Pulse Oximeter Test Report for

Checkme Pro Health Monitor with integrated sensor
Checkme Pro Health Monitor with FP10 sensor

Manufactured by
Shenzhen Viatom Technology CO.,LTD

Conducted June 8, 2014

Bickler Ye Hypoxia Research Laboratory
Shenzhen Medical University
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I verify the accuracy of this report,

Philip Bickler

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Methods

The current study for Shenzhen Viatom Technology CO.,LTD located at C607, Languang Technology Park, No.7 Xinxi Road, Hi-Tech Park North, Nanshan, Shenzhen, 518057, P.R. China included 12 subjects - 4 women and 8 men. The devices under test were;

Checkme Pro Health Monitor with integrated sensor
Checkme Pro Health Monitor with FP10 sensor

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 ≤ 10gm•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 analysis.

Data Set

Data analysis was performed using Microsoft Excel. Files containing the sat value outputs every second form 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 no data points were excluded based on this criterion.

Data Analysis

Analysis of bias[1] 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 SaO_2 (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

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

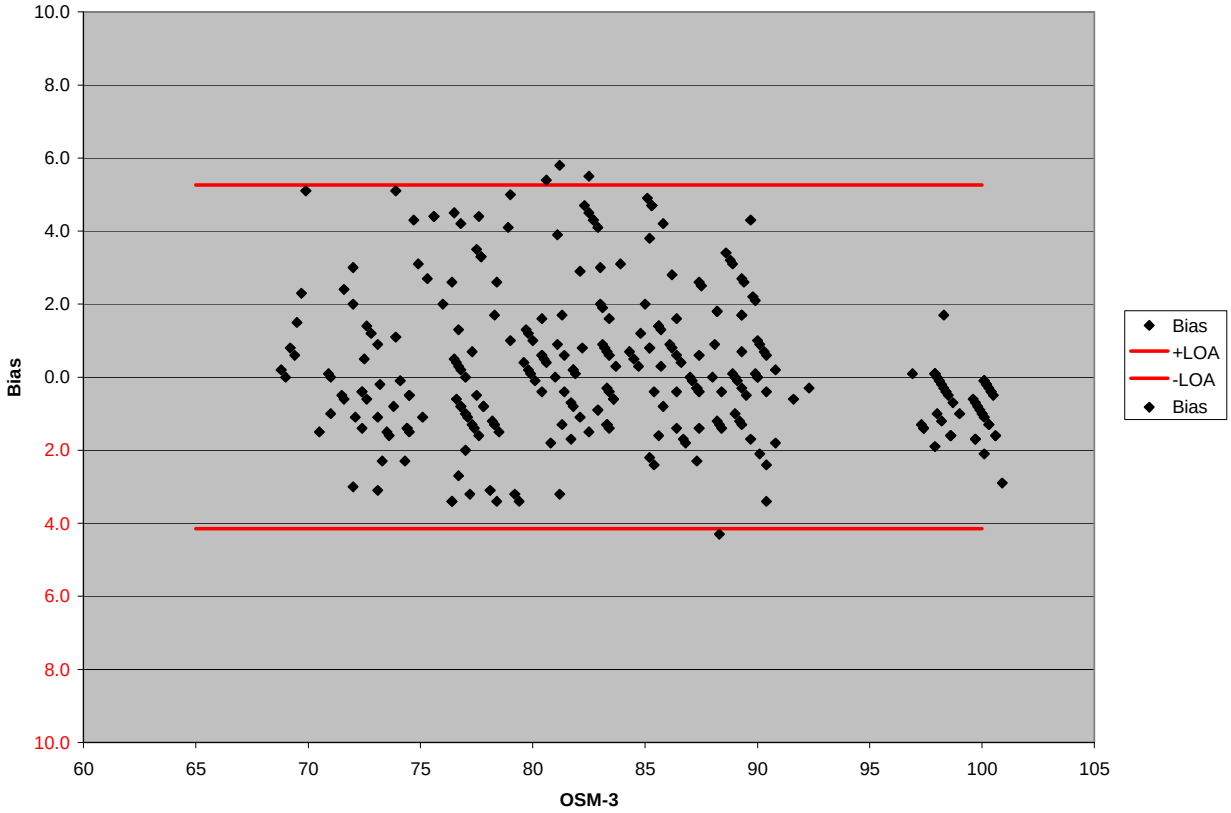
Statistics

Checkme Pro with integrated sensor

2 devices tested

Hemoximeter Range	60-80	80-100	60-100	70-100	60-70	70-80	80-90	90-100
Mean	0.56	0.30	0.39	0.37	1.11	0.51	0.55	-0.22
Count	194	380	574	560	14	180	258	122
Missing Data	0	0	0	0	0	0	0	0
Standard Deviation	2.34	1.91	2.07	2.08	1.53	2.40	1.95	1.75
Standard Error	0.24	0.14	0.12	0.12	0.58	0.25	0.17	0.22
95% CI	0.47	0.27	0.24	0.24	1.13	0.49	0.34	0.44
Upper LOA	5.26	4.12	4.53	4.53	Note 1	5.32	4.44	3.24
Lower LOA	-4.15	-3.51	-3.75	-3.79	Note 1	-4.29	-3.33	-3.68
Maximum	6.70	6.10	6.70	6.70	4.30	6.70	5.80	6.10
Minimum	-4.80	-4.30	-4.80	-4.80	-1.60	-4.80	-4.30	-3.20
Root Mean Square	2.41	1.94	2.11	2.11	1.86	2.45	2.02	1.76

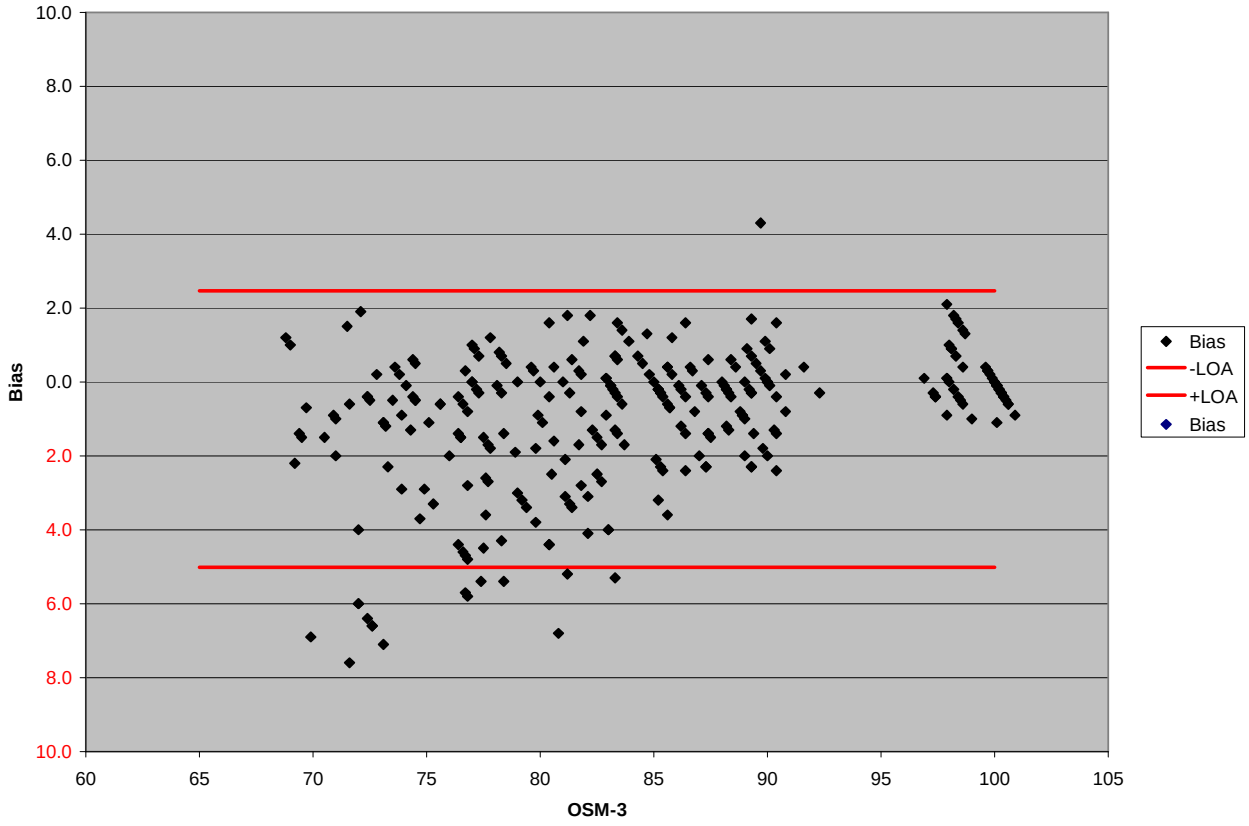
Note 1 - too few data points to calculate limit of agreement per Bland & Altman 2007



Checkme Pro with sensor FP10

2 devices tested

Hemoximeter Range	60-80	80-100	60-100	70-100	60-70	70-80	80-90	90-100
Mean	-1.28	-0.62	-0.84	-0.83	-1.31	-1.28	-0.51	-0.85
Count	194	380	574	560	14	180	258	122
Missing Data	0	0	0	0	0	0	0	0
Standard Deviation	1.88	1.55	1.69	1.68	2.33	1.85	1.46	1.70
Standard Error	0.19	0.11	0.10	0.10	0.85	0.19	0.13	0.22
95% Confidence Interval	0.37	0.22	0.19	0.20	1.66	0.38	0.25	0.42
Upper LOA	2.46	2.44	2.51	2.50	note 1	2.42	2.41	2.45
Lower LOA	-5.02	-3.67	-4.19	-4.15	note 1	-4.97	-3.42	-4.16
Maximum	2.6	4.3	4.3	4.3	1.20	2.6	4.3	1.8
Minimum	-7.6	-6.9	-7.6	-7.1	-7.60	-7.1	-5.4	-6.9
Root Mean Square	2.28	1.66	1.89	1.88	2.53	2.26	1.54	1.89



Raw Data

Subj	OSM-3	IndexFinger Checkme Pro	Pinky Finger Checkme Pro	IndexFinger Checkme Pro + sensor FP-10	IndexFinger Checkme Pro + sensor FP-10
1	97.9	98	98	98	96
	97.9	98	98	98	97
	83.3	84	85	78	79
	82.1	85	86	79	80
	80.4	81	82	76	77
	80.4	82	82	76	77
	76.7	78	80	72	73
	76.4	79	80	72	74
	72.6	74	75	66	68
	73.1	74	76	66	68
	72	75	74	66	68
	72	74	73	66	68
	99.8	99	100	100	100
	100	99	100	100	100
	89.8	92	91	88	88
	89.4	92	91	88	88
	85.1	90	88	83	84
	85.3	90	88	83	84
	83	85	85	79	80
	82.7	87	86	80	82
	77.6	82	81	74	76
	77.5	81	77	73	76
	71.6	74	72	64	67
	69.9	75	73	63	66
2	98.1	98	98	99	99
	98.4	98	97	100	100
	88.8	92	92	88	88
	88.9	92	92	88	89
	85.3	90	89	85	85
	85.3	90	90	85	86
	81.1	85	86	79	80
	80.6	86	86	79	80
	77.7	81	80	76	77
	77.7	81	81	75	76
	73.9	79	80	71	72

	74.7	79	80	71	74
	100.2	100	99	100	100
	100.1	100	99	100	100
	89.3	92	92	89	90
	88.6	92	92	89	90
	85.8	90	90	86	87
	85.2	89	90	85	86
	82.5	87	87	81	82
	82.7	87	87	81	83
	78.9	83	84	77	78
	79	84	84	76	78
	75.3	78	82	72	74
	74.9	78	81	72	74
3	98.3	100	98	99	100
	98	98	98	99	100
	89	89	90	88	89
	88.4	88	90	89	90
	86.1	87	86	86	86
	85.6	87	87	86	87
	80	81	80	80	80
	79.7	81	81	80	80
	77	75	76	77	77
	77.6	76	77	75	77
	75.6	80	78	75	75
	75.6	80	79	75	75
	99.9	99	100	100	100
	100.5	100	100	100	100
	89.7	94	93	94	91
	89.9	92	92	91	91
	86.4	87	88	86	86
	86.4	88	89	88	88
	81.2	87	86	83	83
	83.9	87	88	85	86
	82.3	87	88	81	81
	82.9	87	87	82	82
	76.8	81	79	74	74
	76.5	81	80	75	75
4	98.5	98	99	98	97
	98.6	97	99	99	99
	89.3	90	91	87	87
	89.3	91	93	89	90

	87.5	90	92	86	86
	87.4	90	91	86	87
	83	86	87	79	81
	82.5	88	88	80	82
	78.3	80	83	74	75
	78.4	81	85	77	78
	76	78	80	74	75
	77.4	76	81	72	75
	100.6	99	100	100	100
	100.9	98	99	100	100
	92.3	92	93	92	90
	90.8	91	92	91	91
	87.3	87	88	85	84
	87	87	88	85	85
	81.4	81	83	78	80
	81.1	82	83	78	79
	80.5	81	83	78	80
	81.3	83	81	78	80
	78.4	75	76	73	76
	81.2	78	78	76	82
5	98.7	98	99	100	100
	98.3	98	99	100	100
	86.2	87	88	85	86
	87.3	87	88	85	86
	86.4	85	86	84	86
	85.6	84	85	82	84
	82.1	81	83	78	80
	81.8	82	82	79	80
	79.2	76	80	76	77
	79.4	76	81	76	79
	76.8	76	78	71	73
	76.7	74	76	71	73
	100.3	99	99	100	100
	100.6	99	99	100	100
	90	90	90	88	89
	89	89	88	87	88
	85.4	83	83	83	84
	85.2	83	83	82	83
	80.8	79	77	74	76
	79.8	81	80	76	78
	76.6	76	76	72	75

	76.8	77	76	72	74
	72.6	72	72	66	67
	72.4	72	71	66	67
6	97.4	96	97	97	97
	97.4	96	96	97	97
	88.2	90	89	88	88
	88.2	90	89	88	88
	86.2	89	90	86	86
	87.1	87	88	87	87
	83.4	85	85	83	83
	83.1	84	84	83	83
	77.3	78	80	77	77
	76.6	77	79	76	76
	69.7	72	74	69	69
	69.5	71	72	68	68
	99.6	99	99	100	100
	100	99	99	100	100
	89.9	90	90	90	90
	88.9	89	89	88	88
	85	87	87	85	85
	85.7	87	87	85	86
	79.6	80	80	80	79
	79.8	80	80	78	78
	72.8	74	75	73	72
	72.5	73	74	72	71
	69.4	70	72	68	68
	69.2	70	71	67	66
7	98.2	97	98	98	98
	98.1	98	98	99	98
	89.5	89	89	90	89
	89.3	89	89	90	89
	87.4	87	87	88	87
	86.6	87	87	87	87
	82.2	83	84	84	83
	81.9	82	82	83	82
	74.5	74	73	75	74
	73.6	72	73	74	74
	68.8	69	69	70	68
	69	69	69	70	68
	100.1	99	99	100	100
	100.3	100	100	100	100

	91.6	91	92	92	91
	90.4	88	89	90	89
	90.1	88	88	90	90
	89.7	88	88	90	89
	85.6	87	86	86	86
	84.3	85	84	85	84
	77.8	77	77	79	78
	78.5	77	76	79	78
	72.1	71	71	74	72
	71.5	71	70	73	71
8	98.2	98	97	100	100
	97.9	98	99	100	99
	89	88	88	89	88
	89.1	89	90	90	90
	86.8	85	85	86	85
	86.7	85	85	87	86
	83.1	85	83	83	83
	82.9	82	82	83	84
	77.3	76	75	78	77
	77.2	74	73	77	77
	73.1	72	70	72	73
	73.5	72	71	73	74
	100.1	100	100	100	100
	100.2	100	100	100	100
	90.1	91	91	91	91
	90	91	91	90	91
	85.2	86	86	85	87
	84.8	86	87	85	87
	81	81	80	81	82
	81.3	80	79	81	83
	74.1	74	74	74	74
	73.9	75	74	73	73
	72.4	72	73	72	72
	73.1	70	73	72	70
9	96.9	97	96	97	97
	97.3	96	95	97	97
	88.4	87	88	88	88
	87.3	85	86	87	86
	83.3	82	82	84	84
	82.9	82	83	83	83
	80.1	80	79	79	80

	79	80	78	79	79
	74.4	73	71	75	75
	73.2	73	71	72	74
	71	71	70	70	71
	70.5	69	70	69	70
	99.7	99	99	100	100
	100.1	100	99	100	100
	88.3	87	86	88	88
	88	88	87	88	88
	81.8	81	81	82	82
	81.4	82	81	82	82
	78.1	75	77	78	78
	78.3	77	77	78	79
	74.5	73	74	74	75
	73.8	73	74	74	75
	71.6	71	70	71	72
	70.9	71	70	70	71
10	97.9	96	96	97	97
	98	97	96	98	98
	88.3	84	86	87	87
	87.4	86	87	86	86
	83.3	82	85	82	82
	83.4	82	84	82	81
	81.7	81	81	82	81
	81.7	80	80	80	80
	76.4	73	77	75	74
	76.4	73	77	76	75
	74.5	74	77	74	72
	74.3	72	74	73	72
	99.7	98	99	100	100
	99.7	98	99	100	100
	90.4	87	88	88	88
	88.2	87	88	87	86
	85.7	86	86	85	85
	85.2	86	87	85	85
	83.3	82	81	83	83
	83.6	83	81	83	82
	80.4	80	79	80	79
	79.9	80	79	79	79
	75.1	74	73	74	73
	74.4	73	74	74	73

11	98.6	97	97	98	99
	98.4	98	98	98	99
	90	90	89	90	92
	89.3	91	90	91	92
	84.5	85	85	85	84
	84.7	85	85	86	86
	83.4	84	83	84	85
	83.4	83	83	85	83
	80.6	81	83	81	80
	80.4	81	81	82	83
	78.2	77	78	79	78
	78.3	77	78	79	79
	100.4	100	100	100	100
	100.4	100	100	100	100
	90.4	90	91	89	90
	90.4	91	91	92	92
	85.4	85	85	85	85
	85.8	85	85	87	87
	83.3	83	83	84	83
	83.6	83	83	85	85
	77	77	75	78	78
	77.1	76	75	78	79
	77	76	76	77	76
	76.7	77	76	77	76
12	99	98	99	98	97
	98.6	97	98	100	99
	89.3	88	87	87	86
	89.2	88	88	89	88
	86.4	86	86	85	84
	85.6	87	86	85	83
	82.5	81	80	80	80
	81.8	82	82	81	80
	77.5	77	82	76	77
	76.5	77	81	75	75
	72	69	70	68	69
	71	70	72	69	69
	100.1	98	99	99	100
	100.3	99	99	100	100
	90.8	89	90	90	88
	90.3	91	90	89	88
	88.1	89	90	88	87

87.4	88	85	87	85
83.7	84	82	82	82
83.2	84	82	83	81
77.8	77	73	76	75
76.8	76	73	76	77
73.3	71	73	71	72