

Pulse Oximeter Test Report for

Fingertip Pulse Oximeter

Manufactured by
Shenzhen AEON Technology CO.,LTD.,
FLoor 5, Building 15, Majilong Industrial Area, Nanshan
District, Shenzhen, China

Conducted 26/04 2014

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I verify this report and it's the accuracy for Testing



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Methods

The current study for Shenzhen AEON Technology CO.,LTD. performed in Apr. 26th, 2014, included 12 subjects - 4 women and 8 men. The devices under test were the Fingertip Pulse Oximeter A300 and A310.

A radial arterial cannula was placed in either the left or right wrist of each subject. Blood gas analysis to determine oxyhemoglobin saturation was performed on an OSM-3® multi-wavelength oximeter (Hemoximeter, Radiometer, Copenhagen). No subject was anemic (Hemoglobin $\leq 10\text{gm}\cdot\text{dl}^{-1}$).

Each subject had control data taken at the beginning of each experiment, with two control blood samples drawn while breathing room air. Hypoxia was induced to different levels of oxyhemoglobin saturation (between 70-100%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide. Oxyhemoglobin saturation was reduced to a series of targets and stabilized at the plateau value. Each plateau level of oxyhemoglobin saturation was maintained for at least 30 seconds. Two arterial blood samples were then obtained, approximately 30 seconds apart. A total of 24 samples were obtained per subject. Data were recorded by Bickler-Ye lab and provided for data analysis.

Data Set

Data analysis was performed using Microsoft Excel. Files containing the sat value outputs every second from the test instruments were imported. Co-oximeter values were entered from log sheets.

In this type of study, the central saturation is changed very quickly. Blood takes time to circulate in the human body, so the values change at different times for the different measurement locations. Differences of as much as 30 seconds are common. In order to minimize the impact of this affect on the data, the co-oximeter readings were matched with the plateaus seen in the pulse oximeter data. Data points where a plateau flat within 2 sat points 30 seconds long could not be found were discarded. In this study 1 pair of data points were excluded based on this criterion

Data Analysis

Analysis of bias¹ was performed vs. Hemoximeter data. The limits of agreement shown are calculated per: *Bland JM, Altman D. (2007) Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics 17, 571 – 582.*

Tables of mean absolute deviation, standard deviation, standard error, maximum deviation, 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%.

Root mean square error (RMS error) is calculated as follows:

$$\text{RMS Error} = \sqrt{\frac{\sum (SpO_2 - SaO_2)^2}{n}}$$

¹ Bias is defined as the monitor under test reading minus the OSM3 reading.

Subject Pool

Subject Number	Gender	Ethnicity	Skin Pigmentation
1	Male	Chinese	Light
2	Male	African	Dark
3	Male	African	Dark
4	Male	African	Dark
5	Male	African	Dark
6	Male	Chinese	Light
7	Female	Chinese	Light
8	Female	African	Dark
9	Female	Chinese	Light
10	Male	Chinese	Light
11	Male	European	White
12	Female	Chinese	Light

Testing Device of Pulse Oximeter

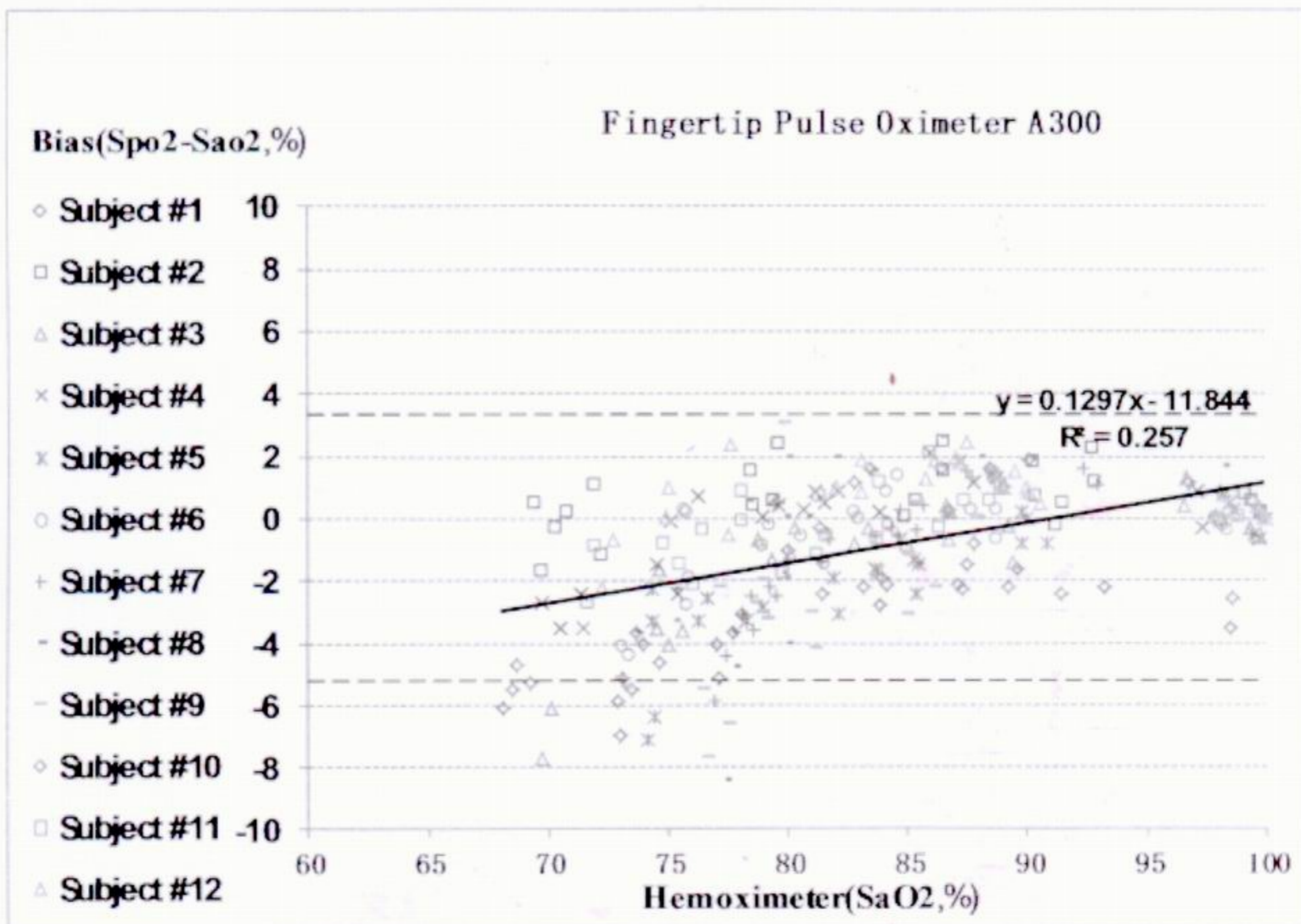
Fingertip Pulse Oximeter A300

Fingertip Pulse Oximeter A310

Statistics

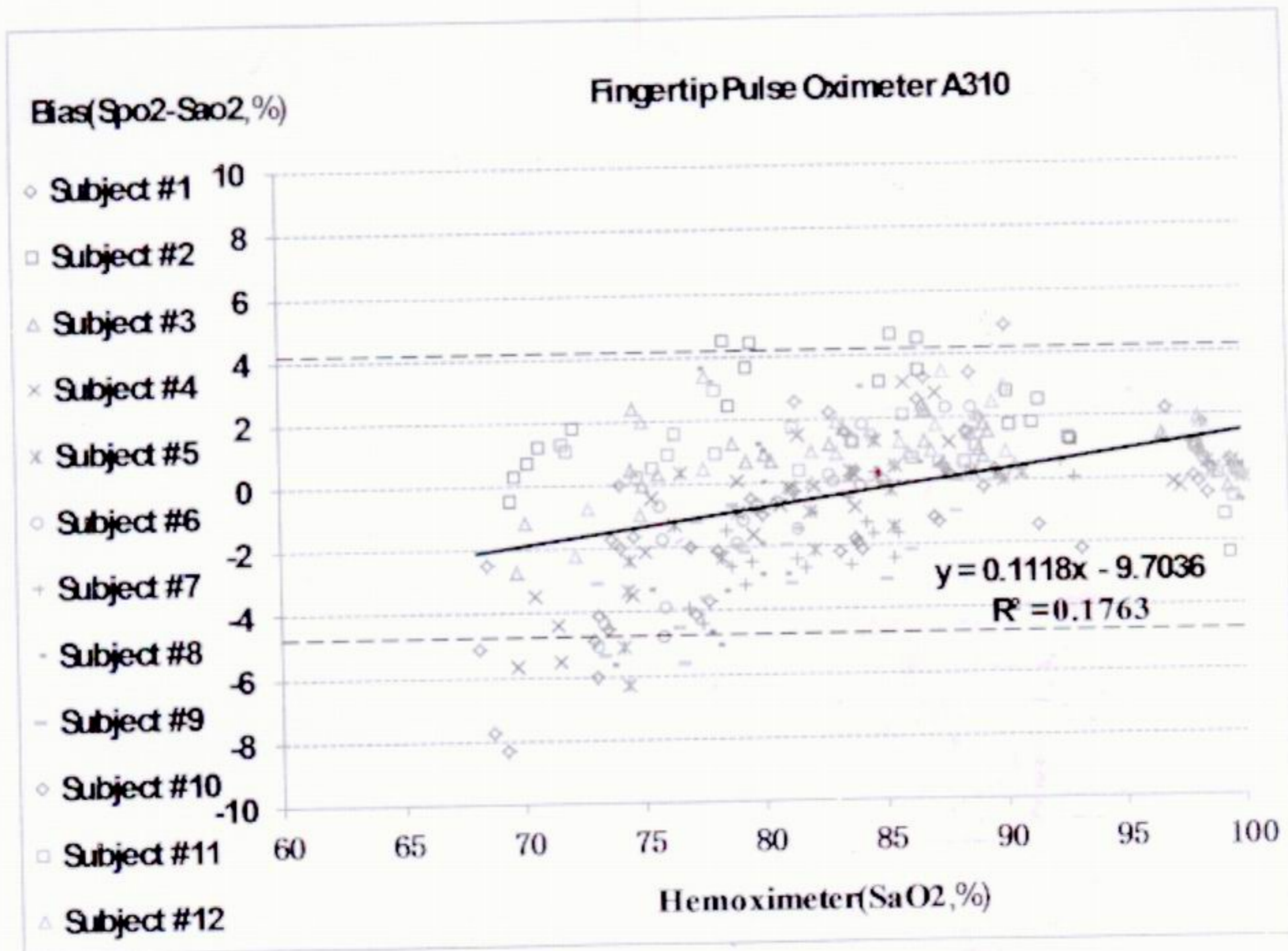
A300

Hemoximeter Range	60-80	80-100	60-100	70-100	60-70	70-80	80-90	90-100
Mean	-2.5	0.03	-0.91	-0.82	-4.15	-2.37	-0.01	0.1
Count	107	180	287	279	8	99	118	62
Missing Data	1	0	1	1	0	1	0	0
Standard Deviation	2.46	1.31	2.2	2.11	2.66	2.41	1.42	1.08
Standard Error	0.24	0.1	0.13	0.13	0.94	0.24	0.13	0.14
95% Confidence Interval	0.47	0.19	0.26	0.25	2.22	0.48	0.26	0.27
Upper LOA	2.32	2.6	3.39	3.32	1.07	2.35	2.78	2.21
Lower LOA	-7.32	-2.54	-5.22	-4.97	-9.37	-7.09	-2.8	-2.02
Maximum	3.1	2.6	3.1	3.1	0.5	3.1	2.6	2.3
Minimum	-8.4	-4.2	-8.4	-8.4	-7.7	-8.4	-4.2	-3.5
Root Mean Square	3.5	1.31	2.38	2.27	4.84	3.37	1.41	1.07



A310

Hemoximeter Range	60-80	80-100	60-100	70-100	60-70	70-80	80-90	90-100
Mean	-1.62	0.52	-0.28	-0.17	-4.03	-1.43	0.53	0.5
Count	107	180	287	279	8	99	118	62
Missing Data	1	0	1	1	0	1	0	0
Standard Deviation	2.7	1.52	2.29	2.17	3.18	2.58	1.68	1.17
Standard Error	0.26	0.11	0.13	0.13	1.13	0.26	0.15	0.15
95% Confidence Interval	0.52	0.22	0.27	0.26	2.66	0.52	0.31	0.3
Upper LOA	3.68	3.49	4.2	4.08	2.22	3.64	3.81	2.79
Lower LOA	-6.92	-2.46	-4.76	-4.43	-10.27	-6.49	-2.76	-1.79
Maximum	4.5	4.9	4.9	4.9	0.3	4.5	4.6	4.9
Minimum	-8.3	-3.2	-8.3	-6.3	-8.3	-6.3	-3.2	-2.4
Root Mean Square	3.14	1.6	2.3	2.17	5.01	2.94	1.75	1.26



Raw Data

Subject	Sample #	OSM-3	A300	A310
1	1	98.5	95	98
1	2	98.6	96	99
1	3	89.6	88	90
1	4	89.2	87	89
1	5	87.8	87	88
1	6	87.5	86	88
1	7	83.8	81	82
1	8	83.2	81	81
1	9	78.1	75	76
1	10	77	73	75
1	11	73.5	68	69
1	12	73.1	68	69
1	13	96.8	98	99
1	14	100.2	98	99
1	15	93.2	91	91
1	16	91.4	89	90
1	17	87.3	85	86
1	18	87.1	85	86
1	19	84.1	82	82
1	20	83.9	82	82
1	21	77.7	74	74
1	22	77.1	72	73
1	23	72.9	67	68
1	24	73	66	67
2	1	99.2	100	98
2	2	99.4	100	97
2	3	92.7	95	94
2	4	92.8	94	94
2	5	90.3	91	92
2	6	90.2	92	93
2	7	86.5	89	91
2	8	86.5	88	90
2	9	79.6	82	84
2	10	79.4	80	83
2	11	70.8	71	72
2	12	70.3	70	71
2	13	99.8	100	100
2	14	100.2	99	100
2	15	91.5	92	94
2	16	91.2	91	93
2	17	85.4	86	90

2	18	84.9	85	88
2	19	78.5	80	83
2	20	78.6	79	81
2	21	72.2	71	74
2	22	71.9	73	73
2	23	69.7	68	70
2	24	69.5	70	69
3	1	96.6	97	98
3	2	96.7	98	98
3	3	89.2	89	91
3	4	89.2	89	90
3	5	86.7	87	89
3	6	86.6	87	89
3	7	83.3	83	85
3	8	82.8	82	84
3	9	79.3	78	80
3	10	78.7	78	80
3	11	74.6	73	77
3	12	74.5	71	75
3	13	99.3	99	99
3	14	99.6	99	100
3	15	89.4	88	91
3	16	89	90	90
3	17	86.8	87	89
3	18	86.7	86	88
3	19	80.3	80	81
3	20	80.1	79	81
3	21	75.6	72	76
3	22	75	71	75
3	23	70.1	64	69
3	24	69.7	62	67
4	1	97.1	98	97
4	2	97.3	97	97
4	3	88.7	90	89
4	4	87.8	89	89
4	5	83.8	84	84
4	6	83.8	84	83
4	7	81.1	82	81
4	8	80.7	81	80
4	9	76.3	77	75
4	10	75.1	75	73
4	11	70.5	67	67
4	12	69.7	67	64
4	13	99.5	99	100
4	14	99.7	99	100

4	15	87.2	89	90
4	16	85.9	88	89
4	17	82.1	83	82
4	18	81.5	82	83
4	19	79.6	80	78
4	20	78.9	79	79
4	21	75.4	73	75
4	22	74.5	73	71
4	23	71.4	69	67
4	24	71.5	68	66
5	1	98.7	99	99
5	2	98.5	99	99
5	3	90	90	90
5	4	89.8	90	90
5	5	85.5	84	86
5	6	85.3	84	85
5	7	83.7	82	84
5	8	83.6	82	84
5	9	78.9	76	78
5	10	78.3	75	76
5	11	74.4	68	72
5	12	74.1	67	69
5	13	100	100	100
5	14	100.3	100	100
5	15	90.8	90	91
5	16	89.8	89	90
5	17	85.4	83	84
5	18	84.7	84	86
5	19	82.1	79	80
5	20	81.9	80	81
5	21	76.6	74	77
5	22	76.3	73	75
5	23	74.3	72	71
5	24	74.3	71	68
6	1	98.4	98	99
6	2	98.2	98	99
6	3	88.7	88	89
6	4	88.5	90	90
6	5	85	84	85
6	6	84.6	86	86
6	7	83	83	83
6	8	82.8	83	83
6	9	78.9	78	77
6	10	79.2	79	78
6	11	75.8	76	74

6	12	75.7	76	75
6	13	99.7	100	100
6	14	99.9	100	100
6	15	88.7	89	91
6	16	87.7	88	90
6	17	84.2	84	86
6	18	84.1	85	84
6	19	81.5	80	80
6	20	80.6	80	80
6	21	75.9	74	72
6	22	75.8	73	71
6	23	73.4	69	69
6	24	73.1	69	68
7	1	98.3	99	100
7	2	98.1	99	99
7	3	85.4	85	83
7	4	85.6	86	84
7	5	83.6	83	81
7	6	83.5	85	83
7	7	84.3	84	83
7	8	84.6	84	83
7	9	81.7	81	79
7	10	81.4	80	79
7	11	79.2	77	76
7	12	79.5	77	77
7	13	100	100	100
7	14	100.2	100	100
7	15	92.9	94	93
7	16	92.4	94	93
7	17	87.7	89	88
7	18	87.5	89	88
7	19	84.7	85	85
7	20	84.7	85	85
7	21	78.6	75	76
7	22	78.5	76	77
7	23	76.9	71	73
7	24	77.4	73	73
8	1	98.3	100	100
8	2	98.2	99	100
8	3	85.5	84	87
8	4	84	84	87
8	5	80	76	81
8	6	79.8	78	81
8	7	77.8	73	81
8	8	77.4	69	81

8	9	75.3	73	72
8	10	75.3	72	72
8	11	73.7	70	68
8	12	77.7	74	73
8	13	99.7	99	99
8	14	99.8	99	99
8	15	88	90	88
8	16	86.4	89	87
8	17	80.9	81	78
8	18	82	84	81
8	19	80	82	80
8	20	79.9	78	77
8	21	79.9	80	78
8	22	78.1	75	73
8	23	78.4	79	75
9	1	97.9	98	99
9	2	97.9	98	99
9	3	79.9	83	79
9	4	81.5	81	80
9	5	78.7	76	78
9	6	79.2	76	77
9	7	77.6	71	74
9	8	76.7	69	71
9	9	76.5	71	72
9	10	77.2	75	76
9	11	73.1	68	70
9	12	73.4	68	68
9	13	99.8	100	100
9	14	100	100	100
9	15	88	88	87
9	16	87.9	88	88
9	17	86.2	84	84
9	18	85.5	86	86
9	19	85.1	82	82
9	20	85.1	84	85
9	21	81.2	77	78
9	22	81	78	79
9	23	79	77	77
9	24	79	76	77
10	1	98.1	99	98
10	2	97.9	98	98
10	3	88.6	90	92
10	4	88.4	90	90
10	5	86.7	87	90
10	6	86.4	88	89

10	7	81.4	79	84
10	8	81.3	81	81
10	9	74.6	70	73
10	10	73.7	70	72
10	11	69.3	64	61
10	12	68.7	64	61
10	13	99.4	100	100
10	14	99.7	100	100
10	15	90.1	92	95
10	16	89	90	91
10	17	83.4	85	85
10	18	82.8	84	85
10	19	80	79	79
10	20	79.5	80	79
10	21	74	70	74
10	22	74	70	72
10	23	68.5	63	66
10	24	68.1	62	63
11	1	98.1	98	99
11	2	98	98	99
11	3	88.9	90	90
11	4	87.4	88	88
11	5	83.8	85	85
11	6	83.7	83	85
11	7	81.2	80	81
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11	9	76.4	76	78
11	10	76.1	74	77
11	11	75.5	74	76
11	12	74.8	74	75
11	13	98.9	99	99
11	14	99.6	99	99
11	15	88.6	90	90
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11	17	86.3	86	87
11	18	85.9	88	88
11	19	81.3	82	83
11	20	81.6	81	82
11	21	78.1	78	79
11	22	78.1	79	81
11	23	71.9	71	73
11	24	71.7	69	73
12	1	98.1	98	100
12	2	98.2	99	100
12	3	90.5	91	91

12	4	90.1	91	91
12	5	88.9	90	91
12	6	87.5	90	91
12	7	85.7	87	87
12	8	86.1	88	87
12	9	83.1	85	85
12	10	83.1	84	84
12	11	77.6	80	81
12	12	77.5	77	78
12	13	99.6	100	100
12	14	99.9	100	100
12	15	90	91	93
12	16	89.5	91	92
12	17	87.2	89	89
12	18	87	89	88
12	19	82	83	83
12	20	82	83	82
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12	24	72.2	70	70