SpO_2 Monitoring

Pulse Oximeter Accuracy Study

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Fighting Disease with Electronics
NIHON KOHDEN

Nihon Kohden commissioned 2 studies to evaluate Nihon Kohden pulse oximeter and probes at the Hypoxia Research Laboratory, University of California, San Francisco in 2008 and 2010. The following document is a summarized version of the report from those studies, created by Nihon Kohden Corporation. This document has been reviewed and approved by the investigators.

Information in this document is true accurate to the best of our knowledge at the time of publication.

SpO_2 Accuracy Study of Nihon Kohden Pulse Oximeters

SpO_2 Accuracy and Specifications

Pulse oximeters measure oxyhemoglobin saturation (SpO_2) from the signals of the red and infrared light transmitted through the tissue. The theoretical formula for calculating the SpO_2 value from transmitted light signals is not completely established and each SpO_2 manufacturer adopts their empirically developed calculation method. Therefore, the SpO_2 accuracy depends on two factors of a) the validity of the calculating formula (the calibration curve) and b) deviations from the calculating formula. For this reason, ISO 80601-2-61: 2011, the International Standard of pulse oximeter equipment, requires each manufacturer to conduct controlled desaturation studies on human subjects and validate the SpO_2 accuracy in comparison to "gold standard (SaO_2 value)" which is intended to include the validation of those two factors previously mentioned. In the ISO 80601-2-61: 2011, the SaO_2 value determined by analyzing arterial blood samples with a Hemoximeter is described as reference, and SpO_2 accuracy of the pulse oximeter equipment is stated in terms of the RMS (root-mean-square) difference between measured value (SpO_2) and reference value (SaO_2). This RMS difference means that two-thirds of the SpO_2 values measured by a pulse oximeter can be expected to fall within the range of RMS.

All pulse oximeters and patient monitors with Nihon Kohden SpO_2 technology are designed and manufactured to meet the same specifications for SpO_2 measurement accuracy. Nihon Kohden SpO_2 accuracy is specified below. These specifications exceed the requirements of ISO 80601-2-61: 2011 as noted.

Table 1. Accuracy criteria for SpO_2 measurement

	SaO_2 range	SpO_2 accuracy (RMS)
Nihon Kohden Pulse Oximeters	80 – 100%	2% or less
	70 – 80%	3% or less
ISO 80601-2-61: 2011	70 – 100%	4% or less

Summary of Invasive Controlled Desaturation Study on Healthy Volunteers

Hypoxia Research Laboratory (University of California, San Francisco) conducted 2 studies, one in 2008 and another in 2010 using Nihon Kohden pulse oximeters, OLV-3100, as a third party and reported the result.

During these studies, each subject was induced hypoxia to different arterial oxyhemoglobin saturation levels between 70% to 100% by controlling the inspired oxygen concentration, the SpO_2 readings of pulse oximeters were recorded simultaneously with drawing arterial blood samples, and statistical analysis was performed between the SpO_2 readings and SaO_2 reference values from the Hemoximeters. The SaO_2 reference values are determined from the readings of the two Hemoximeters.

Exclusion criteria for this statistical analysis were predefined as follows:

- Data which drifted 4% or more during the 10 second plateau reading.

- Data where the two Hemoximeter values disagreed to 2% or more.

A summary for the test result is shown below. The test results show that all tested probes meet the accuracy specifications.

Table 2. SpO_2 accuracy (RMS difference) studied by Hypoxia Research Laboratory, University of California, San Francisco

Probe type		SaO_2 range	
		70 – 80%	80 – 100%
Finger Probe	TL-201T	1.62%	1.07%
Multi-site Y Probe	TL-260T	1.83%	1.56%
Multi-site Y Probe with clip adapter for ear lobe	TL-260T	2.14%	1.62%
Disposable SpO_2 Probe	TL-271T	2.05%	1.39%
Finger Probe	TL-631T	2.79%	1.45%
Disposable SpO_2 Probe	TL-051S	1.93%	1.59%
Disposable SpO_2 Probe	TL-535U	2.01%	1.37%

Details are given on succeeding pages, "Accuracy Study Report of Nihon Kohden Palse Oximeter (excerpted version)" studied by Hypoxia Research Laboratory, University of California, San Francisco.

June 1, 2013

Nihon Kohden Corporation
Telemetry Technology Center

Accuracy Study Report of
Nihon Kohden Pulse Oximeter Report

Hypoxia Research Laboratory
University of California, San Francisco

March 12-13 and April 16, 2008

John R. Feiner, M.D.

Phillip E. Bickler, Ph.D. M.D.

John W. Severinghaus, M.D.

October 20 and 21, 2010

Phillip E. Bickler, Ph.D. M.D.

John R. Feiner, M.D.

Methods

The first study performed March 12-13 and April 16, 2008, included 18 subjects – 5 women and 13 men for four Nihon Kohden oximeter probes, TL-201T, TL-260T, TL-271T, and TL-631T. TL-260T was also tested with a clip adapter for ear lobe in 14 subjects – 4 women and 10 men. And the second study performed October 20 and 21, 2010, included 12 subjects – 7 women and 5 men for 2 probes, TL-535U and TL-051S. All were on model OLV-3100 oximeters. 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 two OSM 3® multi-wavelength oximeters (Hemoximeter, Radiometer, Copenhagen). No subject was anemic (Hemoglobin ≤ 10 gm • 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. Each plateau level of oxyhemoglobin saturation was maintained for at least 30 seconds and until pulse oximeters readings had stabilized. Two arterial blood samples were then obtained, approximately 30 seconds apart. A total of 24 and 20 samples were obtained per subject, respectively, in the first study and the second study. Data were recorded by Nihon Kohden and provided to UCSF for analysis.

Figure 1. Probes and Pulse Oximeter OLV-3100 used for study

Data Analysis

Data analysis was performed on Excel. Data was excluded if Hemoximeter values disagreed to 2 points or more, or if there was failure to achieve stable pulse oximeter measurements. In the figures, a different marker is used for each study subject. Tables of mean, standard deviation, count and root mean square are provided for each oximeter's bias in the following ranges of SaO_2 (Hemoximeter): 70 - 80%, 80 - 100%. Root mean square error (RMS error) is calculated as follows:

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

Table 3 and Table 4 show subject data for the first study. Subject #7 in Table 3 was excluded because of an apparent upper respiratory infection. Subject #9 in Table 3 and Subject #6 in Table 5 was excluded because the subjects were unable to complete the study.
Table 5 shows subject data for the second study.

Table 3. Subject data for the study for TL-201T, TL-260T, TL-271T, and TL-631T

Subject	Ethnicity	Gender	Age	Skin tone
Subject #1	Caucasian	M	30	Medium
Subject #2	African	M	23	Dark
Subject #3	Asian	M	25	Light
Subject #4	Caucasian	F	29	Medium
Subject #5	Caucasian	M	22	Light
Subject #6	Caucasian	M	24	Light
Subject #7	Caucasian	M	33	Light
Subject #8	Caucasian	F	30	Light
Subject #9	Caucasian	F	34	Light
Subject #10	Caucasian	M	28	Light
Subject #11	Caucasian	M	22	Light
Subject #12	Indian	F	25	Dark
Subject #13	Indian	M	25	Medium
Subject #14	African	M	27	Dark
Subject #15	Hispanic/Caucasian	F	23	Medium
Subject #16	Indian	M	21	Med/Dark

Table 4. Subject data for the study for TL-260T with clip adapter for ear lobe

Subject	Ethnicity	Gender	Age	Skin tone
Subject #1	Caucasian	M	30	Medium
Subject #2	Indian	M	28	Medium
Subject #3	Asian	M	25	Light
Subject #4	Caucasian	F	29	Medium
Subject #5	Caucasian	M	22	Light
Subject #6	Caucasian	M	24	Light
Subject #7	Caucasian	M	33	Light
Subject #8	Caucasian	F	30	Light
Subject #9	Caucasian	F	34	Light
Subject #10	Caucasian	M	28	Light
Subject #11	Caucasian	M	22	Light
Subject #12	Hispanic/Caucasian	M	24	Medium
Subject #13	Indian	M	25	Medium
Subject #14	Hispanic/Caucasian	F	23	Medium

Table 5. Subject data for the study for TL-535U and TL-051S

Subject	Ethnicity	Gender	Age	Skin tone
Subject #1	Hispanic	M	28	Medium
Subject #2	Caucasian	F	28	Light/Medium
Subject #3	Indian	M	27	Dark
Subject #4	Indian	F	28	Dark
Subject #5	Asian	M	26	Medium
Subject #6	Hispanic	M	28	Medium
Subject #7	Asian	F	27	Medium
Subject #8	Caucasian	F	23	Light/Medium
Subject #9	Haitian	F	29	Dark
Subject #10	Caucasian	M	24	Light
Subject #11	Hispanic	F	25	Light/Medium
Subject #12	Asian	F	24	Light/Medium

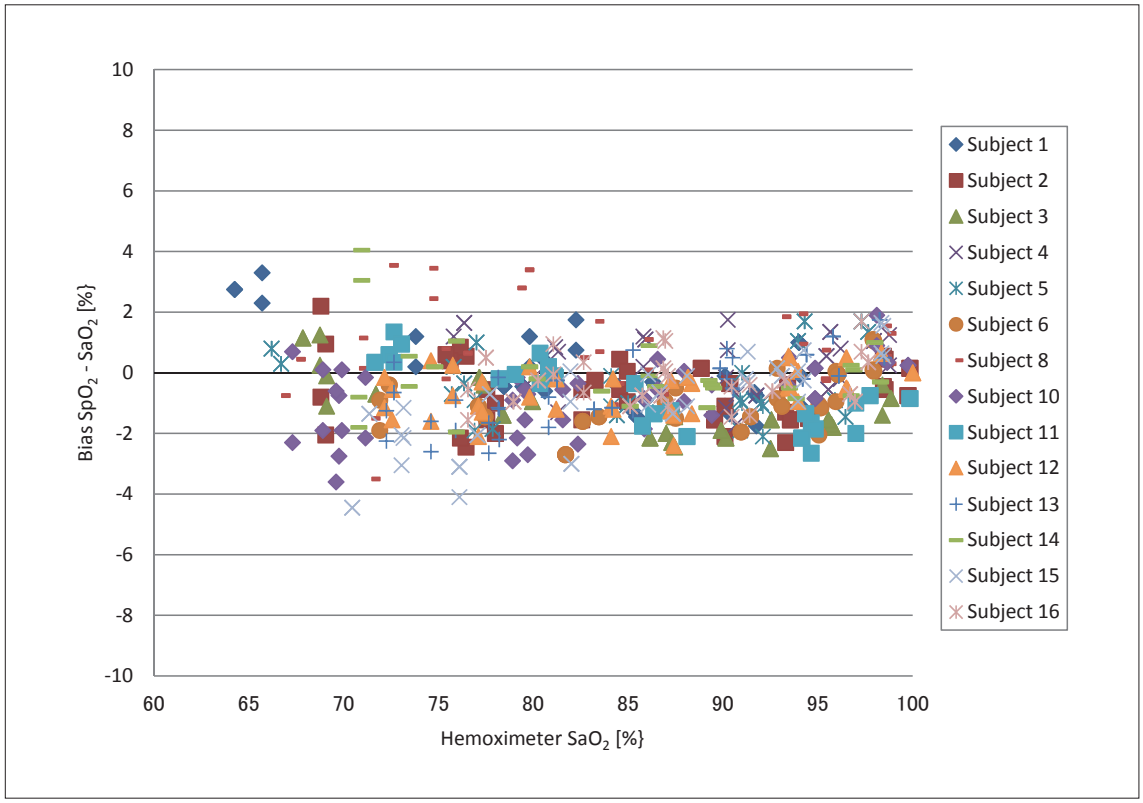
TL-201T Finger Probe

SpO_2 accuracy

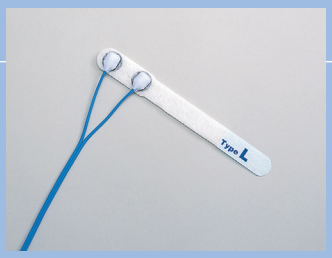
Table 6. Result for TL-201T Bias (SpO_2-SaO_2) Analysis

Probe	TL-201T	
Hemoximeter SaO_2 Range	70 – 80%	80 – 100%
Count	158	464
Mean	–0.47%	–0.46%
Standard Deviation	1.56%	0.97%
Root Mean Square (RMS)	**1.62%**	**1.07%**

Figure 2. TL-201T Bias (SpO_2-SaO_2)



Pulse Oximeter:OLV-3100
Hemoximeter:OSM 3®
Data supply: Hypoxia Research Laboratory, University of California, San Francisco



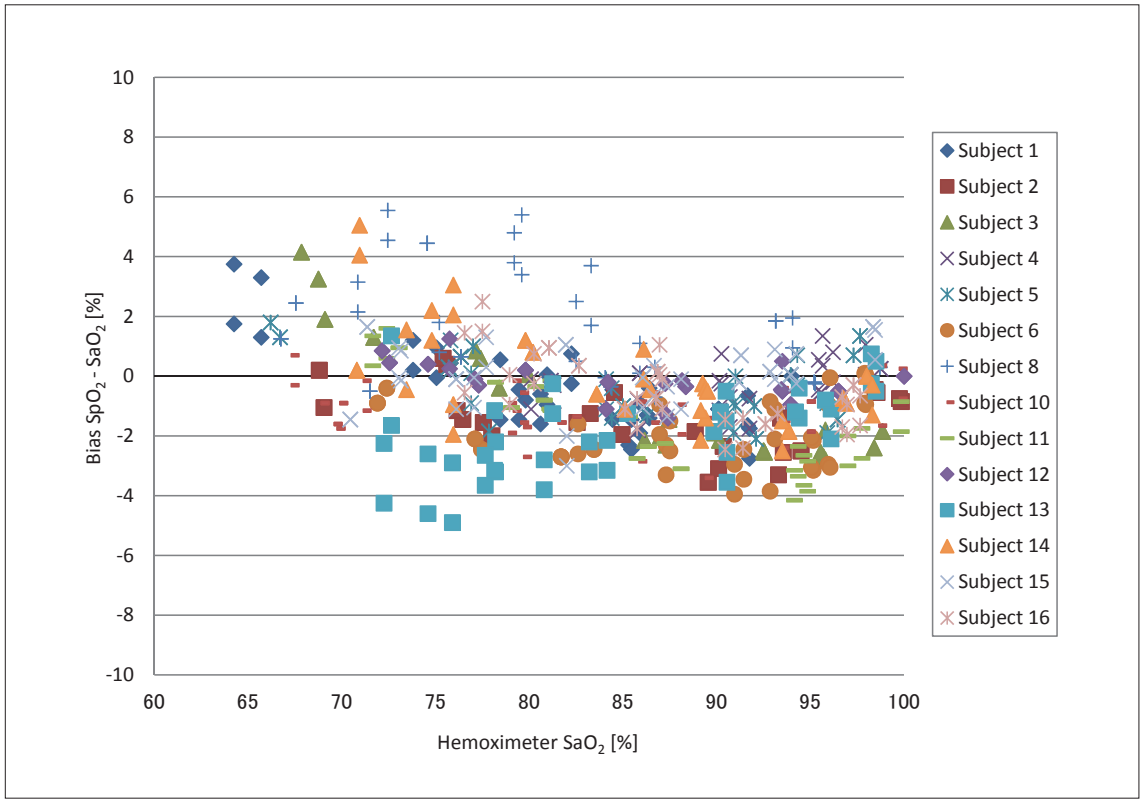
TL-260T Multi-site Y Probe

SpO_2 accuracy

Table 7. Result for TL-260T Bias (SpO_2-SaO_2) Analysis

Probe	TL-260T	
Hemoximeter SaO_2 Range	70 – 80%	80 – 100%
Count	158	464
Mean	0.08%	–1.01%
Standard Deviation	1.84%	1.18%
Root Mean Square (RMS)	**1.83%**	**1.56%**

Figure 3. TL-260T Bias (SpO_2-SaO_2)



Pulse Oximeter:OLV-3100
Hemoximeter:OSM 3®
Data supply: Hypoxia Research Laboratory, University of California, San Francisco

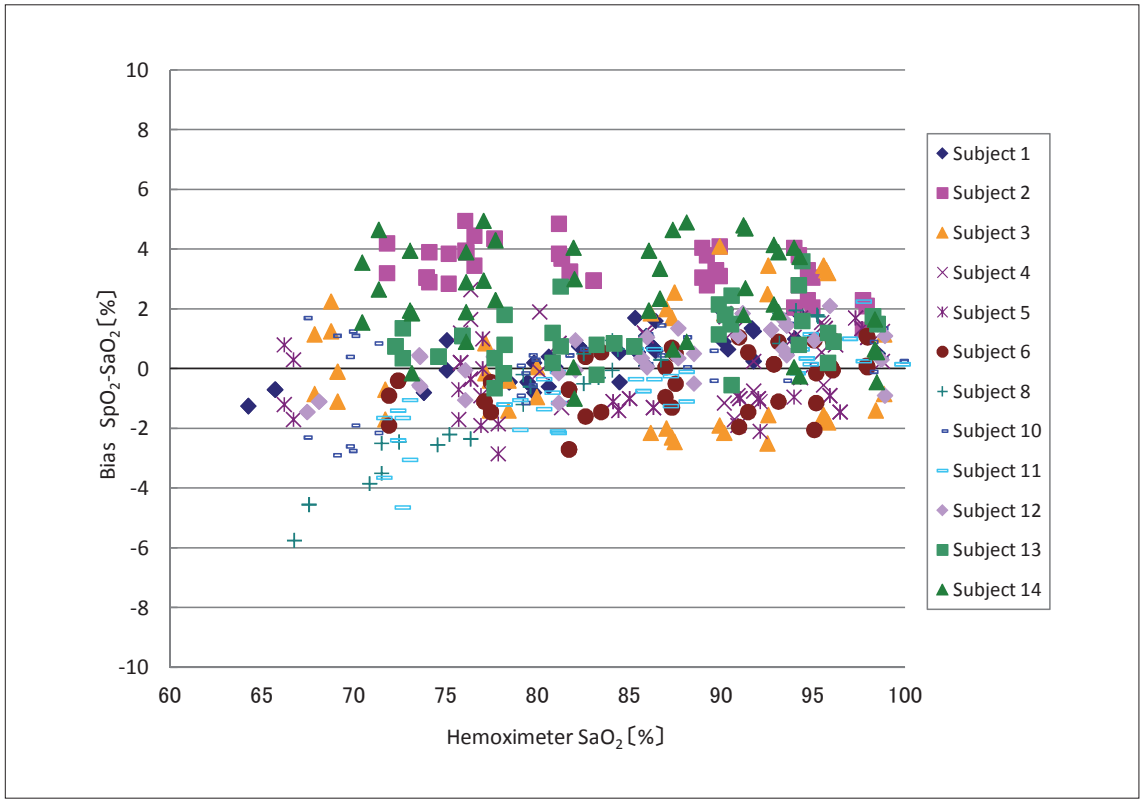
TL-260T Multi-site Y Probe with Clip Adapter for ear lobe

SpO_2 accuracy

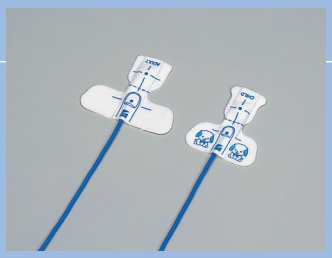
Table 8. Result for TL-260T with clip adapter for ear lobe Bias (SpO_2-SaO_2) Analysis

Probe	TL-260T	
Hemoximeter SaO_2 Range	70 – 80%	80 – 100%
Count	136	394
Mean	0.20%	0.65%
Standard Deviation	2.14%	1.48%
Root Mean Square (RMS)	**2.14%**	**1.62%**

Figure 4. TL-260T with clip adapter for ear lobe Bias (SpO_2-SaO_2)



Pulse Oximeter:OLV-3100
Hemoximeter:OSM 3®
Data supply: Hypoxia Research Laboratory, University of California, San Francisco



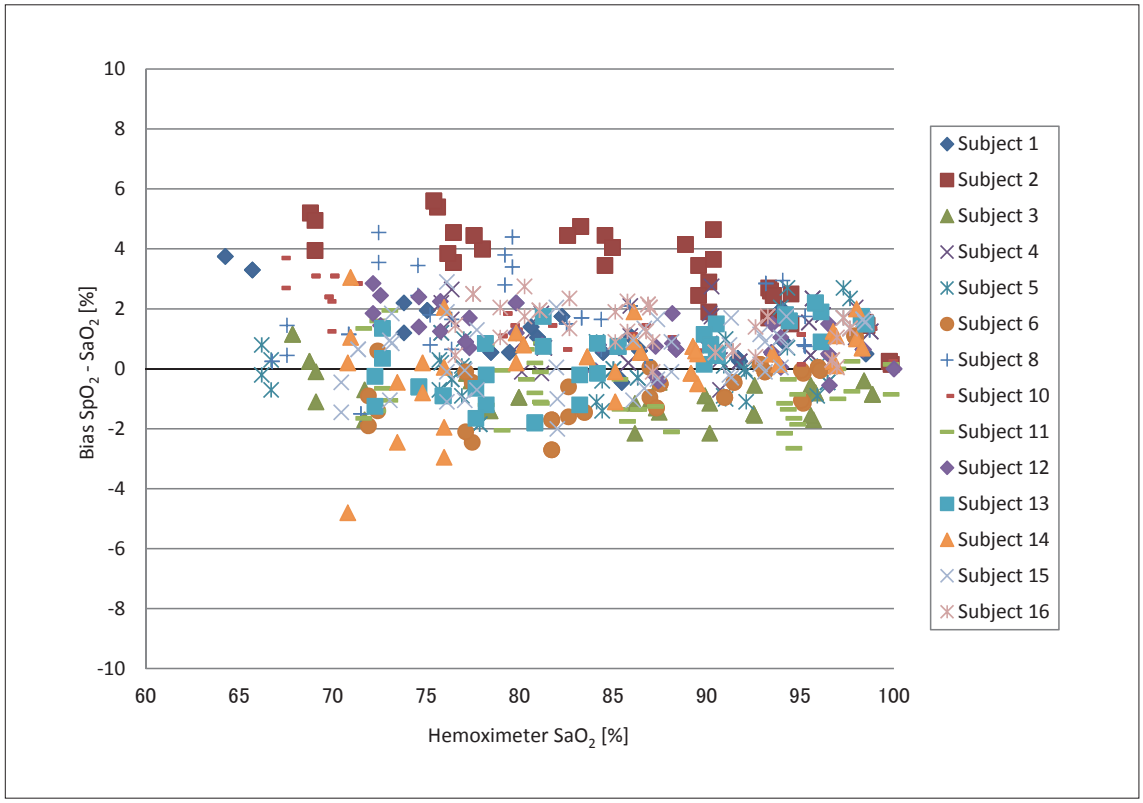
TL-271T Adult Disposable SpO_2 Probe

SpO_2 accuracy

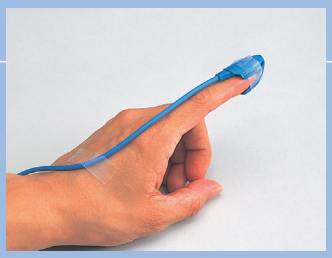
Table 9. Result for TL-271T Bias (SpO_2-SaO_2) Analysis

Probe	TL-271T	
Hemoximeter SaO_2 Range	70 – 80%	80 – 100%
Count	158	464
Mean	0.84%	0.53%
Standard Deviation	1.88%	1.29%
Root Mean Square (RMS)	**2.05%**	**1.39%**

Figure 5. TL-271T Bias (SpO_2-SaO_2)



Pulse Oximeter:OLV-3100
Hemoximeter:OSM 3®
Data supply: Hypoxia Research Laboratory, University of California, San Francisco



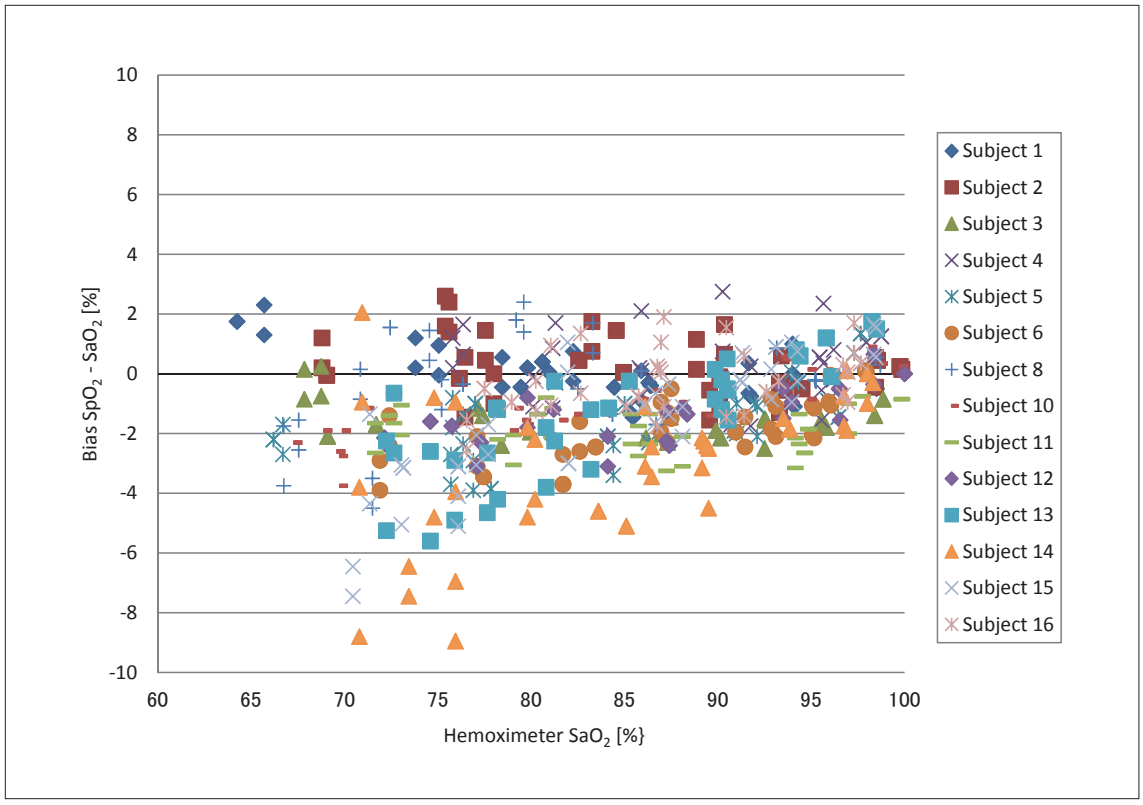
TL-631T Finger Probe

SpO_2 accuracy

Table 10. Result for TL-631T Bias (SpO_2-SaO_2) Analysis

Probe	TL-631T	
Hemoximeter SaO_2 Range	70 – 80%	80 – 100%
Count	158	464
Mean	–1.81%	–0.76%
Standard Deviation	2.13%	1.24%
Root Mean Square (RMS)	**2.79%**	**1.45%**

Figure 6. TL-631T Bias (SpO_2-SaO_2)



Pulse Oximeter:OLV-3100
Hemoximeter:OSM 3®
Data supply: Hypoxia Research Laboratory, University of California, San Francisco

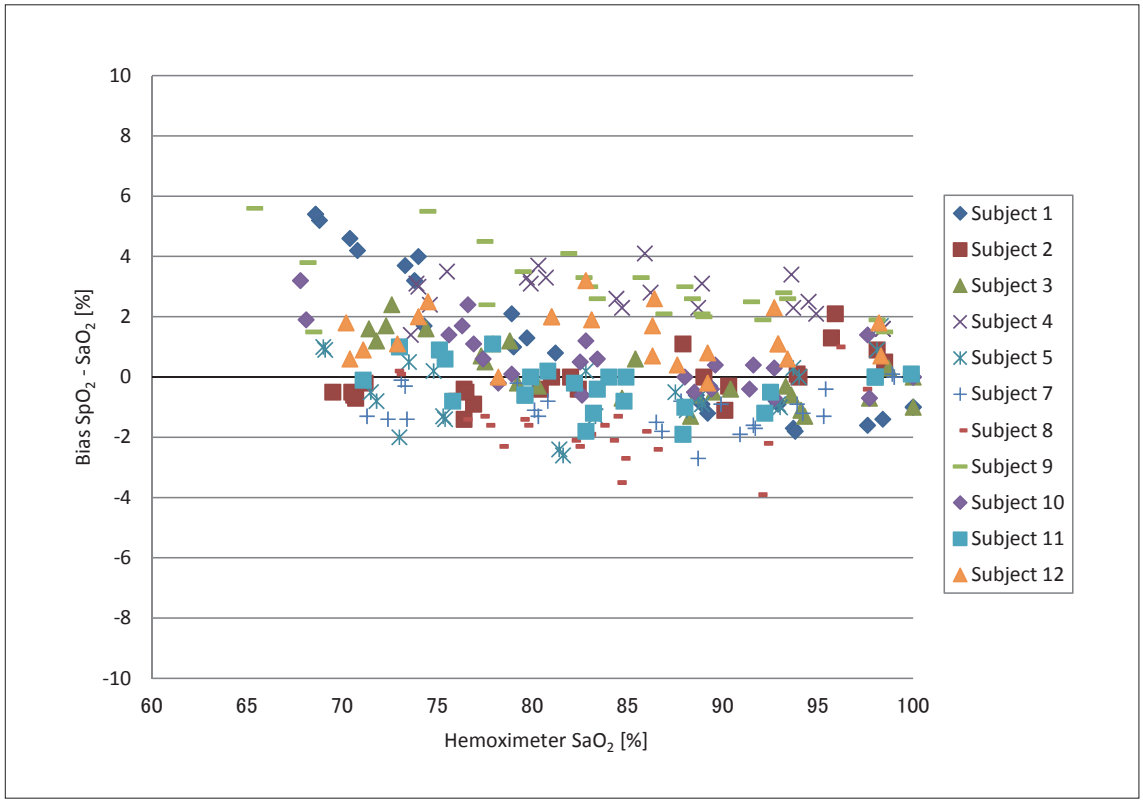
TL-051S Disposable SpO_2 Probe

SpO_2 accuracy

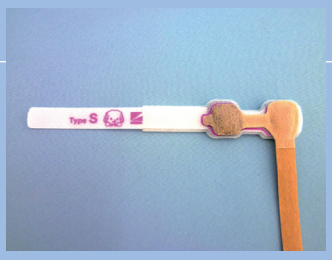
Table 11. Result for TL-051S Bias (SpO_2-SaO_2) Analysis

Probe	TL-051S	
Hemoximeter SaO_2 Range	70 – 80%	80 – 100%
Count	81	178
Mean	0.81%	0.09%
Standard Deviation	1.77%	1.59%
Root Mean Square (RMS)	**1.93%**	**1.59%**

Figure 7. TL-051S Bias (SpO_2-SaO_2)



Pulse Oximeter:OLV-3100
Hemoximeter:OSM 3®
Data supply: Hypoxia Research Laboratory, University of California, San Francisco



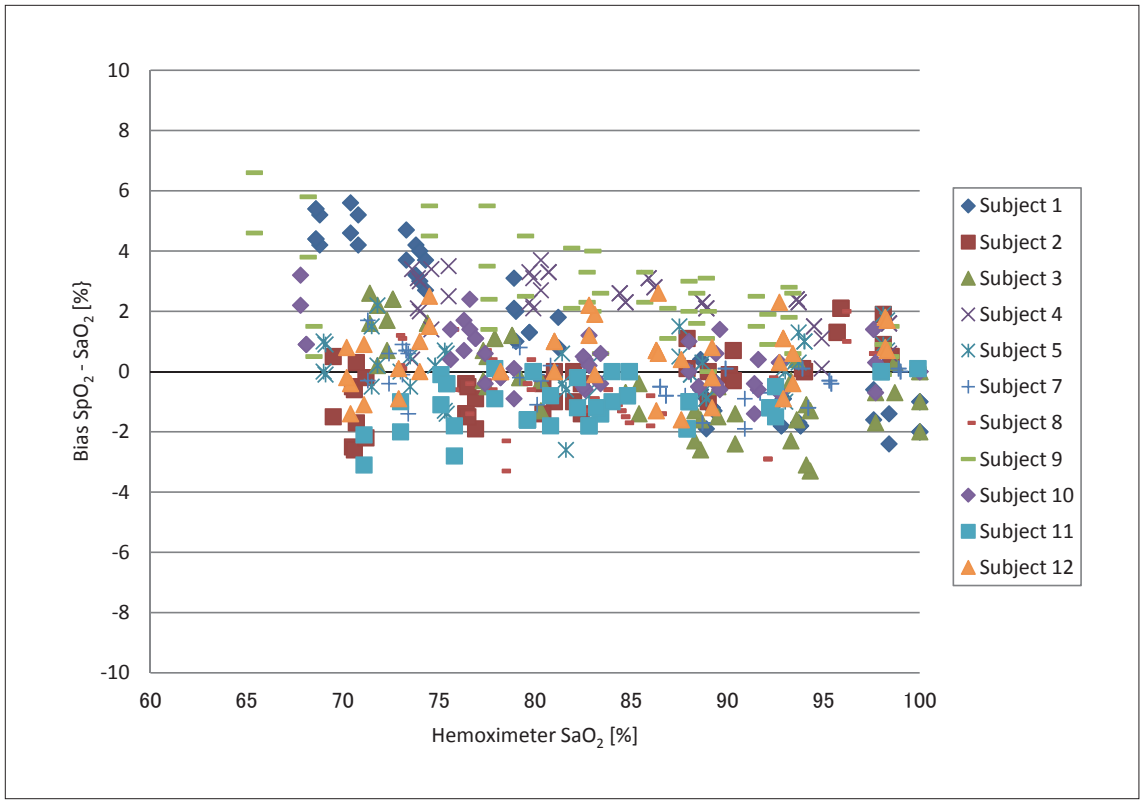
TL-535U Disposable SpO_2 Probe

SpO_2 accuracy

Table 12. Result for TL-535U Bias (SpO_2-SaO_2) Analysis

Probe	TL-535U	
Hemoximeter SaO_2 Range	70 – 80%	80 – 100%
Count	162	356
Mean	0.72%	0.03%
Standard Deviation	1.88%	1.37%
Root Mean Square (RMS)	**2.01%**	**1.37%**

Figure 8. TL-535U Bias (SpO_2-SaO_2)



Pulse Oximeter:OLV-3100
Hemoximeter:OSM 3®
Data supply: Hypoxia Research Laboratory, University of California, San Francisco

First Edition: December 19th, 2008
Second Edition: April 1st, 2014

SpO_2 Monitoring
Pulse Oximeter Accuracy Study
Patient Monitoring Technical Library

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