

A photograph of a male patient lying in a hospital bed, wearing a blue hospital gown and a white cast on his right arm. A blue blood pressure cuff is wrapped around his left arm. A nurse in blue scrubs stands by the bedside, looking at a Philips IntelliVue patient monitor. The monitor displays vital signs. In the background, there is a window with yellow tulips in a vase and a white bedside table.

PHILIPS

IntelliVue

Patient Monitors

Clinical validation of NBP measurement accuracy

Application Note

Introduction

This Application Note discusses the technical developments in the Philips IntelliVue noninvasive blood pressure measurements (NBP). This includes the choices of reference standards, and the clinical validation of measurement accuracy for available reference standards.

The Application Note does not replace the Instructions for Use (IfU) documentation. It is recommended prior to initial use to read, understand, and follow the IfU document.

This Application Note applies to IntelliVue patient monitors Rev. K.2 onwards.

Measurement principle

The NBP measurement employs the oscillometric method to measure arterial blood pressure noninvasively. This measurement is available in the Philips IntelliVue patient monitors (MP2, MP5, MP5SC, MX100) and Philips IntelliVue Multi-Measurement Modules (X2, X3, MMS, MMX). These devices measure the amplitude of pressure changes in the occluding cuff (oscillations) as the cuff deflates from a pressure above the systolic pressure. As the cuff pressure decreases, the oscillations increase in amplitude. They reach a maximum, which approximates to the mean arterial pressure (MAP), and then diminish. This procedure results in a characteristic oscillometric amplitude profile, or “oscillation envelope”.

An algorithm analyzes the oscillation envelope and computes the systolic, diastolic, and mean arterial pressures.

The computation of systolic, diastolic, and mean arterial blood pressures is tuned to match as closely as possible the values of one, or both of the widely accepted reference standards.

Reference standards

There are two widely accepted reference standards that are used to validate the accuracy of NBP devices:

- Intra-arterial reference standard
- Auscultatory reference standard

However, independent studies and our own investigations show that both reference standards may yield different readings, especially in hypotensive and hypertensive measuring ranges.

The following is an abstract of an independent study that compared auscultatory readings and intra-arterial readings over a wide blood pressure range:

“Auscultatory measurement of arterial pressure during anesthesia: A re-assessment of Korotkoff sounds.

Pereira E, Prys-Roberts C, Dagnino J, Anger C, Cooper GM, Hutton P.

The accuracy of the indirect auscultatory method, using the

5th Korotkoff sound for determination of arterial pressures, was investigated by comparison with direct intra-arterial measurements. Eight hundred and sixty-three comparisons were made in 25 patients aged between 27 and 75 years over blood pressures ranging from 59 to 235 mmHg for systolic and 28 to 145 mmHg for diastolic.

The regression equation for all systolic pressure measurements was:

$$y = 13.9 + 0.81x$$

and for all diastolic pressure measurements was:

$$y = 21.4 + 0.71x.$$

Although there was a significant (P less than 0.001) correlation coefficient between direct and indirect measurements for both systolic ($r = 0.93$) and diastolic pressures ($r = 0.79$), the 95% confidence limits (± 22 mmHg for systolic and ± 19 mmHg for diastolic) were very wide, reflecting the influences of observer variation and other sources of error."

The linear factors are significantly different from 1 (0.81 and 0.71, respectively). This indicates that the differences between the auscultatory and intra-arterial readings changed with the level of systolic and diastolic blood pressures. According to the regression equations, the mean differences for systolic and diastolic blood pressures were, for example:

- -1.3 / +6.9 mmHg at 80/50 mmHg
- -8.9 / -1.8 mmHg at 120/80 mmHg
- -20.3 / -10.5 mmHg at 180/110 mmHg

Therefore, the NBP measurement accuracy of Philips IntelliVue NBP measurement devices was validated for adult and pediatric subjects against both reference standards. For the adult and pediatric patient categories, Philips IntelliVue NBP measurement devices allow the selection of the auscultatory or the intra-arterial reference. The selection determines whether the NBP readings match auscultatory or intra-arterial readings within the limits of the respective standards. For the neonatal patient category, the intra-arterial reference is always selected. The auscultatory method is not a valid reference in neonate and infant subjects below the age of three.

Which reference to use

The different reference standards have different behavior especially in hypotension or hypertension. This Application Note shows the statistical variation of NBP readings relative to the chosen reference. (The use of the auscultatory setting can lead to an underestimation of the degree of hypotension. In hypotension, using the invasive intra-arterial reference may indicate lower blood pressure values on the display than the auscultatory reference. In hypertension, the invasive intra-arterial reference may indicate higher blood pressure values on the display than the auscultatory reference.)

The intra-arterial reference is recommended if the NBP measurement replaces or is compared to an invasive ABP measurement. The auscultatory reference is recommended whenever the NBP measurement replaces, or is compared to manual auscultatory measurements.

If the Reference setting is set to **Invasive**, the NBP measurement delivers readings that closely approximate to intra-arterial values. If the Reference setting is set to **Auscultatory**, the NBP measurement delivers readings that closely approximate to auscultatory values.

The selection of the reference method to be used is done for adult and pediatric patients in Configuration Mode during installation and configuration. For neonatal patients, the reference is always set to **Invasive**.

The reference standard being used at each monitor can be identified for adult and pediatric patients in **Main Setup > Measurements > NBP > Reference** by any clinician. However, the setting can only be changed in the password-protected Configuration Mode by an authorized user.

In general, Philips recommends using the same Reference setting in all care areas (for example, OR, PACU, Surgical ICU, and Surgical Floors) among which patients are moved.

Validation of measurement accuracy

Up to, and including Philips IntelliVue patient monitor software release K.1, the NBP measurement accuracy was validated according to the American ANSI/AAMI SP10 standard. This standard has been replaced by the newer international standard ISO 81060-2. While both standards are similar regarding reference methods, procedures, and requirements, they have slightly different gender, pressure, and age distribution requirements. For example, ISO 81060-2 requires a higher number of pediatric patients with an age between 3 and 12 years.

To meet the requirements for mean errors with the changed distribution requirements of ISO 81060-2, the computation of the NBP readings for the auscultatory reference method was changed with Philips IntelliVue patient monitor software release K.2. This change leads on average to slightly higher diastolic and mean arterial pressure readings compared to former releases. No changes were made to the computation of NBP readings for the intra-arterial reference method, including neonate and infant subjects below the age of three.

The intra-arterial reference study for adult and pediatric subjects

A total of 21 subjects (16 adult or adolescent, and 5 pediatric) were included in the study for analysis:

- arm circumference between 17 and 39 cm
- blood pressure ranges:
 - systolic between 69 and 208 mmHg
 - diastolic between 41 and 131 mmHg
 - mean arterial between 54 and 155 mmHg

The findings are summarized as follows:

Blood pressure	Mean error $\leq \pm 5.0$ mmHg	Standard deviation ≤ 8.0 mmHg
Systolic	-0.3	5.5
Diastolic	+1.1	6.8
MAP	-2.7	6.8

All results were well within the limits given in ISO 81060-2.

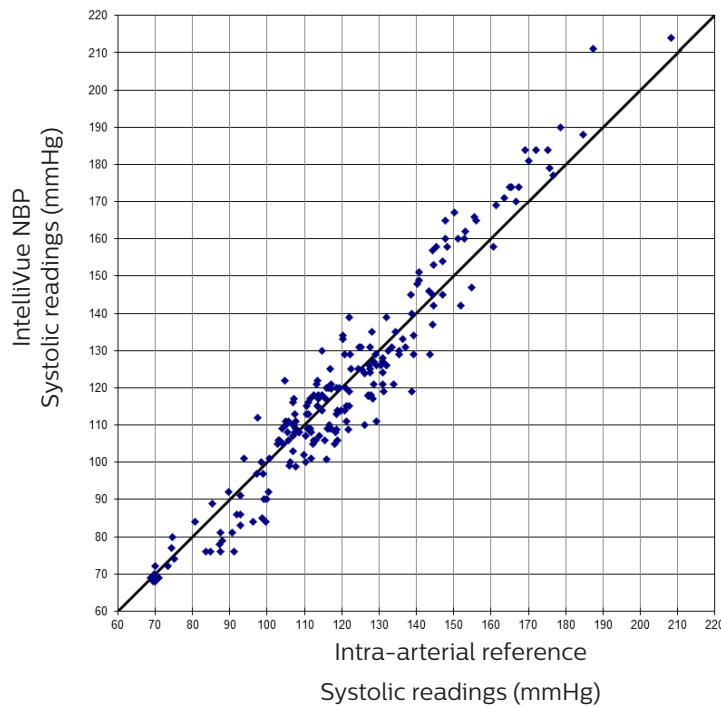


Figure 1: Systolic Pressure — Intra-arterial

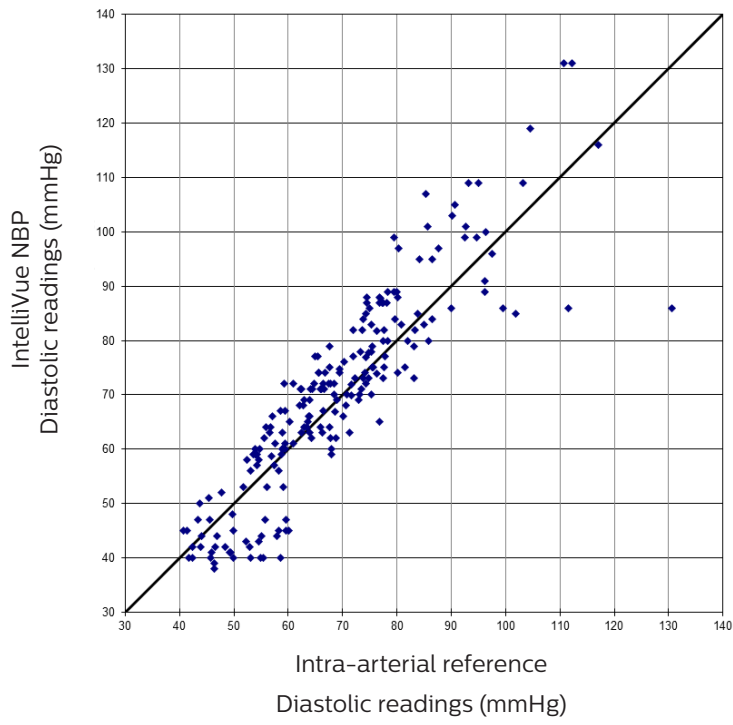


Figure 2: Diastolic Pressure — Intra-arterial

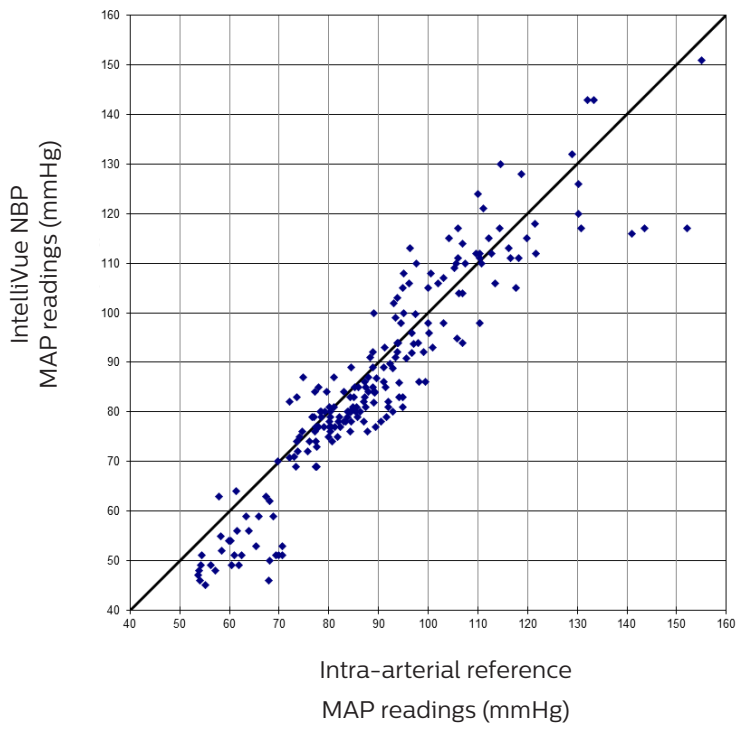


Figure 3: Mean Arterial Pressure — Intra-arterial

The auscultatory reference study for adult and pediatric subjects

A total of 86 subjects (50 adult or adolescent, and 36 pediatric) were included in the study for analysis:

- ages between 3 and 85 years
- arm circumference between 14 and 50 cm
- blood pressure ranges:
 - systolic between 79 and 199 mmHg
 - diastolic between 45 and 120 mmHg
 - mean arterial between 59 and 146 mmHg

The findings are summarized as follows:

Criterion 1

Blood pressure	Mean error $\leq \pm 5.0$ mmHg	Standard deviation ≤ 8.0 mmHg
Systolic	0.5	6.1
Diastolic	-0.1	6.1
MAP	-1.6	4.9

Criterion 2¹

Blood pressure	Standard deviation for subject averages
	- Systolic ≤ 6.92 (ME 0.5)
	- Diastolic ≤ 6.95 (ME -0.1)
	- MAP ≤ 6.76 (ME -1.6)
Systolic	4.87
Diastolic	5.16
MAP	4.3

All results were well within the limits given in ISO 81060-2.

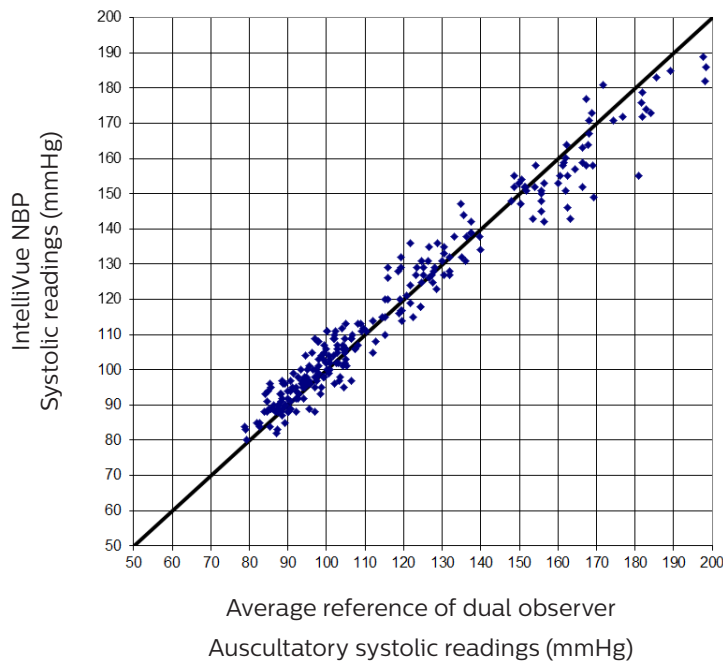
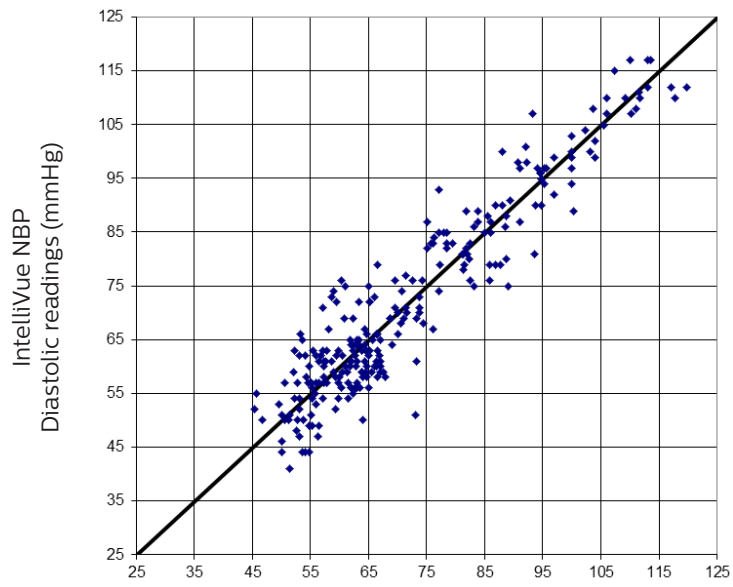


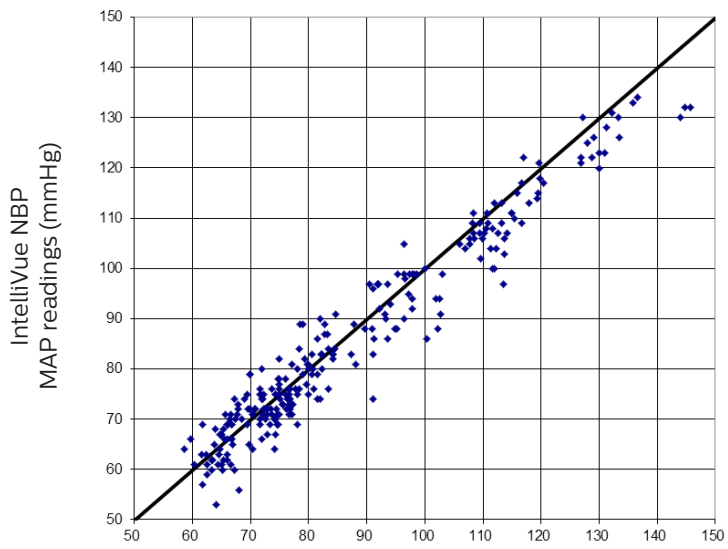
Figure 4: Systolic pressure — auscultatory

1. The auscultatory reference method ISO 81060-2 has two criteria for the standard deviation. The first one for the standard deviation of the individual differences, and the second one for the differences of the subject averages. The maximum permitted standard deviation of the latter depends on the mean error.



Average reference of dual observer
Auscultatory diastolic readings (mmHg)

Figure 5: Diastolic Pressure — Auscultatory



Average reference MAP based on dual observer
Auscultatory systolic and diastolic readings (mmHg)

Figure 6: Mean Arterial Pressure — Auscultatory

The auscultatory reference study for ambulatory subjects

A total of 35 subjects were included in the study for analysis:

- ages between 20 and 64 years
- arm circumference between 23 and 41.5 cm
- blood pressure ranges:
 - systolic between 95 and 226 mmHg
 - diastolic between 39 and 122 mmHg
 - mean arterial between 65.3 and 153.3 mmHg

The findings are summarized as follows:

Criterion 1

Blood pressure	Mean error ≤ ±5.0 mmHg	Standard deviation ≤ 8.0 mmHg
Systolic	0.7	6.9
Diastolic	3.0	7.3
MAP	-0.5	5.4

Criterion 2¹

Blood pressure	Standard deviation for subject averages - Systolic ≤ 6.90 (ME 0.7) - Diastolic ≤ 6.25 (ME 3.0) - MAP ≤ 6.92 (ME -0.5)
Systolic	4.1
Diastolic	5.7
MAP	4.0

All results were well within the limits given in ISO 81060-2.

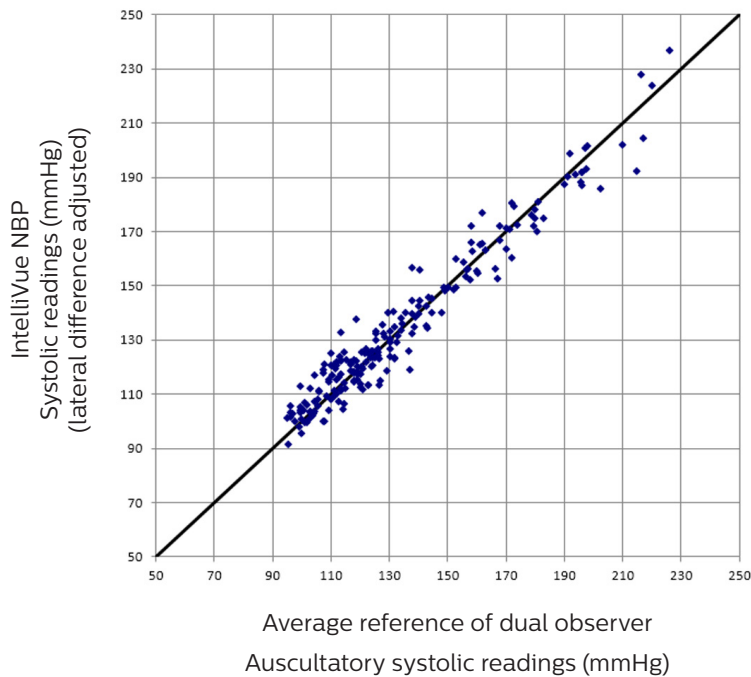


Figure 7: Systolic Pressure — Ambulatory Subjects

1. The auscultatory reference method ISO 81060-2 has two criteria for the standard deviation. The first one for the standard deviation of the individual differences, and the second one for the differences of the subject averages. The maximum permitted standard deviation of the latter depends on the mean error.

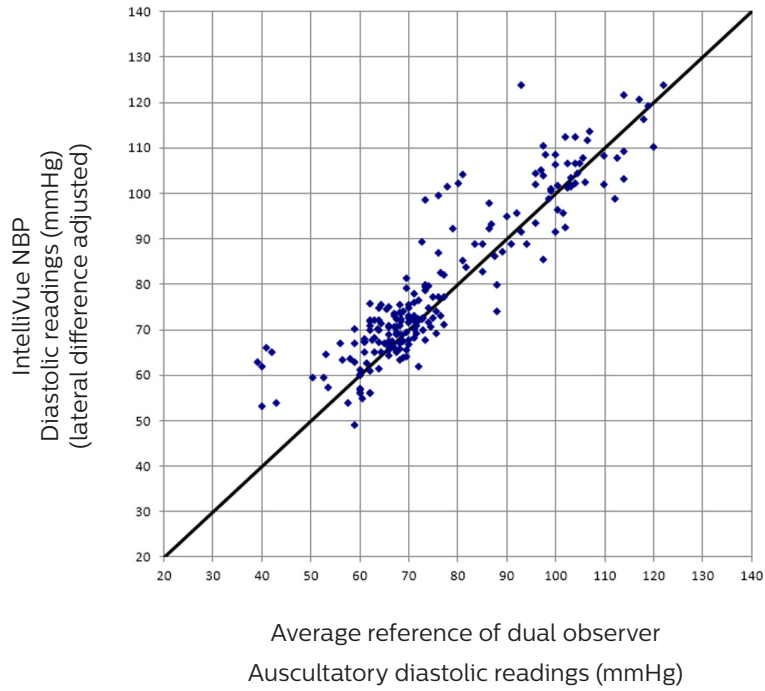


Figure 8: Diastolic Pressure — Ambulatory Subjects

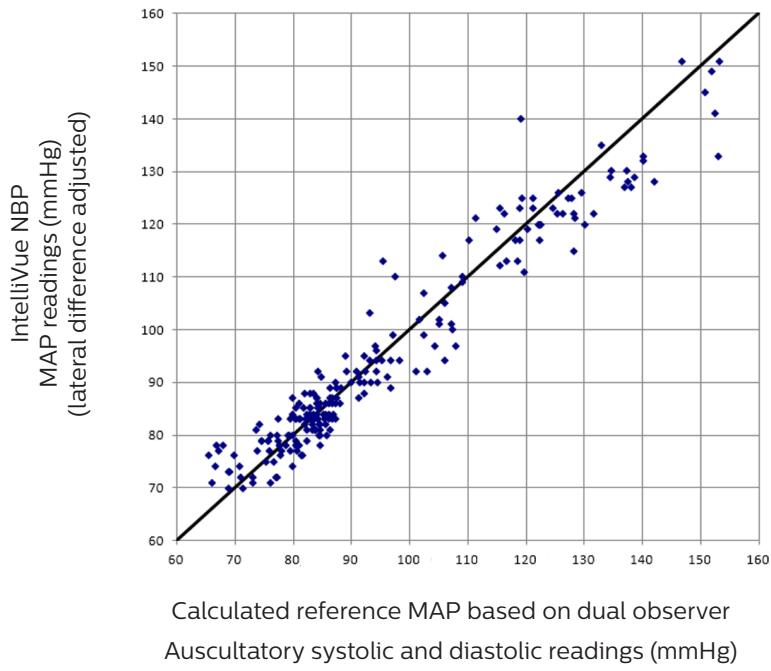


Figure 9: Mean Arterial Pressure — Ambulatory Subjects

The auscultatory reference study for pregnant subjects

A total of 45 pregnant subjects (including preeclamptic subjects) were included in the study for analysis:

- 15 subjects with normal blood pressure
- 15 subjects with hypertension
- 15 subjects with preeclampsia
- arm circumference range between 22.5 and 40 cm
- blood pressure ranges:
 - systolic between 96 and 176 mmHg
 - diastolic between 49 and 115 mmHg
 - mean arterial between 66 and 131 mmHg

The findings are summarized as follows:

Criterion 1

Blood pressure	Mean error ≤ ±5.0 mmHg	Standard deviation ≤ 8.0 mmHg
Systolic	-2.2	7.6
Diastolic	1.4	7.6
MAP	-1.9	6.0

Criterion 2¹

Blood pressure	Standard deviation for subject averages - Systolic ≤ 6.58 (ME 0.7) - Diastolic ≤ 6.80 (ME 3.0) - MAP ≤ 6.68 (ME -0.5)
Systolic	6.36
Diastolic	6.04
MAP	4.64

All results were well within the limits given in ISO 81060-2.

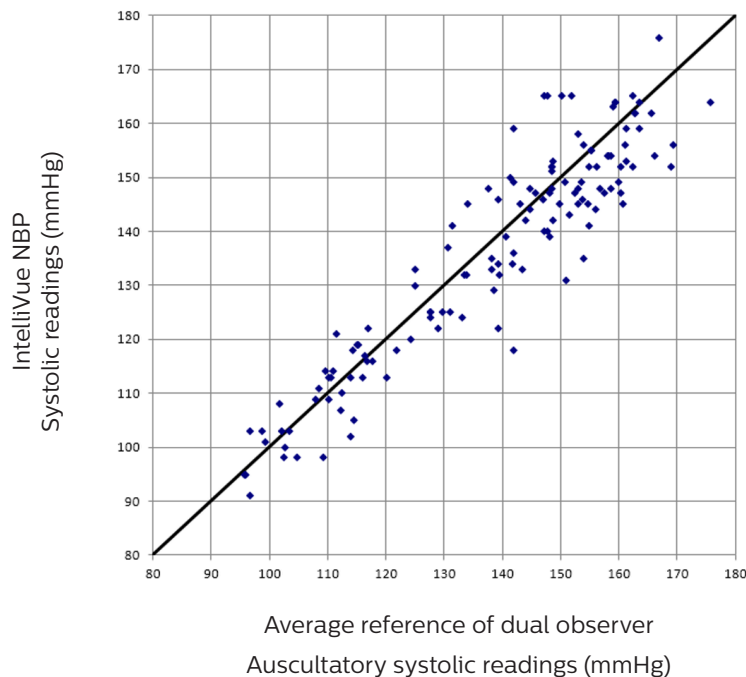


Figure 10: Systolic Pressure — Pregnant Subjects

1. The auscultatory reference method ISO 81060-2 has two criteria for the standard deviation. The first one for the standard deviation of the individual differences, and the second one for the differences of the subject averages. The maximum permitted standard deviation of the latter depends on the mean error.

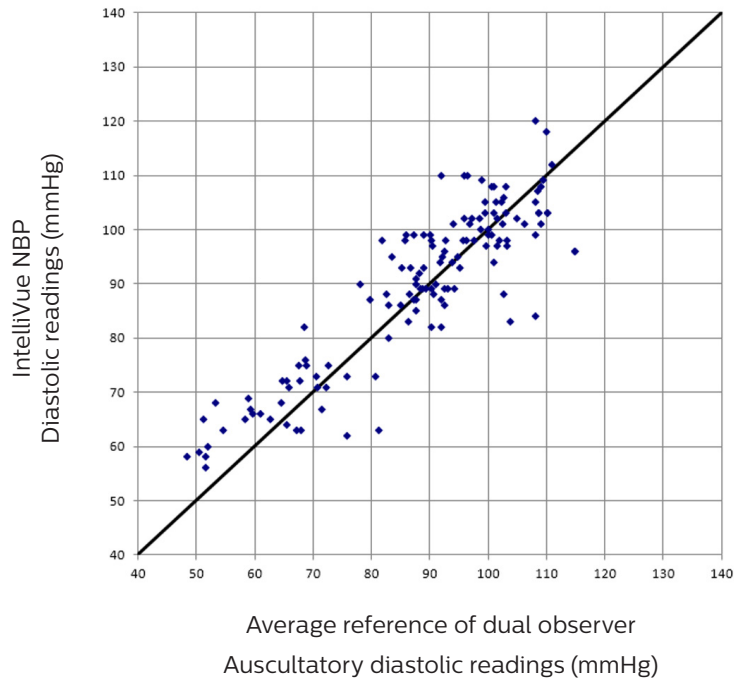


Figure 11: Diastolic Pressure — Pregnant Subjects

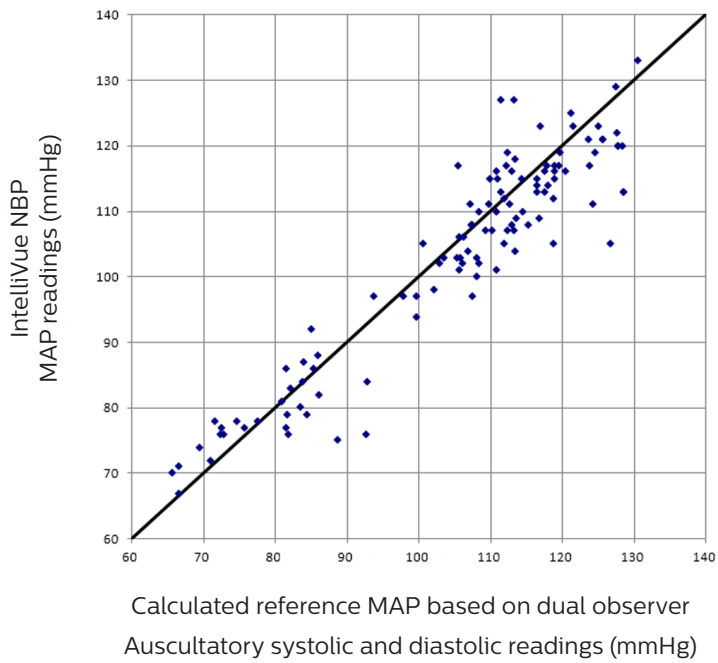


Figure 12: Mean Arterial Pressure — Pregnant Subjects

The intra-arterial reference study for neonate subjects

A total of 16 neonate subjects were included in the study for analysis:

- weight range between 735 g and 3100 g
- limb circumference between 5.75 cm and 13 cm
- blood pressure ranges:
 - systolic between 42 and 89 mmHg
 - diastolic between 20 and 62 mmHg

The findings are summarized as follows:

Blood pressure	Mean error	Standard deviation
	$\leq \pm 5$ mmHg	< 8 mmHg
Systolic	-4.4	5.0
Diastolic	-2.3	4.6



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