SpO_2 Monitoring

Pulse Oximeter Accuracy Study

0614-907889B

Fighting Disease with Electronics
NIHON KOHDEN

Nihon Kohden commissioned the studies to evaluate Nihon Kohden pulse oximeter and probes as below. 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.

Evaluation Date	Principal Investigator	Laboratory
March 12-13 and April 16, 2008	John R. Feiner, M.D. Phillip E. Bickler, Ph.D. M.D. John W. Severinghaus, M.D.	Hypoxia Research Laboratory University of California, San Francisco
January 25 and 26, 2023	Phillip E. Bickler, Ph.D. M.D. John R. Feiner, M.D.	
February 1 and 2, 2023		
April 18 and 19, 2023		

SpO_2 Accuracy Study of Nihon Kohden Pulse Oximeters

SpO_2 Accuracy and Specifications

ISO 80601-2-61, 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)". In the ISO 80601-2-61, the SaO_2 value determined by analyzing arterial blood samples with a CO-oximeter 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 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	70 – 100%	4% or less

Method of Invasive Controlled Desaturation Study on Healthy Volunteers

Hypoxia was induced to different levels of oxyhemoglobin saturation (between 70 - 100%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide. Pulse oximeters readings were recorded at the same time as arterial blood sampling, and statistical analysis of differences from SaO_2 values by CO-oximeter was performed.

Table 2-1. Background of subjects

		Subject group I	Subject group II
Gender	Male	10	9
	Female	4	3
Ethnicity	Caucasian	7	7
	Asian	1	1
	Indian	3	2
	African	2	0
	Hispanic/Caucasian	1	2
	Hispanic	0	0
	Haitian	0	0
	Multiethnic	0	0
	Black	0	0
Age		21-30	22-30
Skin tone	Very light	6	6
	Olive hue	5	6
	Dark Olive	3	0
	Extremely Dark	0	0

Table 2-2. Background of subjects

		Subject group III	Subject group IV	Subject group V
Gender	Male	8	5	7
	Female	3	6	5
Ethnicity	Caucasian	5	3	5
	Asian	3	3	3
	Indian	0	0	0
	African	0	0	2
	Hispanic/Caucasian	0	0	0
	Hispanic	0	1	1
	Haitian	0	0	0
	Multiethnic	2	3	1
	Black	1	1	0
Age		22-35	22-30	22-47
Skin tone*1, *3	I	0	0	1
	II	2	3	1
	III	4	3	2
	IV	2	4	6
	V	2	0	0
	VI	1	1	2

*1 The Fitzpatrick skin type (FST) scale is a numerical classification for skin types. It was developed by dermatologist Thomas B. Fitzpatrick to determine how different skin types react to ultraviolet (UV) light (i.e., ability to tan when exposed to sunlight).*2

*2 Fitzpatrick TB. The validity and practicality of sun-reactive skin types I through VI. Arch Dermatol. 1988;124(6):869-871.

*3 Subject group : Evaluation date
I: March 12-13, 2008
II: March 12-13 and April 16, 2008
III: January 25 and 26, 2023
IV: February 1 and 2, 2023
V: April 18 and 19, 2023

Test Results

The accuracy of SpO_2 of Nihon Kohden pulse oximeter equipment is represented as the Root-Mean-Square (RMS) of the difference between measured values (SpO_{2i}) and reference values (SaO_{2i}), as given by the following formula.

SaO_2: 70-80%, 80-100%

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

Table 3. SpO_2 accuracy test results (RMS difference)

Probe type		SaO_2 range		Subject group
		70 – 80%	80 – 100%	
Finger Probe	TL-201T	2.13%	1.22%	V
Multi-site Y Probe	TL-260T	1.83%	1.56%	I
Multi-site Y Probe with clip adapter for ear lobe	TL-260T	2.14%	1.62%	II
Disposable SpO_2 Probe	TL-271T3	1.64%	1.33%	III
Finger Probe	TL-631T3	2.02%	1.43%	IV
Disposable SpO_2 Probe	TL-535U	1.97%	1.31%	III

A summary for the test result is shown above. The test results show that all tested probes meet the accuracy specifications of ISO 80601 2-61 (SaO_2 range: 70-100%) and also Nihon Kohden criteria (SaO_2 range: 70-80%, 80-100%).

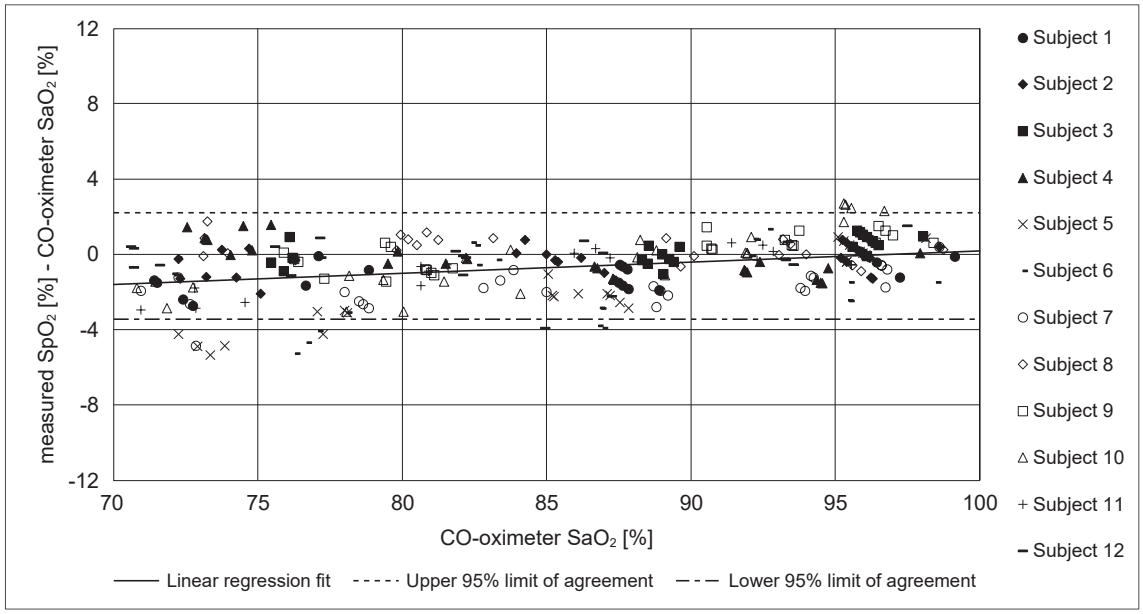
TL-201T Finger Probe

SpO_2 accuracy

Table 4. Result for TL-201T Bias (SpO_2-SaO_2) Analysis

Probe	TL-201T	
CO-oximeter SaO_2 Range	70 – 80%	80 – 100%
Count	86	205
Mean	–1.26%	–0.35%
Standard Deviation	1.74%	1.18%
RMS (Root Mean Square)	**2.13%**	**1.22%**

Figure 1. TL-201T Modified Bland-Altman Plot



Pulse Oximeter: OLV-4202

SpO_2 Connection Cord: JL-400T

CO-oximeter: ABL90

Data supply: Hypoxia Research Laboratory, University of California, San Francisco

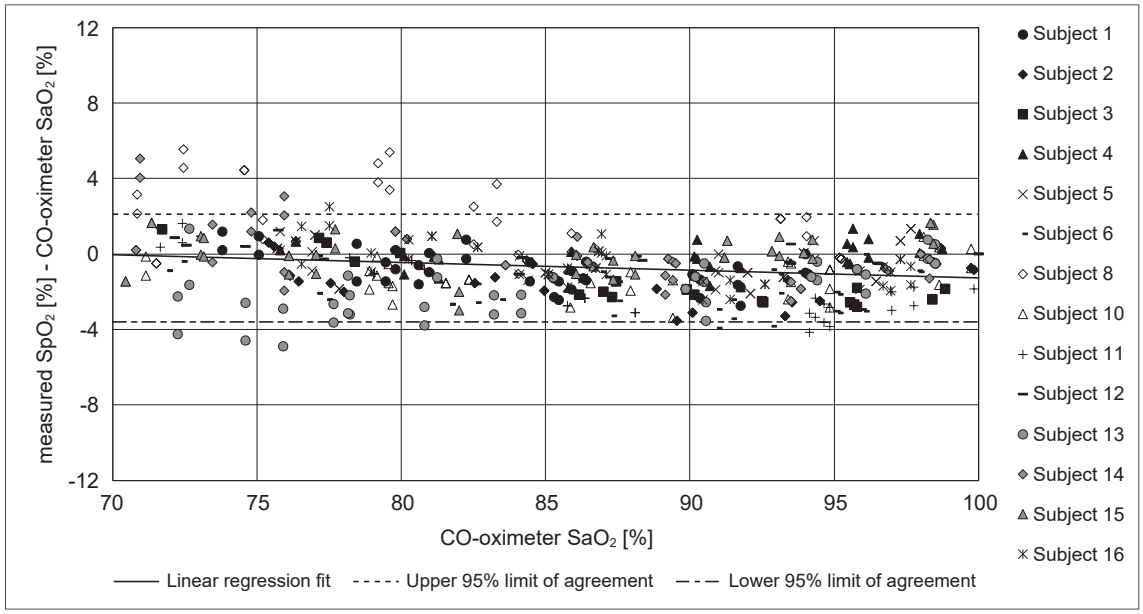
TL-260T Multi-site Y Probe

SpO_2 accuracy

Table 5. Result for TL-260T Bias (SpO_2-SaO_2) Analysis

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

Figure 2. TL-260T Modified Bland-Altman Plot



Pulse Oximeter: OLV-3100

SpO_2 Connection Cable: JL-302T

CO-oximeter: OSM 3

Attachment Tape L : YS-114P6

Data supply: Hypoxia Research Laboratory, University of California, San Francisco

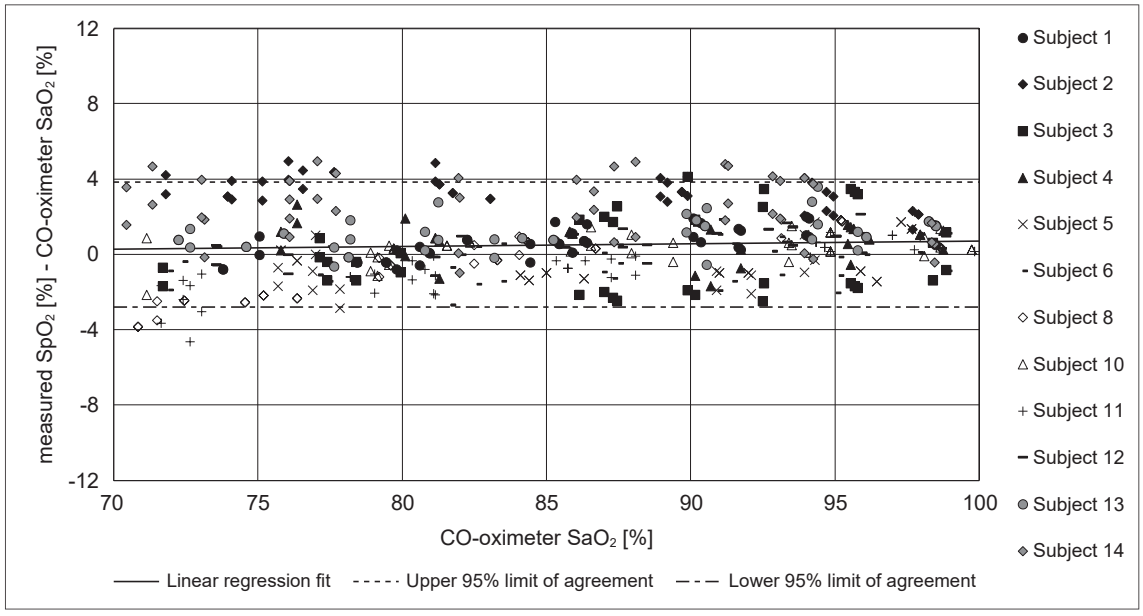
TL-260T Multi-site Y Probe with Clip Adapter for ear lobe

SpO_2 accuracy

Table 6. Result for TL-260T with clip adapter for ear lobe Bias (SpO_2-SaO_2) Analysis

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

Figure 3. TL-260T with clip adapter for ear lobe Modified Bland-Altman Plot



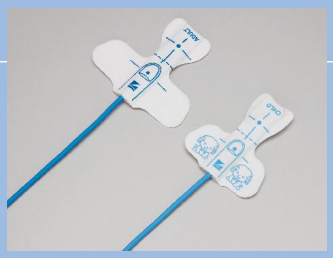
Pulse Oximeter: OLV-3100

SpO_2 Connection Cable: JL-302T

TL-260T Clip Adapter : YS-087P9

CO-oximeter: OSM 3

Data supply: Hypoxia Research Laboratory, University of California, San Francisco



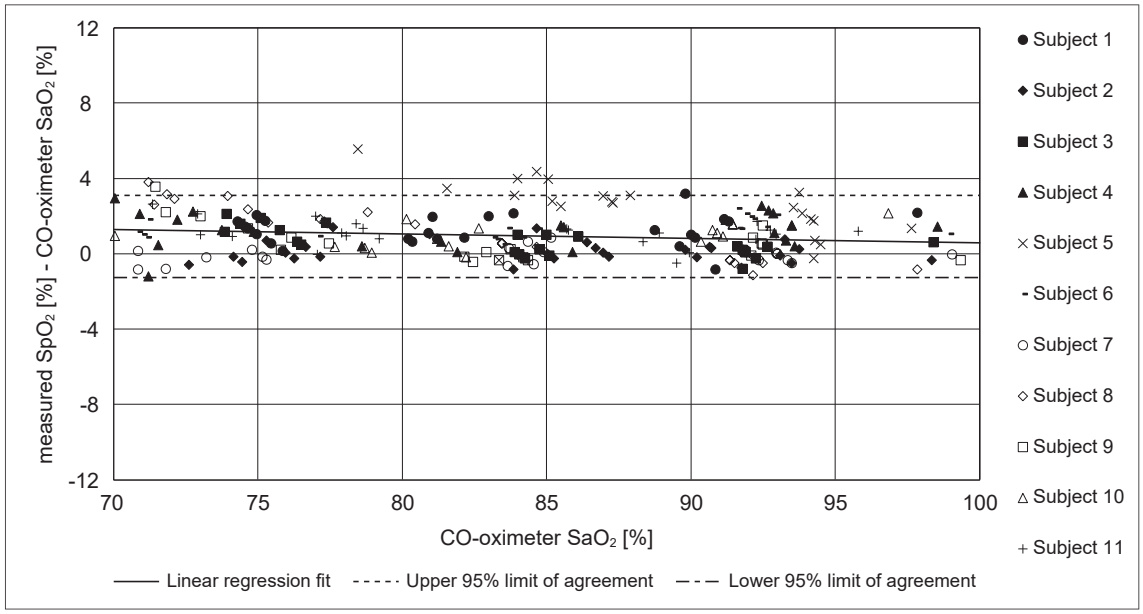
TL-271T3 Adult Disposable SpO_2 Probe

SpO_2 accuracy

Table 7. Result for TL-271T3 Bias (SpO_2-SaO_2) Analysis

Probe	TL-271T3	
CO-oximeter SaO_2 Range	70 – 80%	80 – 100%
Count	83	181
Mean	1.18%	0.82%
Standard Deviation	1.15%	1.06%
RMS (Root Mean Square)	**1.64%**	**1.33%**

Figure 4. TL-271T3 Modified Bland-Altman Plot

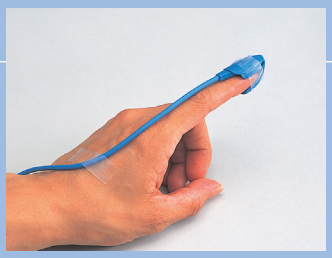


Pulse Oximeter: OLV-4202

SpO_2 Connection Cord: JL-400T

CO-Oximeter: ABL90

Data supply: Hypoxia Research Laboratory, University of California, San Francisco



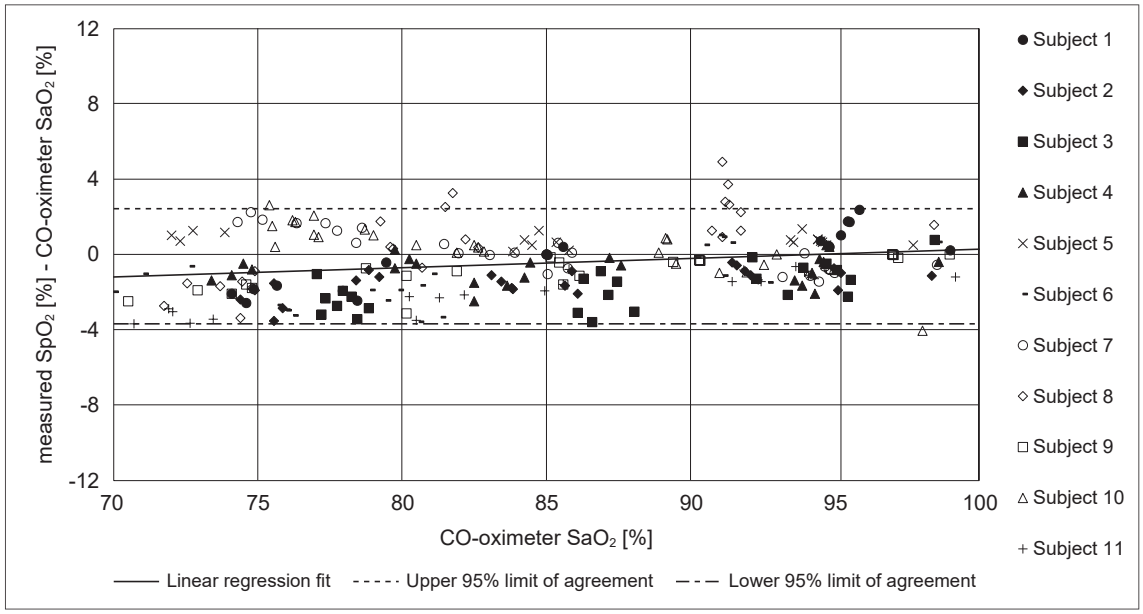
TL-631T3 Finger Probe

SpO_2 accuracy

Table 8. Result for TL-631T3 Bias (SpO_2-SaO_2) Analysis

Probe	TL-631T3	
CO-oximeter SaO_2 Range	70 – 80%	80 – 100%
Count	84	171
Mean	–1.01%	–0.42%
Standard Deviation	1.76%	1.37%
RMS (Root Mean Square)	**2.02%**	**1.43%**

Figure 5. TL-631T3 Modified Bland-Altman Plot



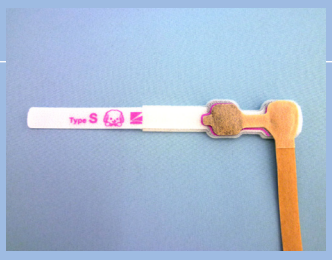
Pulse Oximeter: OLV-4202

SpO_2 Connection Cord: JL-400T

Attachment Tape : YS-111P7

CO-Oximeter: ABL90

Data supply: Hypoxia Research Laboratory, University of California, San Francisco



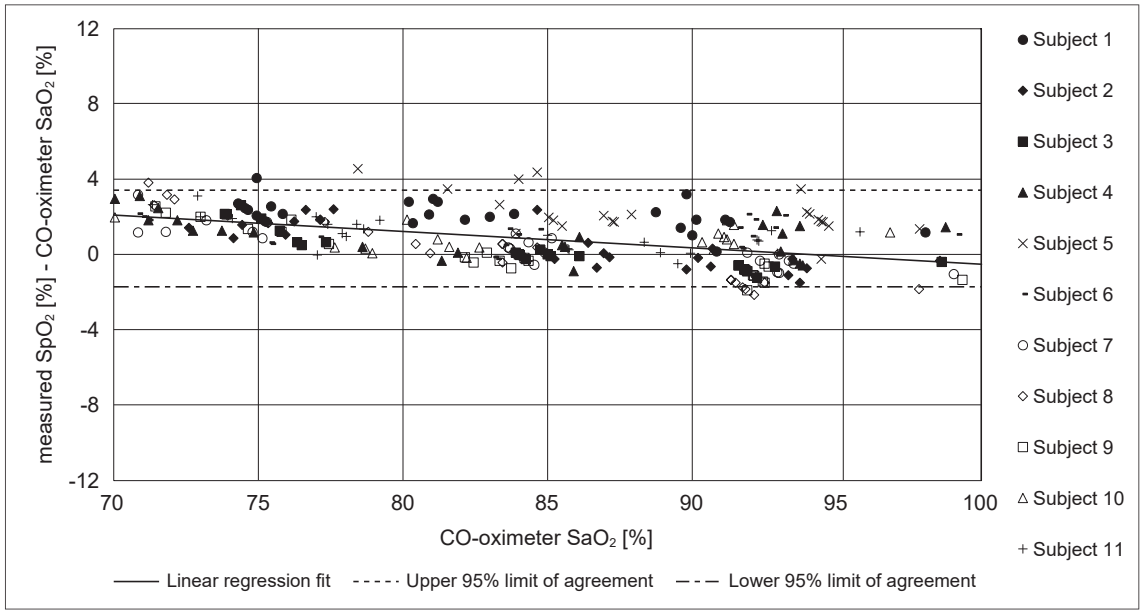
TL-535U Disposable SpO_2 Probe

SpO_2 accuracy

Table 10. Result for TL-535U Bias (SpO_2-SaO_2) Analysis

Probe	TL-535U	
CO-oximeter SaO_2 Range	70 – 80%	80 – 100%
Count	83	181
Mean	1.77%	0.44%
Standard Deviation	0.89%	1.24%
RMS (Root Mean Square)	**1.97%**	**1.31%**

Figure 7. TL-535U Modified Bland-Altman Plot



Pulse Oximeter: OLV-4202

SpO_2 Connection Cord: JL-400T, JL-030U2

Attachment Tape XL: YS-102P2

CO-Oximeter: ABL90

Pulse Oximeter: Hypoxia Research Laboratory, University of California, San Francisco

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SpO_2 Monitoring
Pulse Oximeter Accuracy Study
Patient Monitoring Technical Library

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