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# ANALYSIS OF BLAND-ALTMAN ON WRIST-CUFF BLOOD PRESSURE MONITOR MEASUREMENTS BASED ON OIML R16-2

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**ABSTRACT** Accuracy of wrist-cuff blood pressure monitors is essential for self-monitoring. This study analyzes the accuracy, precision, and agreement of Omron HEM-6161 and HEM-6232T based on OIML R16-2 standards using the Bland-Altman method. Testing involved ten units (five per model) using an at 80/55, 120/80, and 160/100 mmHg. Results showed all units met systolic accuracy with a 100% agreement rate. However, for diastolic parameters, agreement at 80 mmHg decreased to 80% (HEM-6161) and 60% (HEM-6232T), reaching 0% at high pressure (100 mmHg). Precision evaluation showed 100% compliance for all units across all parameters. Bland-Altman analysis revealed HEM-6232T had a higher agreement level, with 98% of data within the (LoA), compared to 92% for HEM-6161. It is concluded that HEM-6232T offers more consistent measurement performance, although both models show accuracy limitations at high diastolic pressure.

**INDEX TERMS** Blood Pressure Monitor, Wrist-Cuff, OIML R16-2, Bland-Altman, Accuracy.

## I. INTRODUCTION

Blood pressure is a vital sign widely used in the diagnosis and treatment of various medical conditions. Monitoring and managing blood pressure are essential components of medical care, particularly in the management of chronic hypertension, intensive care monitoring, and trauma care. [1]. Hypertension, or high blood pressure, is one of the most pressing global public health challenges and a major cardiovascular risk factor worldwide. It is estimated that more than 1.3 billion adults suffer from high blood pressure globally, and this condition contributes to nearly 5 million deaths each year. This crisis is further exacerbated by inequalities in its management; according to the World Health Organization (WHO) report in 2023, despite advancements in measurement technology and the availability of effective medications, a large proportion of patients fail to achieve proper diagnosis and controlled blood pressure targets. [2]. Therefore, accurate blood pressure measurement is crucial both in clinical management and self-monitoring. Digital

sphygmomanometers, or blood pressure monitors (BPM), are instruments used for non-invasive measurement of arterial blood pressure. The method employed in these devices is oscillometry, which involves placing a cuff on a limb and inflating it until arterial blood flow is occluded, followed by a gradual deflation of the cuff pressure [3]. There are two types of blood pressure monitors based on the cuff used: arm-cuff (upper arm cuff) and wrist-cuff (wrist cuff).

In Indonesia, wrist-cuff blood pressure monitors are increasingly popular for self-monitoring of blood pressure. This trend has led to the emergence of various brands with a wide range of prices in the market. Wrist-cuff blood pressure monitors are relatively easy and convenient to use, as the cuff is easier to wrap around the wrist than the upper arm. [4]. The wrist has a different anatomical composition compared to the upper arm, and measurements taken at this site are highly sensitive to body and arm position [5]. Therefore, metrological and clinical verification of these devices is essential to ensure that the data they

produce can be reliably used by both clinicians and patients.

Qi Zhou (2024) evaluated the accuracy of a wrist-cuff blood pressure monitor, model DBP-8278B, based on the universal standard ISO 81060-2:2018/AMD 1:2020 by comparing the device's measurements with reference measurements. The results showed that the blood pressure monitor is recommended for use both at home and in clinical setting [4]. Zoya Hakobyan and her team (2025) also conducted a study evaluating the accuracy of a wrist-cuff blood pressure monitor, model Combei BP880W, based on the same universal standard, ISO 81060-2:2018/AMD 1:2020. The results indicated that the device passed the accuracy test in accordance with the standard. [6]. In line with the need to validate the accuracy of medical devices, the Ministry of Health of the Republic of Indonesia has established a reference for the testing and calibration of blood pressure monitors, namely the OIML R16-2 standard. Based on this, the author intends to analyze and compare the measurement accuracy of wrist-cuff blood pressure monitors with two different types based on the OIML R16-2 standard.

The results of this study are expected to provide an objective overview of the measurement performance of the two BPM types and serve as a reference in the evaluation of wrist-cuff-based blood pressure measuring devices. The evaluation of metrological performance is limited to the parameters of accuracy (mean error) and precision (standard deviation), and therefore does not include other technical tests.

### A. BLOOD PRESSURE

Blood pressure is the pressure generated by the flow of blood pumped by the heart into the blood vessels [7]. Blood pressure is one of the factors that influence overall health. It varies significantly among individuals, from infants and children to adults and the elderly. Blood pressure is also affected by physical activity, age, lifestyle, body weight, and genetics. Normal blood pressure for adults can vary within the range of 95–145/60–90 mmHg. [8]. Blood pressure is divided into two types: systolic blood pressure and diastolic blood pressure, as shown in the Fig. 1.

Systolic blood pressure is the pressure within the blood vessels when the heart contracts or beats. Meanwhile, diastolic blood pressure is the pressure within the blood vessels when the heart is at rest between beats [10].

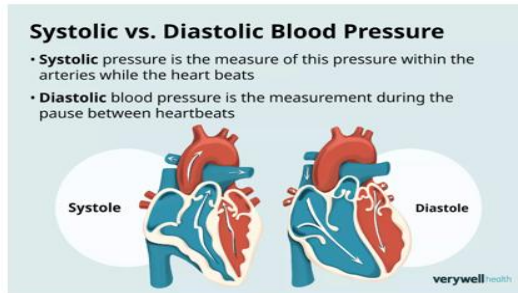


Figure 1. Systolic dan diastolic blood pressure [9]

### B. BLOOD PRESSURE MONITOR

A digital blood pressure monitor (sphygmomanometer) is a non-invasive medical device used to automatically measure and display systolic blood pressure, diastolic blood pressure, and pulse rate [11]. There are two types of blood pressure monitors: the wrist-cuff type and the upper arm type (arm-cuff). In this study, the wrist-cuff type is used, as shown in Fig. 2.



Figure 2. Wrist-cuff blood pressure monitor [12]

A wrist blood pressure monitor is a non-invasive device designed for self-use in measuring blood pressure. Most wrist blood pressure monitors are equipped with a cuff that wraps round the wrist and is connected to a digital display screen to show the measurement results.

### C. NIBP SIMULATOR

An NIBP simulator is a measuring instrument used to test and calibrate blood pressure monitors. [11]. Basically, the NIBP simulator acts as a substitute for the patient as the input to the blood pressure monitor [13]. In this study, an NIBP simulator, model MS200 by Contec, is used, as shown in Fig. 3.



Figure 3. NIBP Simulator [14]

This NIBP simulator is equipped with various operating modes designed to simulate blood pressure conditions and specific physiological characteristics. The preset modes available in this NIBP simulator include static pressure, standard blood pressure (BPM Standard), patient condition, arrhythmias, respiratory artifacts, neonate, wrist, and user-defined modes [14].

#### D. OIML R16-2 STANDARD

The OIML R16-2:2002 (E) standard is an international standard published by the International Organization of Legal Metrology (OIML) that regulates non-invasive automated sphygmomanometers. This standard is used as a reference in the testing, calibration, and performance evaluation of automatic blood pressure measuring devices that operate using a cuff system. OIML R16-2:2002 (E) includes technical and metrological requirements for non-invasive automated blood pressure measuring instruments that use a cuff as the measurement medium. These instruments can be used on parts of the body such as the upper arm, wrist, or thigh. The standard outlines provisions regarding general device specifications, metrological characteristics, technical and safety requirements, as well as testing and verification procedures to ensure that the devices meet accuracy and reliability criteria [3].

The International Organization of Legal Metrology (OIML) establishes Recommendation OIML R16-2 as an international technical guideline for non-invasive automated sphygmomanometers. This standard requires that, for each measurement point, the mean error must not exceed  $\pm 5$  mmHg, with a standard deviation (SD) not greater than 8 mmHg.

#### E. Bland-Altman

The Bland–Altman method (also known as the Bland–Altman plot) is a statistical technique used to evaluate the agreement between two measurement methods that assess the same variable. This method

was introduced by J. Martin Bland and Douglas G. Altman in 1983 and further refined in a 1986 publication. Bland and Altman introduced the Bland–Altman plot to illustrate the agreement between two quantitative measurements by constructing limits of agreement. These statistical limits are calculated using the mean and standard deviation of the differences between the two measurements. Another characteristic of this method is its graphical approach. The mean difference  $\pm 1.96$  standard deviations of the differences between the two measurement techniques is used to determine the limits of agreement (LoA). If the range between the lower and upper LoA is considered not clinically significant, then the two methods are assumed to be equivalent [15].

## II. RESEARCH METHODS

This study is a descriptive quantitative research with a metrological accuracy validation approach. The research design involves comparative testing and agreement testing, in which the measurement results of wrist-cuff blood pressure monitors are systematically analyzed and compared with the standard reference values generated by the NIBP simulator based on the OIML R16-2 standard.

### A. CONCEPTUAL FRAMEWORK

The conceptual framework in this study is designed to evaluate the accuracy and level clinical agreement of wrist-cuff Blood Pressure Monitor (BPM) devices using a legal metrology approach. The relationships between variables in this study are illustrated in Fig. 4.

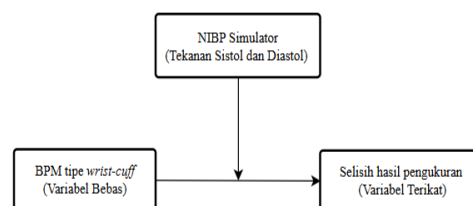


Figure 4. Conceptual framework

The independent variable in this study is the wrist-cuff BPM device. The main focus is on differences in technology and oscillometric algorithms used by the sample units (in this case, models HEM-6161 and HEM-6232T). These devices act as variables whose ability to detect blood pressure signals under various simulated conditions will be tested. The dependent variable is the difference in measurement results, or

the error value produced. This parameter is calculated by determining the absolute difference between the value displayed on the wrist-cuff BPM and the reference value generated by the simulator. This difference data serves as the primary indicator for determining the device’s compliance with the accuracy threshold specified in the OIML R16-2 standard.

The NIBP simulator functions as a control instrument that provides precise and traceable systolic and diastolic pressure inputs. This simulator replicates various arterial pressure conditions (systolic and diastolic) as fixed reference values (gold standard). The relationship between the independent and dependent variables strongly depends on the simulator’s accuracy in delivering stable pressure inputs to the test units.

Systematically, this framework aims to map how variations in technology in wrist-cuff BPM devices (independent variable) respond to pressure inputs from the NIBP simulator, which then produce outputs in the form of measurement differences (dependent variable). These difference data are subsequently analyzed statistically using the Bland–Altman method to identify any systematic bias and the limits of agreement (LoA) of the devices.

**A. RESEARCH INSTRUMENT**

This study used 10 wrist-cuff BPM units (five units of HEM-6161 and five units of HEM-6232T). All tested units were ensured to be in good working condition. The identification of the BPM devices used in this study is presented in the following table.

TABLE I  
 RESEARCH SAMPLE DATA

Device Type	Unit	Serial Number (SN)	Data Type
HEM-6161	BPM 1	202505013557V	Primary
	BPM 2	202503018792V	Primary
	BPM 3	202107000375V	Primary
	BPM 4	202406001719V	Primary
	BPM 5	202507011024V	Secondary
HEM-6232T	BPM 1	202509000661V	Primary
	BPM 2	202504000249V	Primary
	BPM 3	202308001373V	Primary
	BPM 4	202108000128V	Secondary
	BPM 5	202210000401V	Secondary

The research samples used in this study are owned by individuals and healthcare facilities. Based on the type of data, four units of the HEM-6161 BPM are categorized as primary data, while one unit is

categorized as secondary data. Meanwhile, for the HEM-6232T type, two units are primary data and three units are secondary data. Overall, the composition of the data in this study consists of six units of primary data and four units of secondary data. The variation in ownership and data type aims to provide a more representative overview of the performance of the two BPM types being studied.

**B. DATA COLLECTION PROCEDURE**

Data collection was conducted at two different testing locations, namely a calibration laboratory and a hospital. The number of BPM units tested at each location was not equal, depending on the availability of devices at each site. The measurement setting points were not determined randomly but were based on the technical specifications and recommendations stated in the manual book of the NIBP simulator used as the reference instrument. According to the NIBP simulator manual for wrist-cuff blood pressure monitor testing, three pairs of systolic and diastolic pressure settings were defined, namely 80/55 mmHg, 120/80 mmHg, and 160/100 mmHg.

The data collection procedure was carried out through the following steps:

1. Installing the BPM device to the NIBP simulator according to the configuration shown in Figure 5.



Figure 5 Installation of the BPM and NIBP Simulator

2. Connect the NIBP simulator power cable to the PLN electrical power source.
3. Turning on the NIBP simulator by pressing the ON/OFF button.
4. Selecting the “wrist” mode on the NIBP simulator.
5. Selecting the measurement point on the NIBP simulator, starting from the lowest blood pressure setting of 80/55 mmHg.
6. Pressing the Start button on the BPM to initiate one measurement cycle.

7. Waiting until the measurement is completed and the result appears on the BPM display.
8. Recording the measurement results into a table on the worksheet.
9. Waiting approximately  $\pm 1$  minute before starting the next repetition.
10. After the repetitions are completed, continuing the measurements at the 120/80 mmHg and 160/100 mmHg settings.
11. After completing measurements for the HEM-6161 BPM, replacing it with the next BPM and repeating steps 3 to 12.
12. After data collection is completed, turning off the BPM and disconnecting the tubing connected to the NIBP simulator.
13. Turning off the NIBP simulator by pressing the ON/OFF button.

### C. DATA ANALYSIS

The analysis was performed on the measurement data obtained from the wrist-cuff blood pressure monitor (BPM), which were compared with reference values from the NIBP simulator as the standard reference. The evaluation of measurement results was conducted based on the accuracy and precision requirements specified in OIML R16-2, and the level of agreement was analyzed using the Bland–Altman method. The data analysis includes Difference calculation, Mean calculation, Standard deviation calculation, Accuracy evaluation, Precision evaluation, and Bland–Altman analysis

## III. RESULT AND DISCUSSION

### A. EVALUATION OF AGREEMENT RESULT BASED ON OIML R16-2

1. Calculation of the average measurement difference of the BPM

The calculation of the mean difference value was performed to determine the tendency of measurement deviation of the BPM results compared to the reference values at each pressure point. The results of the mean difference calculations for the HEM-6161 and HEM-6232T BPM devices are presented in Table II and Table III.

Based on the comparison of mean measurement differences, both blood pressure monitor types, HEM-6161 and HEM-6232T, show a similar pattern, where the measurement difference tends to increase as the pressure setting increases. At low systolic

pressure, both BPM types show relatively small negative mean differences, while at medium to high systolic pressures, the mean differences tend to approach zero or become positive. However, for diastolic pressure, the HEM-6232T shows larger mean differences compared to the HEM-6161, particularly at 80 mmHg and 100 mmHg diastolic settings, indicating differences in measurement characteristics between the BPM types. Nevertheless, both devices still demonstrate relatively consistent variation in mean differences across pressure levels, suggesting that the observed differences are more reflective of device-type characteristics rather than unit-to-unit variation.

TABLE II  
RESULT OF THE AVERAGE VALUE OF THE DIFFERENCE IN BPM MEASUREMENTS FOR THE HEM-6161

Pressure	Setting (mmHg)	Mean Difference of BPM Type HEM-6161				
		BPM 1	BPM 2	BPM 3	BPM 4	BPM 5
Systolic	80	-3,7	-3,0	-4,0	-3,0	-2,2
	120	0,0	0,3	1,0	2,2	-0,8
	160	1,5	2,3	1,7	2,3	3,2
Diastolic	55	-2,2	-1,2	-2,5	-2,0	2,0
	80	2,0	3,5	4,0	3,2	6,3
	100	5,2	6,0	6,2	6,5	8,3

TABLE III  
RESULT OF THE AVERAGE VALUE OF THE DIFFERENCE IN BPM MEASUREMENTS FOR THE HEM-6232T

Pressure	Setting (mmHg)	Mean Difference of BPM Type HEM-6232T				
		BPM 1	BPM 2	BPM 3	BPM 4	BPM 5
Systolic	80	-3,2	-3,3	-2,7	-2,5	-2,5
	120	-0,7	-0,2	1,0	-0,5	-0,5
	160	0,8	0,7	1,7	1,0	1,3
Diastolic	55	2,2	2,2	1,5	-2,0	-2,0
	80	7,2	5,7	7,2	4,2	3,0
	100	11,3	10,2	11,8	5,5	5,8

2. Calculation of the standard deviation of BPM measurements

The results of this standard deviation calculation are used to determine whether the BPM device remains within the allowable range specified by OIML. The following are the standard deviation results for the

five units of the BPM HEM-6161 presented in Table IV, while the standard deviation results for the five units of the HEM-6232T BPM are presented in Table IV.

TABLE IV  
 RESULT OF STANDARD DEVIATION VALUES FOR BPM MEASUREMENTS OF TYPE HEM-6161

Pressure	Setting (mmHg)	Standard Deviation of BPM Type HEM-6161				
		BPM	BPM	BPM	BPM	BPM
		1	2	3	4	5
Systolic	80	0,8	0,6	0,9	0,6	0,8
	120	0,9	0,5	0,0	0,8	1,2
	160	0,5	0,8	0,8	0,5	0,8
Diastolic	55	0,8	1,0	1,4	1,1	0,9
	80	0,9	0,8	0,0	0,4	0,5
	100	0,8	0,6	0,4	0,5	0,5

Table V presents the results of the standard deviation calculations for the HEM-6232T BPM. The results of the standard deviation calculations in both tables provide a comprehensive overview of the precision and reliability levels of the two tested device types. Based on the data in Table 4.23 for the HEM-6161 model and Table 4.24 for the HEM-6232T model, it can be observed that the standard deviation values for all sample units (BPM 1 to 5) are within a very low range, namely between 0.0 and 1.5 mmHg. This consistency covers all test points, from low systolic pressure (80 mmHg) to high diastolic pressure (100 mmHg).

From a metrological perspective, these findings demonstrate that both device types have a highly stable level of repeatability, as the standard deviation values are far below the maximum allowable limit of 8 mmHg specified in the OIML R16-2 standard. Although there is slight variation in data dispersion at high diastolic pressure in Table 4.24, this does not reduce the validity of the devices. Therefore, it can be concluded that, technically, both blood pressure monitor models exhibit excellent precision performance under laboratory conditions.

TABLE V  
 RESULT OF STANDARD DEVIATION VALUES FOR BPM MEASUREMENTS OF TYPE HEM-6232T

Pressure	Setting (mmHg)	Standard Deviation of BPM Type HEM-6232T				
		BPM	BPM	BPM	BPM	BPM
		1	2	3	4	5
Systolic	80	1,2	0,8	0,5	1,0	1,0
	120	1,0	1,0	0,0	0,8	0,8
	160	0,4	0,5	0,8	0,9	0,8
Diastolic	55	0,8	1,2	0,5	0,9	0,9
	80	0,8	0,5	0,4	1,0	1,4
	100	0,5	1,0	0,4	0,5	1,5

### 3. Evaluation of BPM accuracy and precision conformity

Based on the results of the accuracy and precision conformity evaluation of five units of the HEM-6161 BPM and five units of the HEM-6232T BPM against OIML R16-2, a recapitulation was conducted to determine the overall conformity level of each BPM type. This recapitulation is compiled based on the number of units that meet and do not meet the tolerance criteria at each systolic and diastolic pressure test point. Table 4.29 presents the recapitulation of accuracy and precision conformity results for the HEM-6161 BPM.

Based on the recapitulation of the conformity evaluation results, all units of the HEM-6161 BPM met the accuracy requirements for systolic measurements at all pressure points (80, 120, and 160 mmHg), with a conformity percentage of 100%. For diastolic measurements, all units met the accuracy requirements at 55mmHg; however, at 80 mmHg the conformity percentage decreased to 80%, and at 100 mmHg all units failed to meet the accuracy requirements.

Meanwhile, the precision evaluation results showed that all BPM units met the precision requirements for both systolic and diastolic measurements across all pressure points, with a conformity percentage of 100%. This indicates that the HEM-6161 BPM exhibits good measurement stability and consistency, although there are still limitations in accuracy at higher diastolic pressure levels. The next section presents the recapitulation of accuracy and precision conformity results for the HEM-6232T BPM in the following table.

TABLE VI  
 RECAPITULATION OF ACCURACY AND PRECISION  
 CONFORMITY RESULTS OF HEM-6161 BPM TYPE

Parameter	Type of Pressure	Setting (mmHg)	Unit Pass	Unit Fail	Conformity Percentage
Accuracy	Systolic	80	5	0	100%
		120	5	0	100%
		160	5	0	100%
	Diastolic	55	5	0	100%
		80	4	1	80%
		100	0	5	0%
Precision	Systolic	80	5	0	100%
		120	5	0	100%
		160	5	0	100%
	Diastolic	55	5	0	100%
		80	5	0	100%
		100	5	0	100%

TABLE VII  
 RECAPITULATION OF ACCURACY AND PRECISION  
 CONFORMITY RESULTS OF HEM-6161 BPM TYPE

Parameter	Type of Pressure	Setting (mmHg)	Unit Pass	Unit Fail	Conformity Percentage
Accuracy	Systolic	80	5	0	100%
		120	5	0	100%
		160	5	0	100%
	Diastolic	55	5	0	100%
		80	3	2	60%
		100	0	5	0%
Precision	Systolic	80	5	0	100%
		120	5	0	100%
		160	5	0	100%
	Diastolic	55	5	0	100%
		80	5	0	100%
		100	5	0	100%

Based on the recapitulation of the conformity evaluation results, all BPM units met the systolic measurement accuracy requirements at all pressure points (80, 120, and 160 mmHg), with a conformity percentage of 100%. For diastolic measurements, all units met the accuracy requirements at 55 mmHg; however, there was a decrease in conformity at 80 mmHg, with a percentage of 60%, and at 100 mmHg all units failed to meet the accuracy requirements.

The precision evaluation results show that all BPM units met the precision requirements for both systolic and diastolic measurements across all pressure points, with a conformity percentage of 100%.

**B. BLAND-ALTMAN ANALYSIS**

The Bland–Altman analysis was used to evaluate the level of agreement between the BPM measurement results and the reference values from the NIBP

simulator. This analysis is performed by plotting the differences between the two measurement methods against their mean values, allowing the identification of systematic bias and the distribution of measurement errors. In this study, the Bland–Altman analysis was conducted separately for systolic and diastolic pressures for both the HEM-6161 and HEM-6232T BPM types. The main parameters used in the Bland–Altman analysis include the bias value, the standard deviation of the measurement differences, and the upper and lower limits of agreement (LoA). These values are used to describe the tendency of measurement differences and the range of agreement variability between the BPM devices and the NIBP simulator.

1. Bland–Altman analysis of systolic pressure for the HEM-6161 BPM type

From the three systolic pressure settings obtained, this journal presents the results at the 120mmHg point, as this represents a normal blood pressure level. The analysis begins by calculating the measurement differences, which are then used to obtain the Bland–Altman systolic pressure analysis parameters at 120 mmHg, as shown in Table VIII.

TABLE VIII  
 BLAND–ALTMAN ANALYSIS PARAMETERS FOR SYSTOLIC  
 PRESSURE AT 120 MMHG

Parameter	Value (mmHg)
Bias	0,53
Standard Deviation	1,25
Upper LoA	2,99
Lower LoA	-1,92

Based on Table VIII, a bias of 0.53 mmHg was obtained, indicating that, on average, the BPM readings are slightly higher than the reference values. A bias value close to zero suggests that there is no significant systematic difference between the two measurement methods.

The standard deviation value of 1.25 mmHg indicates that the variation in measurement differences is relatively small, meaning that the data distribution around the bias value is fairly narrow. The limits of agreement obtained are 2.99 mmHg for the upper limit and -1.92 mmHg for the lower limit. This range of limits of agreement is still within the allowable tolerance range. The Bland–Altman plot for the HEM-6161 BPM systolic pressure test at 120 mmHg shows the relationship between the

measurement differences on the Y-axis and the mean values of the BPM readings and reference values on the X-axis. The central horizontal line represents the bias value of 0.53 mmHg, while the two dashed lines indicate the upper limit of agreement at 2.99 mmHg and the lower limit of agreement at -1.92 mmHg. The distribution of data points appears relatively symmetric around the bias line, with measurement differences ranging from approximately -2 to 3 mmHg. Most of the data points lie within the upper and lower limits of agreement (LoA), indicating a good level of agreement between the BPM and the reference values at the systolic pressure of 120 mmHg.

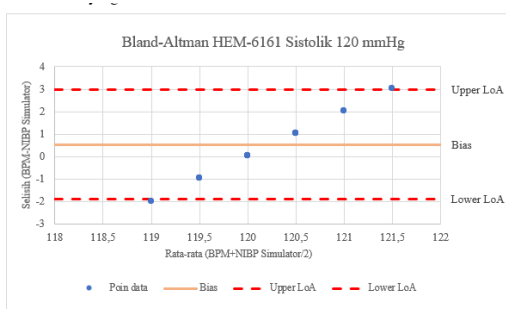


Figure 6. Bland–Altman Plot of Systolic Pressure at 120 mmHg for HEM-6161 BPM Type

## 2. Bland-Altman Analysis of Diastolic Pressure for HEM-6161 BPM Type

The Bland–Altman analysis was conducted to evaluate the level of agreement between the HEM-6161 device and the NIBP simulator as the reference standard for the diastolic parameter. From the three test points performed (55, 80, and 100 mmHg), this sub-section focuses on the diastolic pressure point at 80 mmHg. The selection of the 80 mmHg point as the main representation is based on its clinical significance, as this value represents the normal cut-off threshold for adult diastolic blood pressure according to international health standards.

TABLE IX  
BLAND–ALTMAN ANALYSIS PARAMETERS FOR DIASTOLIC PRESSURE AT 80 MMHG

Parameter	Value (mmHg)
Bias	3,80
Standard Deviation	1,56
Upper LoA	6,86
Lower LoA	0,74

By mapping the bias and limits of agreement (LoA) at this point, an accurate overview of the device’s performance in detecting normotensive

conditions can be obtained, which is the most common usage scenario for self-monitoring in home settings.

The results of the analysis indicate a tendency toward systematic difference, where the tested device produces slightly higher values compared to the reference device. However, the variation in measurement differences is relatively small, indicating good consistency (precision). The relatively narrow limits of agreement suggest that most of the differences remain controlled and do not deviate significantly. This indicates that the level of agreement between the test device and the reference remains acceptable, although a slight bias is present.

Furthermore, to observe the pattern of difference distribution and potential bias visually, a Bland–Altman plot is used and presented in Fig. 7.

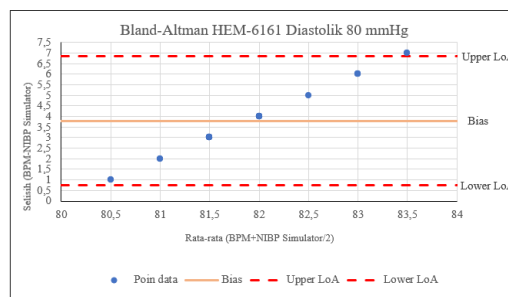


Figure 7. Bland–Altman Plot of Diastolic Pressure at 80 mmHg for HEM-6161 BPM Type

The Bland–Altman plot for the diastolic measurement at 80 mmHg shows that all data points lie within the upper limits of agreement (Upper LoA) and lower limits of agreement (Lower LoA). This indicates that there are no outliers or extreme deviations between the test device and the reference measurements. The distribution of data points appears relatively orderly and follows an increasing pattern, with all difference values located above the bias line.

This condition indicates a positive bias tendency, where the test device consistently produces higher values compared to the reference device. In addition, the relatively small spread between data points suggests that the variation in measurement differences is low, indicating good precision of the device. The relatively narrow range between the Upper LoA and Lower LoA also shows that the differences between the two methods remain well controlled.

### 3. Systolic Pressure Analysis at 120 mmHg for HEM-6232T BPM Type

The Bland–Altman analysis results for systolic pressure measurement at 120 mmHg using the HEM-6232T BPM are presented. From the three test points conducted, only the data at 120 mmHg is displayed as a representative sample. This presentation includes the analysis parameters and the Bland–Altman plot to illustrate the level of agreement between the test device and the reference instrument. The calculated measurement difference data are then used to determine the Bland–Altman analysis parameters, as shown in the following table.

TABLE X  
BLAND–ALTMAN ANALYSIS PARAMETERS FOR SYSTOLIC PRESSURE AT 120 MMHG

Parameter	Nilai (mmHg)
Bias	-0,23
Standard Deviation	0,97
Upper LoA	1,67
Lower LoA	-2,14

The results of the analysis show that a bias value close to zero indicates no significant systematic difference between the test device and the reference instrument. This means that, on average, both devices produce nearly identical measurement results.

The relatively small data dispersion indicates that the variation in measurement differences is minimal, suggesting good consistency (precision) of the device. In addition, the relatively narrow limits of agreement indicate that most of the measurement differences are within a controlled range and do not deviate significantly.

Overall, these results demonstrate that the level of agreement between the test device and the reference instrument is good, with small differences and stable measurement performance. A visual representation of the Bland–Altman analysis results is presented in the Fig. 8.

The Bland–Altman plot in Fig. 8 shows a comparison of systolic pressure measurements at 120 mmHg between the HEM-6232T BPM and the NIBP simulator. The horizontal axis represents the mean values of both devices, while the vertical axis represents the differences between the measurements. The obtained bias value is -0.23 mmHg, indicating that the BPM tends to produce slightly lower readings compared to the simulator.

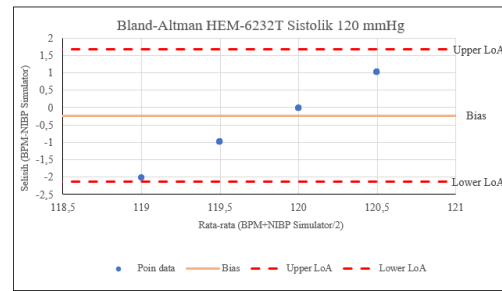


Figure 8. Bland–Altman Plot of Systolic Pressure at 120 mmHg for HEM-6232T BPM Type

All data points lie within the upper and lower limits of agreement (LoA), indicating that the level of agreement between the two measurement methods remains acceptable. The relatively small number of points displayed on the plot suggests the presence of repeated measurement values, which may be caused by the limited resolution of the device.

### 4. Diastolic Pressure Analysis at 80 mmHg for HEM-6232T BPM Type

The data obtained from the HEM-6232T BPM at diastolic pressure points of 55 mmHg, 80 mmHg, and 100 mmHg were first processed to calculate the mean values and differences, which were then used to determine the Bland–Altman analysis parameters. From these three test points, the results presented are focused on the 80 mmHg point as a representative value, as it falls within the range commonly observed under normal physiological conditions.

Furthermore, the results of the Bland–Altman parameter calculations at the 80 mmHg point are presented in Table XI to provide a quantitative overview.

TABLE XI  
BLAND–ALTMAN ANALYSIS PARAMETERS FOR DIASTOLIC PRESSURE AT 80 MMHG

Parameter	Value (mmHg)
Bias	5,43
Standard Deviation	1,87
Upper LoA	9,10
Lower LoA	1,77

The Bland–Altman analysis at a diastolic pressure of 80 mmHg using the HEM-6232T BPM shows a bias of 5.43 mmHg, indicating that the BPM tends to produce higher readings compared to the reference value. The standard deviation of 1.87 mmHg suggests that the variation in measurement differences is still relatively controlled. The limits of agreement range

from 1.77 to 9.10 mmHg, indicating that most of the measurement differences fall within this interval.

These results suggest that the HEM-6232T BPM demonstrates a reasonably good level of agreement.

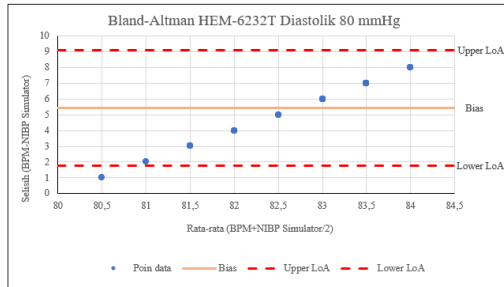


Figure 9. Bland–Altman Plot of Diastolic Pressure at 80 mmHg for HEM-6161 BPM Type

The Fig. 9 shows the Bland–Altman plot of diastolic pressure measurements at 80 mmHg using the HEM-6232T BPM compared with the NIBP simulator as the reference device. The horizontal axis represents the mean of the two measurements, while the vertical axis represents the difference between them (BPM – NIBP simulator).

Based on the graph, a bias value of 5.43 mmHg is obtained, indicated by the central line. This bias shows that, on average, the HEM-6232T BPM produces higher readings than the reference value at a diastolic pressure of 80 mmHg. The limits of agreement (LoA) range from 1.77 mmHg to 9.10 mmHg. Most of the data points lie within these limits, indicating generally good agreement.

However, there is one measurement point located below the lower limit of agreement (Lower LoA). This indicates a single measurement with a deviation outside the defined agreement range. This condition may be caused by random variation in the measurement process or device response and does not indicate a systematic error, as only a very small number of points fall outside the limits of agreement.

5. Result of the Bland-Altman Suitability Analysis Agreement interpretation aims to assess the validity of wrist-cuff BPM devices based on the distribution of data in the Bland–Altman method, specifically by examining the proportion of data points that fall within the limits of agreement (LoA). The results show that both BPM types, HEM-6161 and HEM-6232T, demonstrate a good level of agreement, with approximately 95% of the data lying within the LoA range. The highest bias value of 8.23 mmHg was

observed in the diastolic measurement at 100 mmHg for the HEM-6232T BPM. Nevertheless, the HEM-6232T showed better overall performance, with 98% of data within the LoA, compared to 92% for the HEM-6161.

#### IV. CONCLUSION

Based on the results of the study, the wrist-cuff Blood Pressure Monitor (BPM) types HEM-6161 and HEM-6232T showed good performance in systolic pressure measurements, with all units meeting the accuracy criteria based on the OIML R16-2 standard. The precision evaluation also showed consistent results, where all measurements were within the allowable tolerance limits. However, for diastolic pressure, the accuracy of the devices decreased, particularly at higher pressure levels, indicating limitations in performance under such conditions.

The Bland–Altman analysis shows that both BPM types demonstrate a good level of agreement with the reference device, with most data points falling within the limits of agreement (LoA). Among the two, the HEM-6232T showed better performance with an agreement level of 98%, compared to 92% for the HEM-6161. Overall, both devices exhibit good precision, but limitations in diastolic pressure accuracy especially at higher pressure levels should be taken into consideration.

#### REFERENCES

- [1] X. Quan et al., “Advances in non-invasive blood pressure monitoring,” *Sensors*, vol. 21, no. 13, pp. 1–20, 2021, doi: 10.3390/s21134273.
- [2] S. R. Mishra et al., “Closing the Gap in Global Disparities in Hypertension Control,” *Hypertension*, vol. 82, no. 3, pp. 407–410, 2025, doi: 10.1161/HYPERTENSIONAHA.124.24137.
- [3] OIML, “recommendation 16-2: Non-invasive automated sphygmomanometers,” *Water*, vol. 2006, pp. 1–45, 2006.
- [4] Q. Zhou, “Validation of the DBP-8278B Wrist-type Fully Automatic Blood Pressure Monitor in the general population according to the ISO 81060-2:2018/AMD 1:2020 protocol,” *Blood pressure monitoring*, vol. 30, no. 1, pp. 36–39, 2025, doi: 10.1097/MBP.0000000000000717.
- [5] K. Kario, “Home blood pressure monitoring: Current status and new developments,” *American Journal of Hypertension*, vol. 34, no. 8, pp. 783–794, 2021, doi: 10.1093/ajh/hpab017.
- [6] Z. Hakobyan, P. Zelveian, H. Gharibyan, J. Topouchian, and R. Asmar, “Accuracy of the Combei BP880W Wrist Device for Self-Blood Pressure Measurements in General Population According to the International Organization for Standardization Universal Standard (ISO 81060-2:2018/AMD 1:2020) Protocol,” *Vascular Health and Risk Management*, vol. 21, no. February, pp. 75–84, 2025, doi: 10.2147/VHRM.S513013.
- [7] S. Rahayu and A. Budiasri, “Membangun Kesehatan Bersama: Program Sosial Cek Tekanan Darah,” *Jurnal Pengabdian dan Pemberdayaan Masyarakat ALIFA*, vol. 2, no. 1, pp. 11–14, 2022, doi: 10.70371/jppma.v2i1.162.

- [8] E. R. Dumalang, F. Lintong, and V. R. Danes, "Analisa Perbandingan Pengukuran Tekanan Darah antara Posisi Tidur dan Posisi Duduk pada Lansia," *Jurnal Biomedik: JBM*, vol. 14, no. 1, pp. 96–101, 2022, doi: <https://doi.org/10.35790/jbm.v14i1.37592>.
- [9] "Systolic vs. Diastolic Blood Pressure." Accessed: Nov. 06, 2025. [Online]. Available: <https://www.verywellhealth.com/systolic-and-diastolic-blood-pressure-1746075>
- [10] P. Studi, S. Keperawatan, and U. Hafshawaty, "© 2025 Jurnal Keperawatan," Hubungan Efikasi Diri Dengan Kekambuhan Pada Pasien Hipertensi Di Posbindu Desa Senduro Di Wilayah Upt.Puskesmas Senduro, pp. 99–108, 2025.
- [11] "Analisis Perbandingan Pengukuran Blood Pressure Monitor Menggunakan Internal Cuff dan Eksternal Cuff pada Alat NIBP Simulator | REPOSITORY." Accessed: Nov. 06, 2025. [Online]. Available: [https://repository.poltekkesjkt2.ac.id/index.php?p=show\\_detail&id=10393&keywords=internal](https://repository.poltekkesjkt2.ac.id/index.php?p=show_detail&id=10393&keywords=internal)
- [12] "HEM-6161 - Monitor Tekanan Darah (Pergelangan tangan) - OMRON Healthcare Indonesia." Accessed: Jan. 28, 2026. [Online]. Available: <https://www.omronhealthcare-ap.com/id/product/344-hem-6161>
- [13] Fluke, Manual Book BP Pump 2, no. June. 2007.
- [14] Manual Book NIBP Simulator Contec MS200.
- [15] P. S. P. Silveira, J. E. Vieira, and J. de O. Siqueira, "Is the Bland-Altman plot method useful without inferences for accuracy, precision, and agreement?," *Revista de Saude Publica*, vol. 58, pp. 1–15, 2024, doi: 10.11606/s1518-8787.2024058005430.