88	85	86	85	n/a
P08	8	82,2	83	84	82	83	82	n/a

		Reference	OxyTrue® A					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P08	9	81,6	82	84	82	83	81	n/a
P08	10	78,5	79	81	80	80	78	n/a
P08	11	77,7	79	80	79	79	78	n/a
P08	12	74,4	76	77	76	77	74	n/a
P08	13	75,3	76	76	76	76	74	n/a
P08	14	100,7	100	100	100	100	100	n/a
P08	15	92,5	93	94	91	93	91	n/a
P08	16	92,2	92	94	91	92	92	n/a
P08	17	87,7	89	90	87	89	87	n/a
P08	18	86,3	89	89	87	88	86	n/a
P08	19	82,1	84	84	82	84	82	n/a
P08	20	83,8	85	85	83	84	83	n/a
P08	21	80,0	83	83	81	83	80	n/a
P08	22	78,4	82	81	81	81	78	n/a
P08	23	74,4	76	75	75	75	75	n/a
P08	24	77,9	76	76	76	76	75	n/a
P08	25	76,5	77	77	77	77	74	n/a
P09	1	98,7	100	100	100	100	NaN	EP7500 No value
P09	2	95,1	95	97	95	97	94	n/a
P09	3	95,0	96	97	95	97	94	n/a
P09	4	92,8	93	94	93	96	93	n/a
P09	5	93,5	94	95	93	97	93	n/a
P09	6	90,8	90	91	89	95	91	n/a
P09	7	91,3	91	92	90	94	91	n/a
P09	8	86,2	88	88	87	90	87	n/a
P09	9	86,0	88	86	86	91	87	n/a
P09	10	82,6	85	83	83	87	84	n/a
P09	11	81,8	84	83	82	87	83	n/a
P09	12	78,6	81	79	80	84	79	n/a
P09	13	77,9	80	78	78	85	79	n/a
P09	14	100,6	100	100	100	100	99	n/a
P09	15	92,1	96	94	94	98	92	n/a
P09	16	91,6	96	94	93	98	91	n/a
P09	17	84,9	88	88	87	92	85	n/a
P09	18	83,7	87	85	86	91	84	n/a
P09	19	84,9	85	81	81	87	81	n/a
P09	20	83,1	83	79	81	85	79	n/a
P09	21	73,1	77	73	76	81	73	n/a
P09	22	79,9	76	70	73	80	70	All excluded, see Figure 12.22
P09	23	66,7	70	66	69	76	69	n/a
P09	24	68,9	71	65	70	74	67	n/a
P09	25	68,9	70	65	71	73	66	n/a
P10	1	97,9	100	100	99	100	98	n/a
P10	2	93,9	94	95	94	96	93	n/a
P10	3	94,0	94	95	94	96	94	n/a
P10	4	90,1	90	91	90	91	90	n/a
P10	5	89,5	89	90	89	91	89	n/a
P10	6	85,8	86	87	86	87	85	n/a
P10	7	84,0	83	85	84	85	83	n/a
P10	8	81,5	81	83	80	82	82	n/a
P10	9	80,4	80	81	80	81	82	n/a
P10	10	77,6	77	79	76	78	78	n/a
P10	11	76,7	76	77	75	76	78	n/a
P10	12	71,6	72	73	70	72	72	n/a
P10	13	69,6	70	72	69	70	71	n/a
P10	14	100,7	100	100	100	100	100	n/a
P10	15	94,2	94	96	95	96	95	n/a
P10	16	93,8	93	96	94	95	94	n/a
P10	17	87,2	86	89	87	89	89	n/a
P10	18	86,2	85	88	86	87	87	n/a
P10	19	79,8	79	81	79	80	81	n/a
P10	20	77,2	77	79	77	78	79	n/a
P10	21	72,4	73	75	72	74	74	n/a
P10	22	70,8	71	72	70	72	73	n/a
P10	23	63,9	63	66	61	65	63	n/a

		Reference	OxyTrue® A					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P10	24	64,7	63	65	60	64	62	n/a
P10	25	61,5	60	62	59	62	61	n/a
P11	1	98,7	97	98	97	99	97	n/a
P11	2	93,0	91	92	91	92	90	n/a
P11	3	92,2	90	91	90	91	90	n/a
P11	4	87,0	86	86	86	86	85	n/a
P11	5	85,9	84	84	84	83	84	n/a
P11	6	82,3	82	82	82	81	81	n/a
P11	7	82,0	82	82	82	81	80	n/a
P11	8	77,3	78	77	78	76	75	n/a
P11	9	77,5	78	77	78	75	74	n/a
P11	10	74,1	75	72	74	71	73	n/a
P11	11	73,4	74	71	72	70	70	n/a
P11	12	100,8	100	100	100	100	100	n/a
P11	13	92,9	90	91	91	92	89	n/a
P11	14	90,3	88	89	89	89	86	n/a
P11	15	86,5	85	85	85	85	83	n/a
P11	16	86,1	84	85	85	84	82	n/a
P11	17	79,1	79	77	79	77	75	n/a
P11	18	77,8	78	76	77	76	75	n/a
P11	19	73,1	74	72	72	71	69	n/a
P11	20	74,1	73	71	72	71	69	n/a
P11	21	73,5	74	72	73	71	69	n/a
P11	22	73,4	74	72	72	71	68	n/a
P11	23	71,2	72	70	71	69	66	n/a
P11	24	71,5	71	68	69	67	65	n/a
P11	25	71,6	71	69	70	68	66	n/a
P12	1	98,4	96	99	99	99	NaN	EP7500 No value
P12	2	93,3	91	93	94	95	NaN	EP7500 No value
P12	3	92,6	90	93	93	94	NaN	EP7500 No value
P12	4	88,0	86	88	89	90	NaN	EP7500 No value
P12	5	86,2	84	87	88	88	NaN	EP7500 No value
P12	6	84,1	82	84	85	86	NaN	EP7500 No value
P12	7	82,6	81	84	85	85	NaN	EP7500 No value
P12	8	77,8	78	78	79	80	NaN	EP7500 No value
P12	9	75,8	76	77	78	79	NaN	EP7500 No value
P12	10	71,8	73	73	75	75	NaN	EP7500 No value
P12	11	71,1	73	73	75	75	NaN	EP7500 No value
P12	12	100,7	100	100	100	100	NaN	EP7500 No value
P12	13	92,6	90	93	93	95	NaN	EP7500 No value
P12	14	91,6	90	93	93	94	NaN	EP7500 No value
P12	15	87,3	85	88	89	90	NaN	EP7500 No value
P12	16	86,6	85	87	88	90	NaN	EP7500 No value
P12	17	80,4	80	81	83	84	NaN	EP7500 No value
P12	18	82,0	81	83	84	85	NaN	EP7500 No value
P12	19	77,2	78	78	80	81	NaN	EP7500 No value
P12	20	75,5	77	78	79	80	NaN	EP7500 No value
P12	21	73,7	76	76	76	77	NaN	EP7500 No value
P12	22	73,1	75	75	76	77	NaN	EP7500 No value
P12	23	71,0	74	73	73	75	NaN	EP7500 No value
P12	24	70,1	72	71	72	75	NaN	EP7500 No value
P12	25	68,2	72	70	71	74	NaN	EP7500 No value

12.2.2 CapnoTrue® (SMARTsat OEM II)

		Reference	CapnoTrue®					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P01	1	98,4	98	98	98	100	99	n/a
P01	2	93,2	93	94	94	95	96	n/a
P01	3	92,8	92	93	94	95	95	n/a
P01	4	86,2	86	86	87	87	89	n/a
P01	5	85,9	85	86	87	87	89	n/a
P01	6	78,5	79	79	82	79	79	n/a
P01	7	73,9	75	74	77	75	78	n/a
P01	8	73,3	74	74	77	73	77	n/a
P01	9	100,7	100	100	100	100	100	n/a
P01	10	100,6	100	100	100	100	98	n/a
P01	11	88,5	88	88	89	89	91	n/a
P01	12	88,1	87	87	88	88	90	n/a
P01	13	84,1	84	84	86	85	88	n/a
P01	14	84,1	83	83	85	84	87	n/a
P01	15	78,8	79	79	81	80	83	n/a
P01	16	78,0	78	78	81	79	82	n/a
P01	17	75,4	76	75	79	77	79	n/a
P01	18	74,7	75	74	79	76	79	n/a
P01	19	71,8	73	72	76	74	77	n/a
P01	20	71,5	72	72	76	73	76	n/a
P01	21	68,1	69	69	72	70	73	n/a
P01	22	68,0	70	70	72	71	74	n/a
P01	23	65,0	67	66	71	67	70	n/a
P01	24	65,6	66	65	71	67	69	n/a
P01	25	100,5	100	100	100	100	100	n/a
P02	1	97,5	99	100	98	100	97	n/a
P02	2	91,0	91	92	91	93	91	n/a
P02	3	90,1	90	92	90	92	90	n/a
P02	4	94,8	96	97	96	97	95	n/a
P02	5	95,4	96	98	96	97	96	n/a
P02	6	88,9	87	90	88	89	88	n/a
P02	7	86,9	86	87	86	88	86	n/a
P02	8	82,4	82	83	82	83	81	n/a
P02	9	81,7	81	83	81	83	82	n/a
P02	10	77,7	77	79	78	80	77	n/a
P02	11	76,7	75	76	76	77	75	n/a
P02	12	72,5	73	74	73	73	71	n/a
P02	13	71,2	71	71	72	73	70	n/a
P02	14	100,2	100	100	100	100	100	n/a
P02	15	100,3	100	100	100	100	99	n/a
P02	16	91,3	90	92	91	92	91	n/a
P02	17	90,0	89	93	90	89	90	n/a
P02	18	78,9	77	80	78	79	77	n/a
P02	19	76,7	75	76	76	76	75	n/a
P02	20	74,2	72	72	73	71	72	n/a
P02	21	70,7	70	69	70	68	68	n/a
P02	22	73,8	72	72	72	70	71	n/a
P02	23	83,0	82	81	82	82	82	n/a
P02	24	81,4	78	80	79	82	79	n/a
P02	25	100,4	100	100	100	100	100	n/a
P03	1	98,3	99	99	100	100	99	n/a
P03	2	90,7	90	91	92	92	93	n/a
P03	3	90,3	89	91	91	91	93	n/a
P03	4	86,6	86	87	87	87	90	n/a
P03	5	86,1	85	86	86	86	89	n/a
P03	6	83,9	83	84	84	85	87	n/a
P03	7	83,0	83	83	83	84	87	n/a
P03	8	75,5	75	76	75	77	80	n/a
P03	9	75,5	75	76	75	77	80	n/a
P03	10	69,0	69	71	68	71	73	n/a
P03	11	66,2	66	68	64	68	71	n/a
P03	12	100,6	100	100	100	100	100	n/a

		Reference	CapnoTrue®					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P03	13	100,7	100	100	100	100	100	n/a
P03	14	88,6	87	88	88	88	91	n/a
P03	15	89,5	89	90	90	90	91	n/a
P03	16	87,5	87	88	87	88	89	n/a
P03	17	87,0	86	87	87	87	89	n/a
P03	18	79,2	78	80	78	80	83	n/a
P03	19	78,7	78	80	78	80	82	n/a
P03	20	72,8	73	75	72	75	76	n/a
P03	21	71,8	72	74	71	73	76	n/a
P03	22	64,8	66	67	64	67	69	n/a
P03	23	63,2	64	66	61	65	69	n/a
P03	24	64,3	64	66	62	66	69	n/a
P03	25	63,5	64	64	60	65	69	n/a
P04	1	97,6	97	98	96	99	97	n/a
P04	2	91,9	91	91	90	93	93	n/a
P04	3	92,2	91	92	90	93	93	n/a
P04	4	84,8	84	84	83	85	86	n/a
P04	5	82,7	82	82	81	83	85	n/a
P04	6	78,6	77	78	77	78	80	n/a
P04	7	78,7	78	79	78	79	80	n/a
P04	8	75,9	74	75	74	75	76	n/a
P04	9	75,5	74	74	74	74	76	n/a
P04	10	71,5	72	72	71	71	72	n/a
P04	11	70,2	72	73	72	72	70	n/a
P04	12	100,7	100	100	100	100	99	n/a
P04	13	100,7	100	100	100	100	100	n/a
P04	14	88,7	88	88	87	90	89	n/a
P04	15	86,9	87	87	87	90	88	n/a
P04	16	79,2	77	77	76	79	79	n/a
P04	17	78,2	77	77	77	79	78	n/a
P04	18	72,7	73	72	72	73	72	n/a
P04	19	74,3	73	73	72	74	73	n/a
P04	20	72,3	73	73	72	73	73	n/a
P04	21	69,8	72	72	72	71	71	n/a
P04	22	73,1	70	70	70	70	70	n/a
P04	23	70,8	70	70	70	70	70	n/a
P04	24	74,8	71	71	71	71	72	n/a
P04	25	72,2	70	70	70	69	70	n/a
P05	1	98,6	98	95	100	100	98	n/a
P05	2	91,7	92	95	93	95	92	n/a
P05	3	91,3	94	94	93	95	92	n/a
P05	4	87,2	88	89	88	90	88	n/a
P05	5	87,2	89	89	88	89	88	n/a
P05	6	83,6	85	85	83	85	85	n/a
P05	7	83,2	85	82	83	84	85	n/a
P05	8	81,7	81	82	78	82	81	n/a
P05	9	79,2	81	79	78	82	81	n/a
P05	10	73,5	73	76	70	74	74	n/a
P05	11	72,8	73	74	70	74	74	n/a
P05	12	100,5	NaN	NaN	100	NaN	98	SC7500, SF7500, 10-Ap No value
P05	13	100,5	99	NaN	100	NaN	98	SF7500, 10-Ap No value
P05	14	94,2	97	97	95	86	94	n/a
P05	15	94,0	95	96	95	88	94	n/a
P05	16	89,1	90	91	89	91	89	n/a
P05	17	88,9	90	92	90	92	90	n/a
P05	18	85,9	89	89	86	90	87	n/a
P05	19	85,6	88	88	84	88	86	n/a
P05	20	79,4	81	82	79	81	79	n/a
P05	21	78,5	80	81	78	81	80	n/a
P05	22	71,8	73	73	70	74	72	n/a
P05	23	71,0	72	72	70	71	72	n/a
P05	24	62,6	64	62	60	66	61	n/a
P05	25	61,0	59	60	56	61	59	n/a
P06	1	98,6	99	100	99	100	97	n/a

		Reference	CapnoTrue®					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P06	2	91,5	92	94	92	95	92	n/a
P06	3	91,1	91	92	91	95	91	n/a
P06	4	85,8	86	87	85	89	86	n/a
P06	5	85,3	86	86	85	89	85	n/a
P06	6	83,2	82	83	82	85	83	n/a
P06	7	83,9	83	83	83	86	83	n/a
P06	8	82,1	81	82	82	85	81	n/a
P06	9	80,9	81	82	81	84	81	n/a
P06	10	73,7	75	74	75	77	74	n/a
P06	11	73,6	74	74	74	76	71	n/a
P06	12	100,7	100	100	100	100	100	n/a
P06	13	100,6	100	100	100	NaN	99	EP7500 No value
P06	14	92,5	95	96	96	97	92	n/a
P06	15	90,5	94	94	94	96	91	n/a
P06	16	82,9	83	85	84	86	83	n/a
P06	17	81,7	82	83	82	85	82	n/a
P06	18	79,3	81	82	81	83	80	n/a
P06	19	78,5	80	80	80	83	80	n/a
P06	20	79,9	79	82	80	83	80	n/a
P06	21	80,6	80	81	81	82	82	n/a
P06	22	73,1	77	76	76	76	74	n/a
P06	23	72,4	73	74	74	76	72	n/a
P06	24	69,6	68	70	70	70	70	n/a
P06	25	69,7	70	71	72	73	69	n/a
P07	1	97,7	99	99	98	99	97	n/a
P07	2	92,3	92	94	91	93	91	n/a
P07	3	91,7	90	93	90	92	91	n/a
P07	4	84,5	83	86	85	85	84	n/a
P07	5	84,6	83	86	84	85	83	n/a
P07	6	81,5	79	81	80	81	82	n/a
P07	7	81,0	79	81	80	81	81	n/a
P07	8	80,5	78	80	79	80	80	n/a
P07	9	80,0	79	80	80	80	80	n/a
P07	10	72,7	70	72	72	71	72	n/a
P07	11	70,5	70	71	71	71	71	n/a
P07	12	100,6	100	100	100	100	99	n/a
P07	13	95,1	95	95	95	96	94	n/a
P07	14	95,0	94	94	94	95	94	n/a
P07	15	87,2	85	86	86	87	87	n/a
P07	16	86,5	86	85	86	87	87	n/a
P07	17	84,0	82	81	82	82	84	n/a
P07	18	84,3	82	82	82	82	83	n/a
P07	19	79,9	78	79	80	80	80	n/a
P07	20	78,9	77	77	78	78	79	n/a
P07	21	74,7	73	74	74	74	76	n/a
P07	22	74,1	72	72	74	72	74	n/a
P07	23	70,2	67	67	68	68	68	n/a
P07	24	70,0	67	67	68	68	69	n/a
P07	25	69,6	65	66	67	67	68	n/a
P08	1	98,1	98	99	98	99	99	n/a
P08	2	93,8	93	94	93	95	94	n/a
P08	3	93,8	93	94	93	96	94	n/a
P08	4	90,6	89	90	89	92	90	n/a
P08	5	90,4	89	90	89	91	91	n/a
P08	6	85,1	85	84	84	86	85	n/a
P08	7	85,2	84	85	84	86	85	n/a
P08	8	82,2	82	81	81	83	82	n/a
P08	9	81,6	82	81	81	82	81	n/a
P08	10	78,5	78	78	78	79	78	n/a
P08	11	77,7	78	77	77	79	78	n/a
P08	12	74,4	76	73	74	76	73	n/a
P08	13	75,3	75	72	74	75	73	n/a
P08	14	100,7	100	100	100	100	100	n/a
P08	15	92,5	93	92	92	94	92	n/a
P08	16	92,2	92	92	92	94	92	n/a

		Reference	CapnoTrue®					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P08	17	87,7	86	88	87	90	87	n/a
P08	18	86,3	87	86	87	89	86	n/a
P08	19	82,1	82	81	82	84	82	n/a
P08	20	83,8	83	82	83	85	83	n/a
P08	21	80,0	81	80	81	83	79	n/a
P08	22	78,4	81	78	80	81	78	n/a
P08	23	74,4	74	71	73	76	73	n/a
P08	24	77,9	74	74	74	76	74	n/a
P08	25	76,5	74	74	75	77	73	n/a
P09	1	98,7	100	NaN	100	100	NaN	SF7500 excluded (section 10.3); EP7500 No value
P09	2	95,1	95	NaN	95	98	95	SF7500 excluded (section 10.3)
P09	3	95,0	96	NaN	95	98	95	SF7500 excluded (section 10.3)
P09	4	92,8	93	NaN	92	96	93	SF7500 excluded (section 10.3)
P09	5	93,5	94	NaN	93	96	94	SF7500 excluded (section 10.3)
P09	6	90,8	90	NaN	89	92	92	SF7500 excluded (section 10.3)
P09	7	91,3	92	NaN	91	93	92	SF7500 excluded (section 10.3)
P09	8	86,2	82	NaN	86	90	88	SF7500 excluded (section 10.3)
P09	9	86,0	78	NaN	86	90	87	SF7500 excluded (section 10.3)
P09	10	82,6	81	NaN	82	86	84	SF7500 excluded (section 10.3)
P09	11	81,8	82	NaN	81	85	84	SF7500 excluded (section 10.3)
P09	12	78,6	79	NaN	78	82	80	SF7500 excluded (section 10.3)
P09	13	77,9	78	NaN	77	82	81	SF7500 excluded (section 10.3)
P09	14	100,6	100	NaN	100	100	NaN	SF7500 excluded (section 10.3), EP7500 No value
P09	15	92,1	95	NaN	94	96	92	SF7500 excluded (section 10.3)
P09	16	91,6	94	93	93	95	92	n/a
P09	17	84,9	87	86	87	90	86	n/a
P09	18	83,7	84	86	84	88	85	n/a
P09	19	84,9	82	81	80	83	82	n/a
P09	20	83,1	79	80	79	84	80	n/a
P09	21	73,1	76	74	73	78	75	n/a
P09	22	79,9	70	72	72	75	72	All excluded, see Figure 12.22
P09	23	66,7	67	68	67	70	70	n/a
P09	24	68,9	68	66	66	71	69	n/a
P09	25	68,9	68	66	66	70	69	n/a
P10	1	97,9	100	100	99	100	99	n/a
P10	2	93,9	94	95	94	96	95	n/a
P10	3	94,0	95	95	94	96	96	n/a
P10	4	90,1	90	91	90	92	91	n/a
P10	5	89,5	90	90	89	91	91	n/a
P10	6	85,8	86	87	86	88	88	n/a
P10	7	84,0	84	84	84	86	86	n/a
P10	8	81,5	81	81	81	83	83	n/a
P10	9	80,4	80	80	80	82	83	n/a
P10	10	77,6	77	76	77	79	80	n/a
P10	11	76,7	75	75	76	78	78	n/a
P10	12	71,6	71	70	72	74	73	n/a
P10	13	69,6	70	69	70	73	70	n/a
P10	14	100,7	100	100	100	100	100	n/a
P10	15	94,2	95	96	95	96	95	n/a
P10	16	93,8	94	96	94	95	95	n/a
P10	17	87,2	88	89	87	90	89	n/a
P10	18	86,2	86	87	86	88	88	n/a
P10	19	79,8	80	80	80	82	81	n/a
P10	20	77,2	78	78	77	80	79	n/a
P10	21	72,4	74	73	73	76	75	n/a
P10	22	70,8	72	71	71	74	73	n/a
P10	23	63,9	64	62	65	66	64	n/a
P10	24	64,7	63	60	64	65	62	n/a
P10	25	61,5	61	58	61	63	59	n/a
P11	1	98,7	97	99	98	98	97	n/a
P11	2	93,0	91	92	92	91	92	n/a
P11	3	92,2	90	92	92	90	91	n/a

		Reference	CapnoTrue®					
Subject #	Syringe #	ABL90 FLEX	SC7500	SF7500	W7500	10-Ap	EP7500	Reason for data exclusion
P11	4	87,0	85	87	87	85	85	n/a
P11	5	85,9	84	84	84	83	82	n/a
P11	6	82,3	82	83	83	81	80	n/a
P11	7	82,0	81	83	82	81	80	n/a
P11	8	77,3	77	79	78	77	75	n/a
P11	9	77,5	77	78	77	75	74	n/a
P11	10	74,1	73	75	73	73	70	n/a
P11	11	73,4	73	73	72	72	69	n/a
P11	12	100,8	100	100	100	100	100	n/a
P11	13	92,9	91	93	92	91	92	n/a
P11	14	90,3	88	91	89	88	88	n/a
P11	15	86,5	85	88	86	85	85	n/a
P11	16	86,1	84	86	85	84	84	n/a
P11	17	79,1	78	80	78	78	76	n/a
P11	18	77,8	77	78	77	76	75	n/a
P11	19	73,1	73	75	72	73	68	n/a
P11	20	74,1	72	73	71	72	67	n/a
P11	21	73,5	73	75	73	74	69	n/a
P11	22	73,4	72	73	72	72	68	n/a
P11	23	71,2	70	73	70	71	66	n/a
P11	24	71,5	69	70	68	70	64	n/a
P11	25	71,6	69	71	68	70	64	n/a
P12	1	98,4	98	99	98	99	NaN	EP7500 No value
P12	2	93,3	93	94	92	93	NaN	EP7500 No value
P12	3	92,6	92	94	92	93	NaN	EP7500 No value
P12	4	88,0	88	89	87	88	NaN	EP7500 No value
P12	5	86,2	87	87	86	87	NaN	EP7500 No value
P12	6	84,1	85	85	84	84	NaN	EP7500 No value
P12	7	82,6	84	84	83	83	NaN	EP7500 No value
P12	8	77,8	80	79	78	79	NaN	EP7500 No value
P12	9	75,8	78	77	76	78	NaN	EP7500 No value
P12	10	71,8	75	73	73	73	NaN	EP7500 No value
P12	11	71,1	75	74	72	73	NaN	EP7500 No value
P12	12	100,7	100	100	100	100	NaN	EP7500 No value
P12	13	92,6	92	94	92	94	NaN	EP7500 No value
P12	14	91,6	92	94	92	93	NaN	EP7500 No value
P12	15	87,3	88	89	86	88	NaN	EP7500 No value
P12	16	86,6	87	88	87	88	NaN	EP7500 No value
P12	17	80,4	83	82	80	82	NaN	EP7500 No value
P12	18	82,0	84	84	82	83	NaN	EP7500 No value
P12	19	77,2	80	79	77	78	NaN	EP7500 No value
P12	20	75,5	80	79	78	79	NaN	EP7500 No value
P12	21	73,7	77	77	73	76	NaN	EP7500 No value
P12	22	73,1	77	76	73	75	NaN	EP7500 No value
P12	23	71,0	75	74	70	73	NaN	EP7500 No value
P12	24	70,1	74	73	69	72	NaN	EP7500 No value
P12	25	68,2	74	72	68	72	NaN	EP7500 No value

12.3 Excluding data points

- Sample 1 to 15 of subject 9; sensor SoftFlap (SF7500) on CapnoTrue® (OEM II):

Samples were excluded as no stable measurement was obtained. During the measurement the sensor slipped slowly of the little finger (right hand). The sensor was too large for the finger. In the second run the sensor was moved to the thumb and measurement continued.

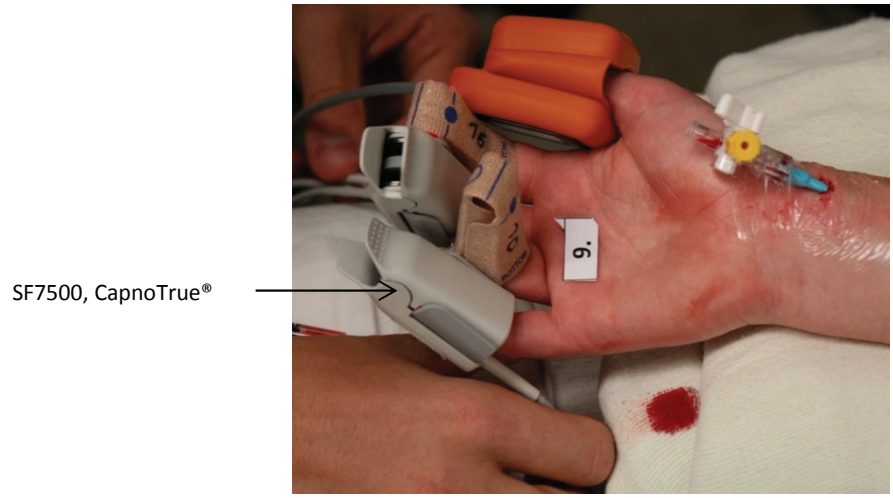


Figure 12.21: Right hand subject 9 (SF7500 at little finger slipped off during first run)

- Sample 22 of subject 9, all sensors on OxyTrue® (OEM III) and CapnoTrue® (OEM II):

The sample was excluded as the reference value was identified as outlier. The BGA value showed a deviation of more than 5 digits compared to all other oximeters including the non-invasive control device (Nellcor). In addition the next BGA reference value taken 60 seconds later had a value of 15 SpO2 digits lower (refer to figure 10.22)

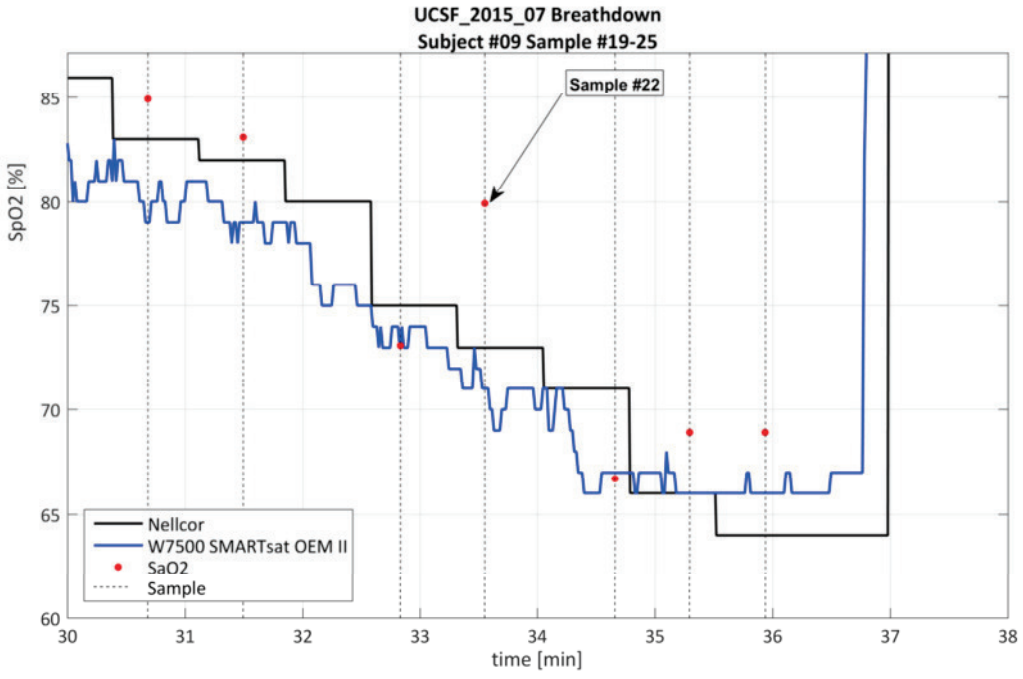


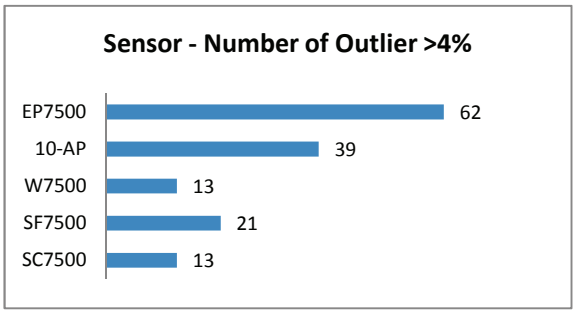
Figure 12.22: BGA Reference value - sample 22, subject 9 excluded

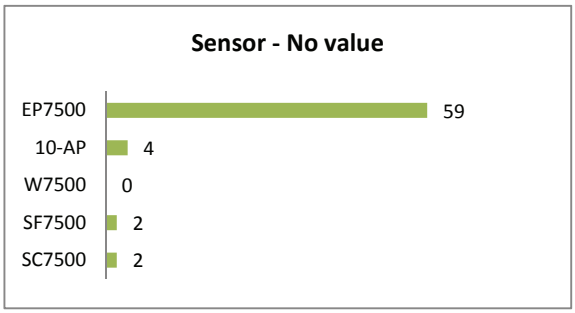
12.4 Discussion of Outlier > 4% and No Value

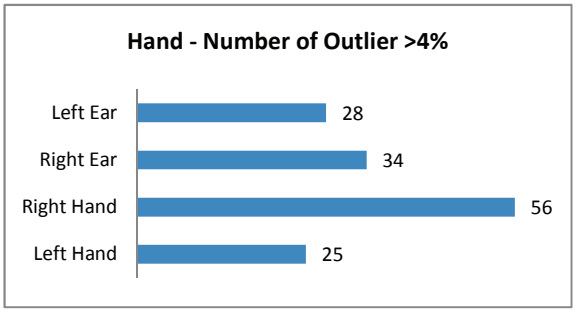
The following diagrams plot the number of *outlier* with error >4% and the number of *no value* for each sensor, application side (left or right), application finger, SpO2 monitor, skin color and subject separately.

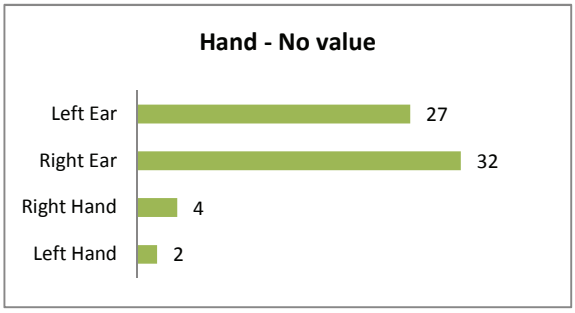
In addition the relative number of outliers for each monitor and sensor are listed below the plots.

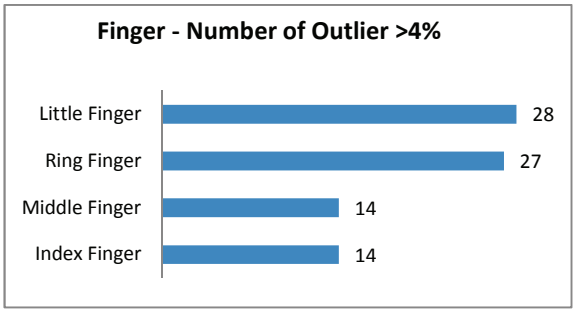
Each outlier was analyzed. Although the readings were high bias, the magnitude of error was within expected deviations for oximetry and is clinically safe.

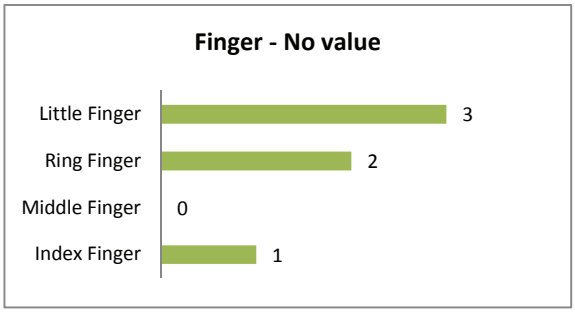


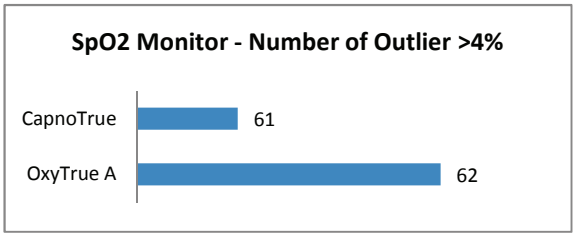


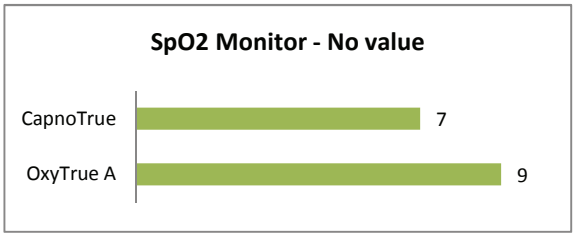


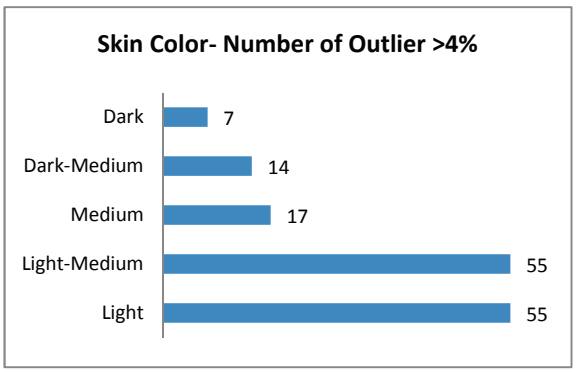


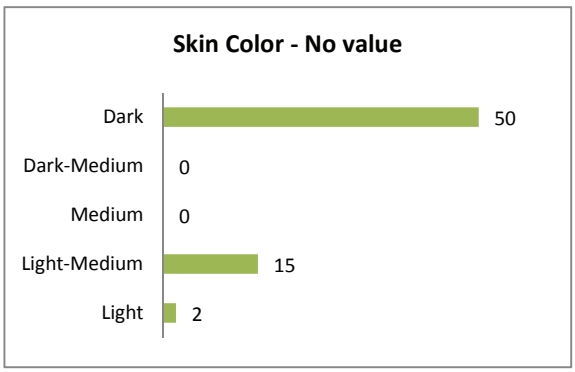


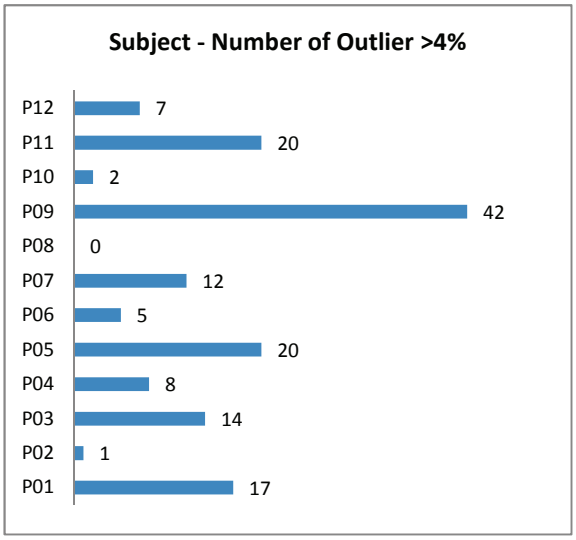


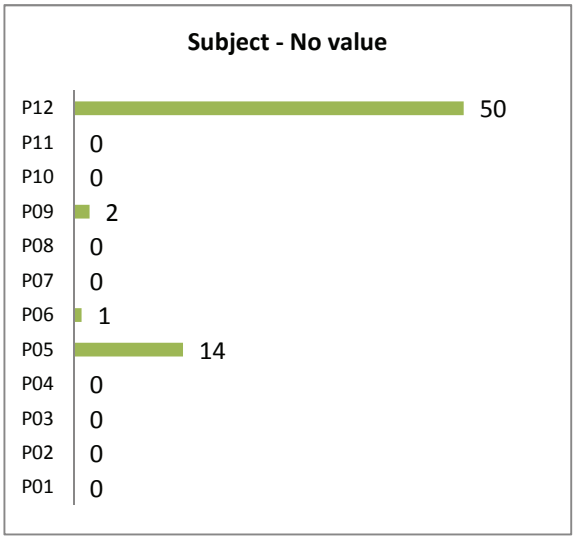












OxyTrue® A with 10-Ap Disposable SpO2 sensor

In 28 cases the absolute error was > 4% for the 10-AP SpO2 Sensor with the OxyTrue® A pulse oximeter. This corresponds to 9.4% (28/298) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

OxyTrue® A with EP7500 Ear SpO2 sensor

In 27 cases the absolute error was > 4% for the EP7500 SpO2 Sensor with the OxyTrue® A pulse oximeter. This corresponds to 10.0% (27/266) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

OxyTrue® A with SF7500 SpO2 sensor

In 5 cases the absolute error was > 4% for the SF7500 SpO2 Sensor with the OxyTrue® A pulse oximeter. This corresponds to 1.7% (5/299) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

OxyTrue® A with SC7500 SpO2 sensor

In 5 cases the absolute error was > 4% for the SC7500 SpO2 Sensor with the OxyTrue® A pulse oximeter. This corresponds to 2.0% (6/298) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

OxyTrue® A with W7500 SpO2 sensor

In 4 cases the absolute error was > 4% for the W7500 SpO2 Sensor with the OxyTrue® A pulse oximeter. This corresponds to 1.3% (4/299) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

CapnoTrue® with 10-Ap Disposable SpO2 sensor

In 11 cases the absolute error was > 4% for the 10-AP SpO2 Sensor with the CapnoTrue ® pulse oximeter. This corresponds to 3.7% (11/296) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

CapnoTrue ® with EP7500 Ear SpO2 sensor

In 28 cases the absolute error was > 4% for the EP7500 SpO2 Sensor with the CapnoTrue® pulse oximeter. This corresponds to 10.3% (28/272) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

CapnoTrue ® with SF7500 SpO2 sensor

In 1 cases the absolute error was > 4% for the SF7500 SpO2 Sensor with the CapnoTrue ® pulse oximeter. This corresponds to 0.0% (1/282) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

CapnoTrue ® with SC7500 SpO2 sensor

In 7 cases the absolute error was > 4% for the SC7500 SpO2 Sensor with the CapnoTrue ® pulse oximeter. This corresponds to 2.3% (7/298) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

CapnoTrue ® with W7500 SpO2 sensor

In 9 cases the absolute error was > 4% for the W7500 SpO2 Sensor with the CapnoTrue ® pulse oximeter. This corresponds to 3.0% (9/299) of SpO2 reading have a deviation of >4% from the reference CO-Oximeter.

12.5 „ACCURACY OF PULSE OXIMETERS WITH PROFOUND HYPOXIA“

EXHIBIT A (pages 9 - 10) of CLINICAL TRAIL AGREEMENT: CTA Master BLUE05_150708_FE_7.7.15

IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

Agreed and Accepted By:

BLUEPOINT MEDICAL GMBH & CO. KG ("SPONSOR"):

By: _____

Name: Dana Lindner

Title: Authorized Manager

Date: July 1, 2015

bluepoint medical GmbH & Co. KG
An der Trave 15
D-23923 Selmsdorf
Tel.: +49(0) 38823-548-8001
Fax: +49(0) 38823-548-8029

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ("UCSF"):

By: _____

Name: _____

Title: _____

Date: 7/7/15

Erick S. Lee, J.D., LL.M.
Industry Contracts Officer
Innovation, Technology & Alliances
University of California
San Francisco

Read and Understood:

By (Principal Investigators): _____

Name: Philip Bickler, MD, PhD
Professor of Anesthesia

_____

Name: John Feiner, MD
Professor of Clinical Anesthesia

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EXHIBIT A
PROTOCOL

ACCURACY OF PULSE OXIMETERS WITH PROFOUND HYPOXIA

Test program and protocol
Revision: Feb 2005

This laboratory has developed methods that permit us to test 1 to 10 pulse oximeters simultaneously. We induce sudden profound and brief stable arterial oxygen desaturation in normal, paid volunteers and sample arterial blood when a stable level of hypoxia has been attained, for analysis in a gold standard bench CO-oximeter. This document describes the program and arrangements. 6 to 8 subjects can be studied in a single day, with 20-25 arterial blood samples from each subject. 10 to 12 subjects can be studied over two days, with 20-25 arterial blood samples each.

The key to this is a computer program that permits the inspired gas mixture to be adjusted by an operator who observes a breath-by-breath display of the arterial saturation computed from end tidal Po_2 and Pco_2, which is continuously monitored by mass spectrometry. Typically, saturation is determined once with air breathing and then reduced suddenly to one of 6 levels, range as requested, e.g. 94%, 90%, 85%, 80%, 75% and 70%, for about 30-60 seconds at each level. An arterial blood sample is obtained from an indwelling catheter at the end of each hypoxic plateau. The operator changes the inspired oxygen concentration at the end of each blood sampling, and the sudden change this produces in the oximeter recording is used as a time marker for subsequent analysis.

A "run" takes 5-7 minutes, during which several plateaus are obtained, e.g. 90%, 80%, and 70%; the run is terminated by a breath of 100% O_2 followed by room air. Two runs together compose the six levels of saturation previously mentioned. Saturation of each arterial blood sample is determined by direct oximetry in a Radiometer OSM-3 multi-wavelength oximeter.

Normally, each tested oximeter should provide an electrical analog output signal that we record with LabView in the computer for subsequent plotting and statistical analysis. The timing of the arterial sample on the pulse oximeter recording is obtained from the record of that oximeter using the abrupt fall to a lower plateau or rise produced by re-oxygenation. The mean oximeter output between 6 and 12 seconds before the sudden change of SpO_2 is recorded and is read by cursor on a color terminal, and the value transferred to a file for statistical analysis in Excel. The output files include data collected at 2 Hz for each oximeter, and are available on CD or other media such as Zip disks, for analysis. A study normally consists of one normoxic and 19-24 hypoxic comparisons for each subject.

In many modern pulse oximeters, no analog output is provided. If the manufacturer chooses to record the data in a portable computer at a rate of at least 1 Hz, that data can also be submitted to us for data analysis without extra charge. If we are not asked to analyze data, the charge will be as shown for the first 4 instruments, with additional oximeters counted as non-recorded instruments in the following table.

If a manufacturer prefers to collect and analyze the data, the continuous digital signal of each oximeter should be read, for comparison with the blood sample, 9 seconds before the record shows a sudden fall or rise in oxygen saturation, **not at the time of blood sampling**. This procedure accounts for the delays of finger circulation and uses the estimated delay from the

lung to the sample site. There is no useful correlation between the actual time of blood sampling and the oximeter recording because of the extreme variability of tissue blood flow lag.

These studies are done with approval of the UCSF Committee on Human Research. The study takes about 1 hour of each subject's time. Reduction of the data requires several days. Manufacturer's representatives may be present for these tests, and may mount the probes. An extra charge is made if no representative is present, requiring us to mount the probes.

In all cases, the blood analysis data are provided, including the SaO_2, MetHb, COHb and Hgb concentration.

The data analysis report will consist of the following:

1. Graphic plots of the saturation values of each pulse oximeter at each blood sample time plotted against SaO2, the hemoximeter (blood) value.
2. Regression equations for the overall response of each instrument.
3. Plot of the bias values of all samples and all instruments against SaO2.
4. Tables of the mean error or bias, its standard deviation, standard error, 95% confidence interval, maximum and minimum and RMS, all computed both overall and by several sub-ranges of desaturation.

Technically, we can record data if each oximeter control unit provides a single ended analog output signal with BNC terminal mounted on the box. We provide cables to connect this to our computer. The oximeter probe leads should be at least 8 ft long. If no analog outputs are supplied, the manufacturer will be responsible for data recording.

Manufacturers must provide their own pulse oximeters and probes. Each individual manufacturer is charged an amount determined by the number of subjects, the number of samples per subject, and the number of oximeters (as shown by the cost table on the next page) plus the departmental and UCSF overheads. Sites may include the fingers, ears, forehead and bridge of the nose.

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