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# Validation of Philips FAST SpO<sub>2</sub> measurement accuracy

## Application Note

### Introduction

This Application Note discusses the validation of the Philips FAST SpO<sub>2</sub> measurement accuracy and the detailed results of the corresponding desaturation study.

The Application Note does not replace the Instructions for Use (IFU) documentation. Philips recommends to read, understand, and follow the IFU document prior to initial use.

This Application Note covers the Philips FAST SpO<sub>2</sub> measurement in the following devices:

- IntelliVue X3 (867030), MX100 (867033), and MMX (867036)
- IntelliVue X2 (M3002A), MP2 (M8102A), and MMS (M3001A)
- IntelliVue MP5 (M8105A), and MP5SC (M8105AS)
- IntelliVue M1020B (862112)
- Fetal Monitors Avalon FM20 (M2702A), FM30 (M2703A), FM40 (M2704A), and FM50 (M2705A)

**Note:** Not all sensors listed in this Application Note might be compatible with your device. For a list of the supported sensors, see the Instructions for Use.

### Measurement principle

Pulse oximetry is a non-invasive method of measuring arterial oxygenation saturation (SaO<sub>2</sub>) using light transmitted through tissue. The measurement principle of pulse oximetry is based on the different red and infrared light absorption characteristics of oxygenated and deoxygenated hemoglobin.

### Validation of SpO<sub>2</sub> measurement accuracy

The SpO<sub>2</sub> accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. In a controlled desaturation study, healthy adult volunteers with saturation levels between 70% and 100% SaO<sub>2</sub> were studied.

The population characteristics for these studies were:

- gender: about 50% female and 50% male subjects
- age range: 19 to 39
- skin tone: from light to dark brown

**Note:** A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor. However, it can be used to demonstrate that a particular pulse oximeter monitor reproduces a calibration curve that has been independently demonstrated to fulfill a particular accuracy specification.

## Results of desaturation study

In a desaturation study, representative SpO<sub>2</sub> sensors were tested to cover all the compatible SpO<sub>2</sub> sensors. All representative sensors were tested with healthy adult subjects with the previously mentioned population characteristics. For each tested sensor, more than 300 blood samples were available for comparison, which are equally spread over the range from 70% to 100% SaO<sub>2</sub>.

To determine the accuracy of the SpO<sub>2</sub> readings, the SpO<sub>2</sub> values were directly compared with the SaO<sub>2</sub> values from the blood samples to derive A<sub>RMS</sub> as the root-mean-square (RMS) difference between measured values (SpO<sub>2</sub>) and reference values (SaO<sub>2</sub>) as defined by the international standard for pulse oximeters [1, 2].

**Note:** The A<sub>RMS</sub> values shown in the following sections, especially the values in the sub-ranges from 70-80%, 80-90%, and 90-100% SaO<sub>2</sub>, are not to be understood as new accuracy specifications, but only represent the calculated results of the desaturation study.

Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

Besides calculating the A<sub>RMS</sub> values over the range from 70% to 100% SaO<sub>2</sub> as required by the international standard for pulse oximeters [1, 2], the desaturation study data was also evaluated according to the method that was described by Bland and Altman [3]. As recommended, graphical presentations are provided in the following sections.

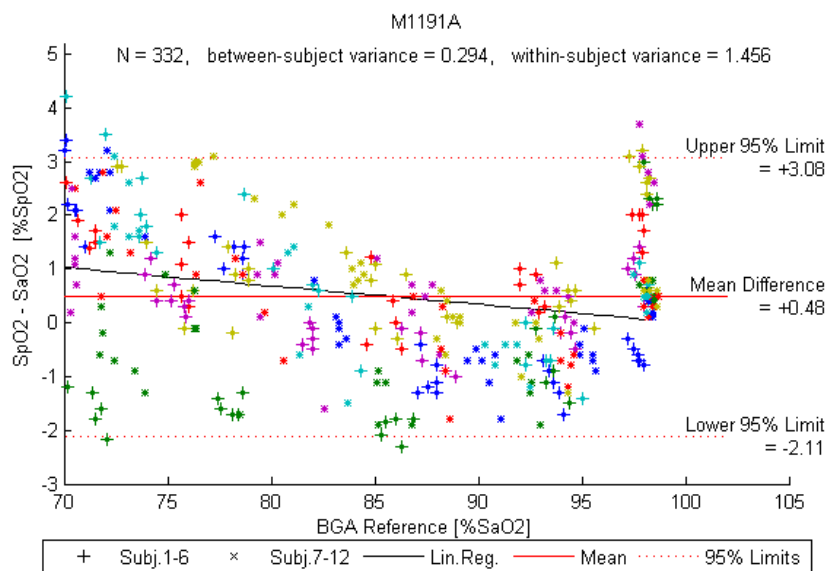
All tested SpO<sub>2</sub> sensors have shown to measure SpO<sub>2</sub> values within the specified limits.

### M1191A

Due to construction similarities, the Philips sensor M1191A was tested representatively also for the Philips sensors M1191AL and M1192A.

The following table shows the A<sub>RMS</sub> values measured in the desaturation study using the M1191A:

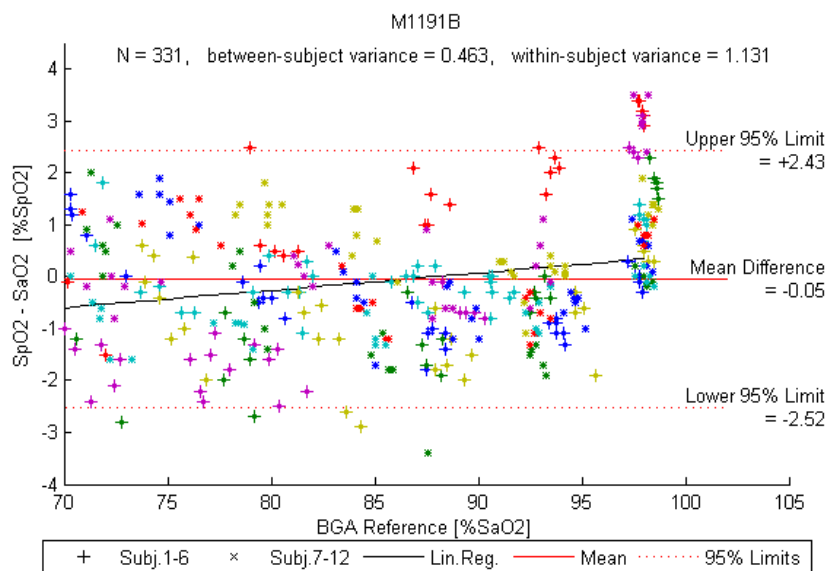
SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
A <sub>RMS</sub> value [%]	1.40	1.81	1.00	1.22



### M1191B

Due to construction similarities, the Philips sensor M1191B was tested representatively also for the Philips sensor M1191BL. The following table shows the  $A_{rms}$  values measured in the desaturation study using the M1191B:

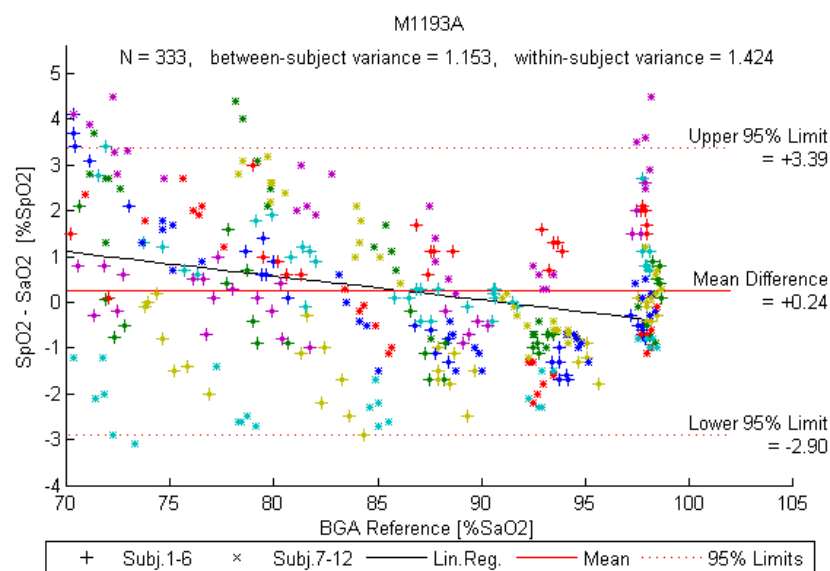
SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.25	1.24	1.14	1.32



### M1193A

Due to construction similarities, the Philips sensor M1193A was tested representatively also for the Philips sensor M1195A. The following table shows the  $A_{rms}$  values measured in the desaturation study using the M1193A:

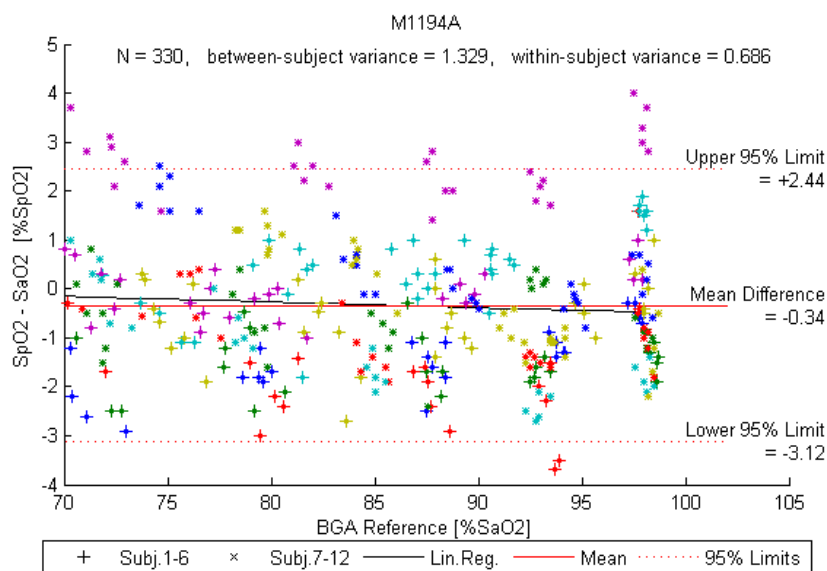
SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.59	2.15	1.33	1.25



## M1194A

The following table shows the  $A_{rms}$  values measured in the desaturation study using the M1194A:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.42	1.39	1.41	1.44

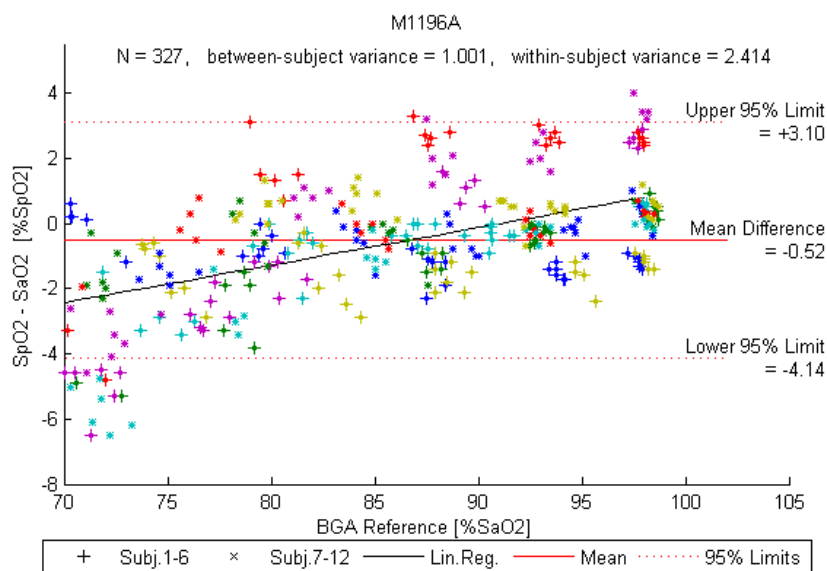


## M1196A

Due to construction similarities, the Philips sensor M1196A was tested representatively also for the Philips sensors M1196S and M1196T.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the M1196A:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.90	2.82	1.33	1.35

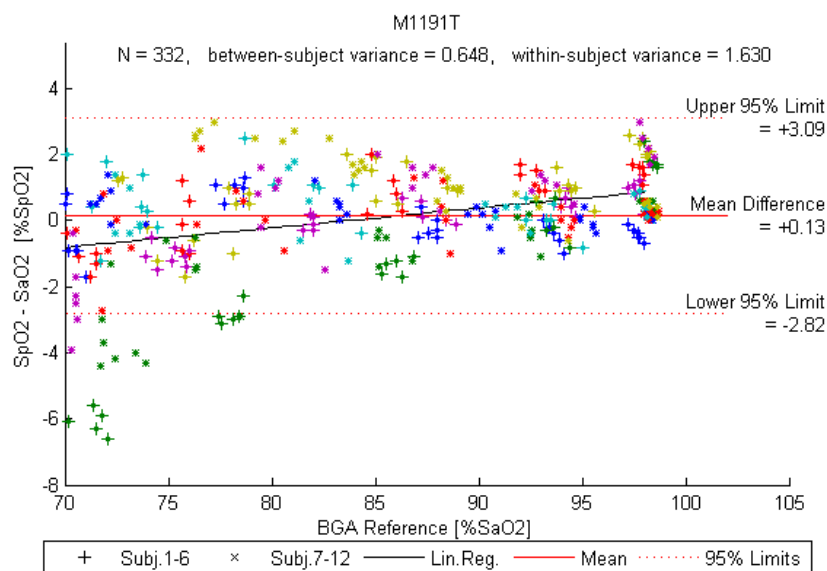


### M1191T

Due to construction similarities, the Philips sensor M1191T was tested representatively also for the Philips sensor M1192T.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the M1191T:

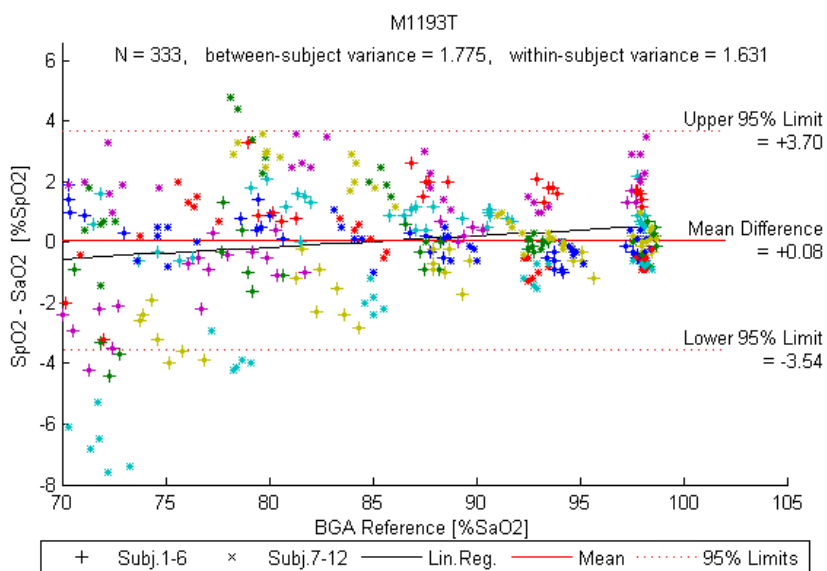
SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.50	2.13	1.15	0.99



### M1193T

The following table shows the  $A_{rms}$  values measured in the desaturation study using the M1193T:

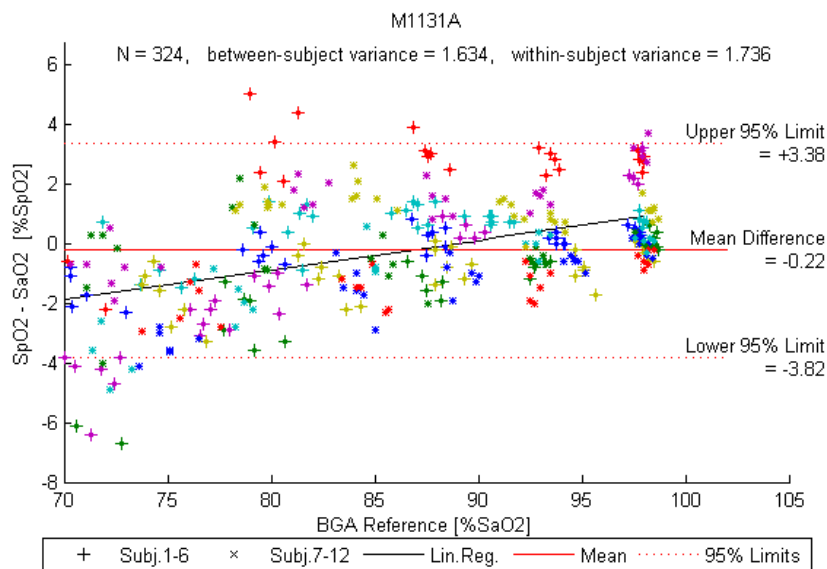
SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.80	2.72	1.46	0.98



## M1131A

The following table shows the  $A_{rms}$  values measured in the desaturation study using the M1131A:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.81	2.53	1.57	1.29

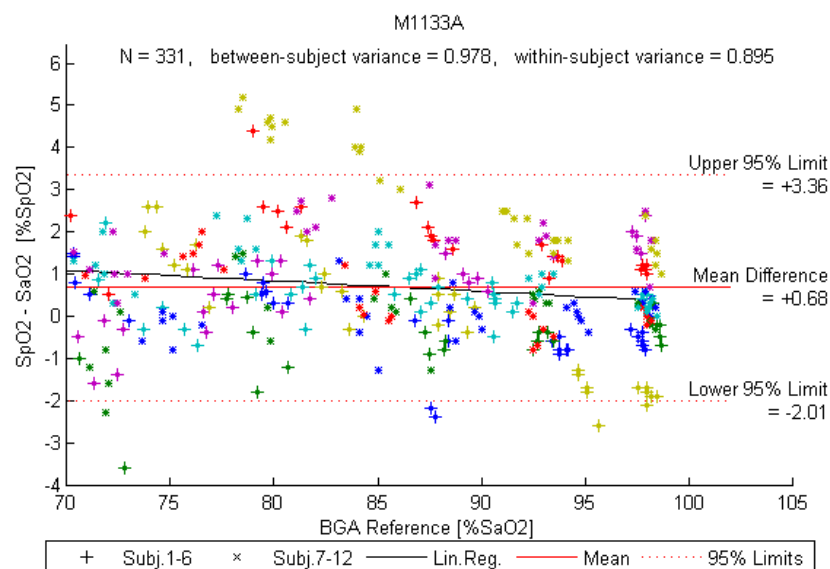


## M1133A

Due to construction similarities, the Philips sensor M1133A was tested representatively also for the Philips sensors M1132A and M1134A.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the M1133A:

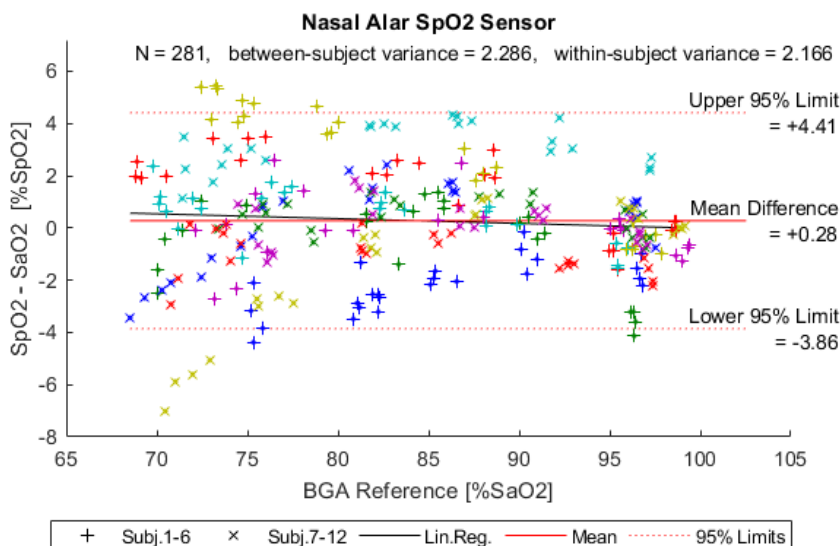
SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.50	1.76	1.61	1.16



## Nasal Alar

The following table shows the  $A_{rms}$  values measured in the desaturation study using the Nasal Alar sensors 989803205381, 989803205391, and 989803205401:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	2.07	2.66	1.98	1.41

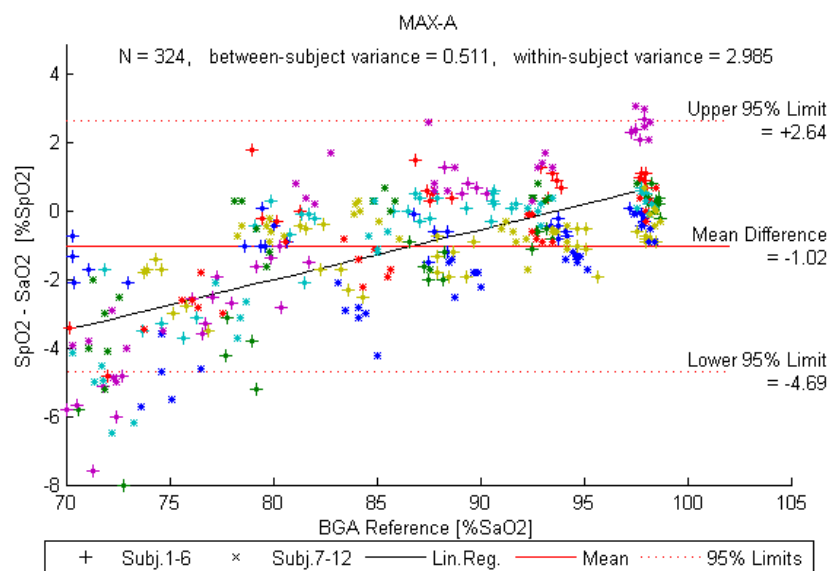


## MAXA

Due to construction similarities, the Covidien/Nellcor sensor MAXA was tested representatively also for the Covidien/Nellcor sensors MAXAL, MAXP, Oxisensor II D-25, and Oxisensor II D-20, and the Philips sensors M1903B and M1904B.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the MAXA:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	2.12	3.50	1.39	0.98

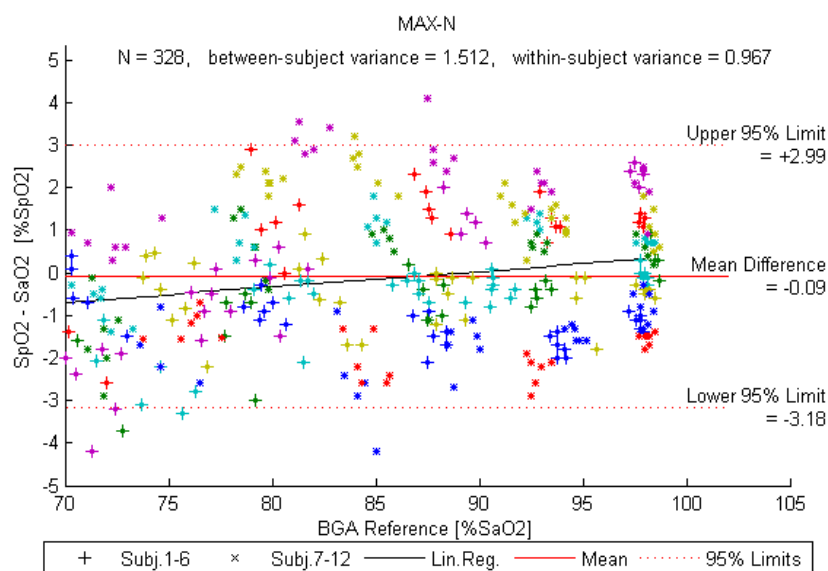


## MAXN

Due to construction similarities, the Covidien/Nellcor sensor MAXN was tested representatively also for the Covidien/Nellcor sensors MAXI, Oxisensor II N-25, and Oxisensor II I-20, and the Philips sensors M1901B and M1902B.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the MAXN:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.54	1.59	1.75	1.30

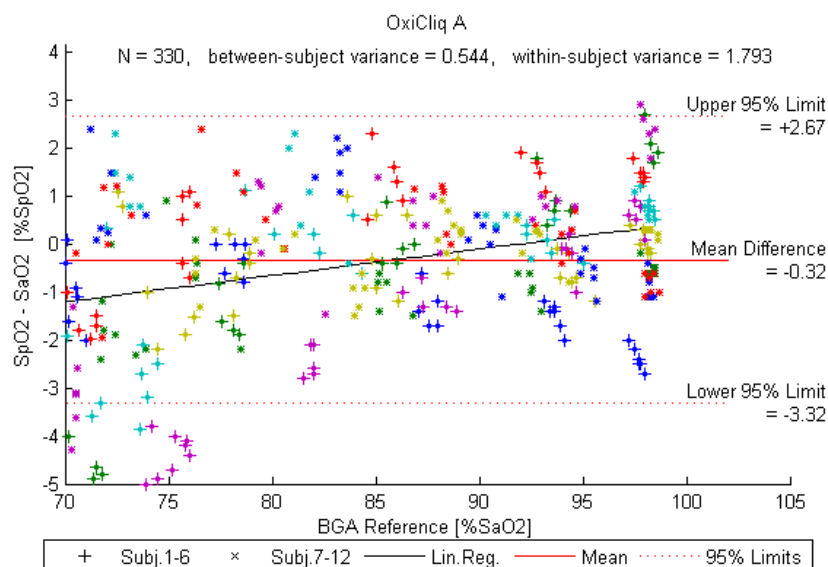


## OxiCliq A

Due to construction similarities, the Covidien/Nellcor sensor OxiCliq A was tested representatively also for the Covidien/Nellcor sensor OxiCliq P.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the OxiCliq A:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.55	2.15	1.19	1.12



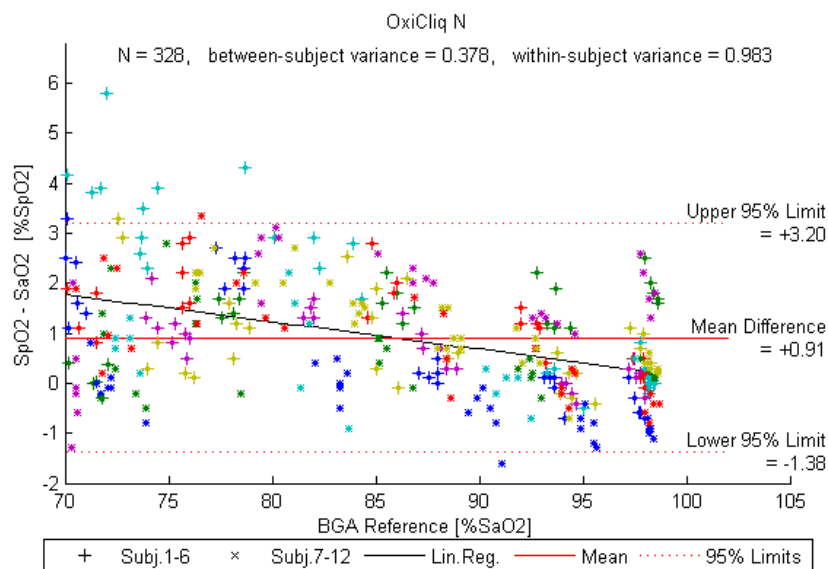


## OxiClq N

Due to construction similarities, the Covidien/Nellcor sensor OxiClq N was tested representatively also for the Covidien/Nellcor sensor OxiClq I.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the OxiClq N:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.47	1.95	1.51	0.85

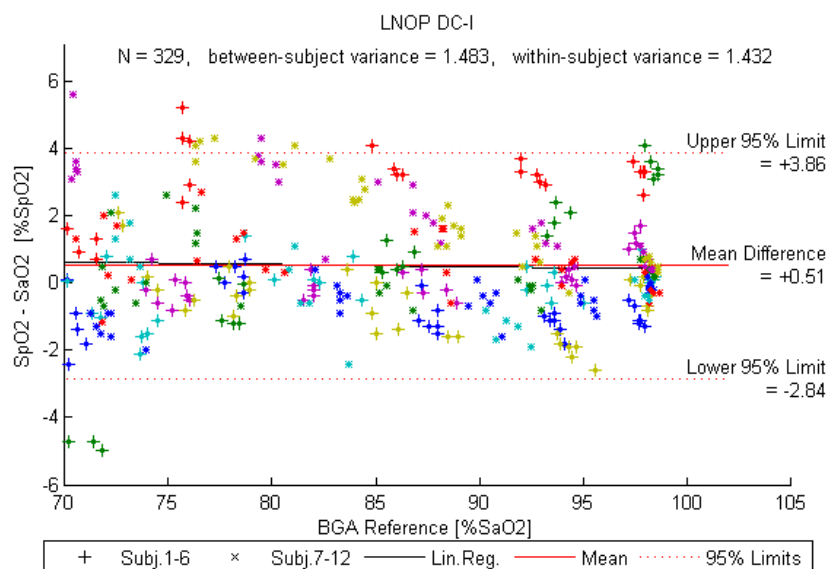


## LNOP DC-I

Due to construction similarities, the Masimo sensor LNOP DC-I was tested representatively also for the Masimo sensors LNOP DC-IP, LNOP DC-195, LNCS DC-I, LNCS DC-IP, M-LNCS DCI, M-LNCS DCIP, RD SET DCI, and RD SET DCIP.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the LNOP DC-I:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.75	2.12	1.67	1.44

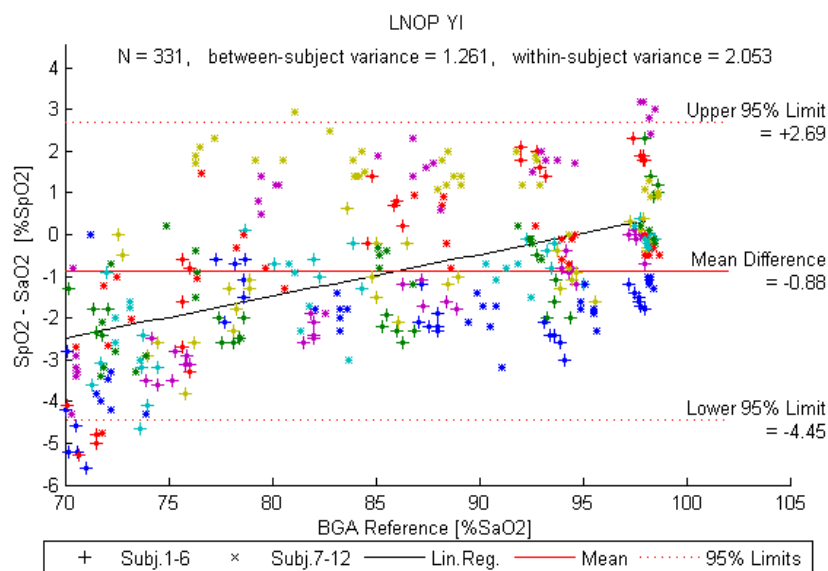


## LNOP YI

Due to construction similarities, the Masimo sensor LNOP YI was tested representatively also for the Masimo sensors LNCS YI , M-LNCS YI , and RD SET YI.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the LNOP YI:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.99	2.77	1.62	1.38

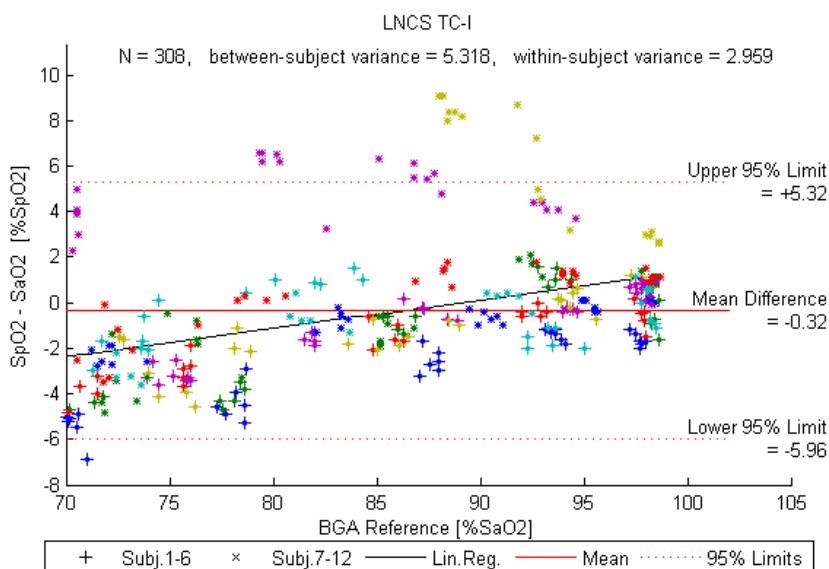


## LNCS TC-I

Due to construction similarities, the Masimo sensor LNCS TC-I was tested representatively also for the Masimo sensors LNOP TC I, M-LNCS TC-I, and RD SET TC-I.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the LNCS TC-I:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	2.81	3.49	3.29	1.80

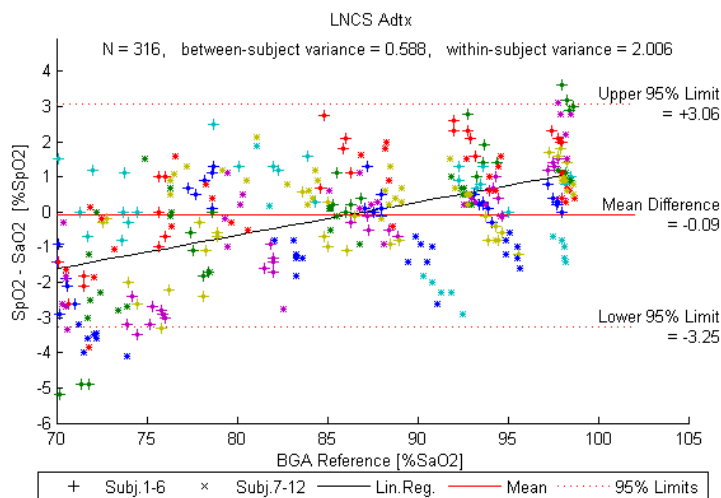


## LNCS Aadx

Due to construction similarities, the Masimo sensor LNOP Aadx was tested representatively also for the Masimo sensors LNOP Aadt, LNOP Aadx, LNOP Pdt, LNOP Pdtx, LNCS Aadx 3, LNCS Pdtx, LNCS Pdtx 3, M-LNCS Aadx, M-LNCS Pdtx, M-LNCS Aadx-3, M-LNCS Pdtx-3, RD SET Aadt, RD SET Aadt (CS-2), RD SET Aadt (CS-3), RD SET Pdt, RD SET Pdt (CS-2), and RD SET Pdt (CS-3).

The following table shows the  $A_{rms}$  values measured in the desaturation study using the LNOP Aadx:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.60	2.10	1.05	1.41

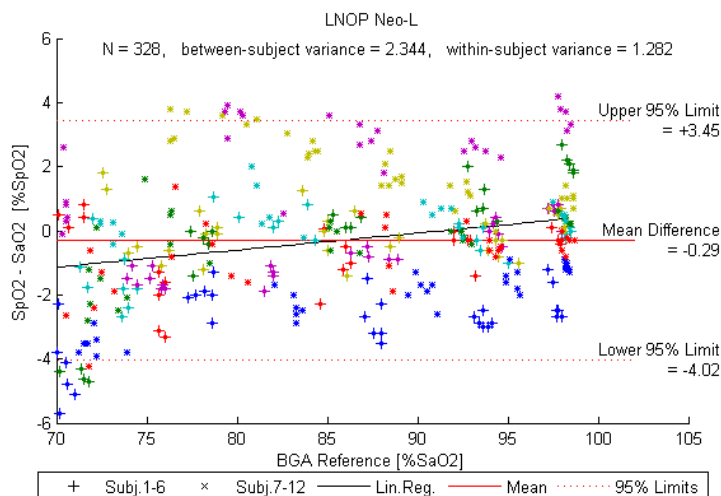


## LNOP Neo-L

Due to construction similarities, the Masimo sensor LNOP Neo-L was tested representatively also for the Masimo sensors LNOP NeoPt L, LNOP Inf L, LNOP Neo, LNOP Neo Pt, LNOP Newborn Neonatal, LNOP Newborn Infant/Pediatric, LNOP Trauma, LNCS Inf, LNCS Inf-L, LNCS Inf 3, LNCS Neo, LNCS Neo-L, LNCS Neo 3, LNCS NeoPt, LNCS NeoPt-L, and LNCS NeoPt 3, LNCS Newborn Neonatal, LNCS Newborn Infant/Pediatric, LNCS Trauma, M-LNCS Inf, M-LNCS Neo, M-LNCS Inf-3, M-LNCS Neo-3, M-LNCS Inf-L, M-LNCS Neo-L, M-LNCS NeoPt, M-LNCS NeoPt-3, M-LNCS NeoPt-L, M-LNCS Newborn Neonatal, M-LNCS Newborn Infant/Pediatric, M-LNCS Trauma, RD SET Inf, RD SET Inf (CS-2), RD SET Inf (CS-3), RD SET Neo, RD SET Neo (CS-2), RD SET Neo (CS-3), RD SET NeoPt, RD SET NeoPt (CS-2), RD SET NeoPt (CS-3), RD SET Newborn Neonatal, RD SET Newborn Infant/Pediatric, and RD SET Trauma.

The following table shows the  $A_{rms}$  values measured in the desaturation study using the LNOP Neo-L:

SaO <sub>2</sub> range [%]	70-100	70-80	80-90	90-100
$A_{rms}$ value [%]	1.87	2.32	1.85	1.44



## References

[1] ISO, "ISO 80601-2-61:2011. Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment." Edition 1, April 2011.

[2] ISO, "ISO 80601-2-61:2017. Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment." Edition 2, December 2017, corrected version February 2018.

[3] Bland, J. M., Altman, D. G. "Agreement between methods of measurement with multiple observations per individual." *Journal of Biopharmaceutical Statistics*, Vol. 17, No. 4: 571-582, June 2007.

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