EVERGREEN - Joint Journal of Novel Carbon Resource Sciences & Green Asia Strategy, Vol. 13, Issue 01, pp. 364-372, March, 2026

Evaluation of Sphygmomanometer Dial Performance Across Variable Temperatures and Pressure Conditions

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(Received May 27, 2025; Revised December 29, 2025; Accepted February 17, 2026)

Abstract: In this study, we evaluated the performance of aneroid sphygmomanometers dials manufacture under specific temperatures. Five different Sphygmomanometer dials were placed inside the chamber. The dials were kept in the chamber with five different temperature settings for 1 hour, and the pressures were applied to the dial from 0 to 300 mmHg and vice versa. The result shows that the performance of all the dial models based on a one-factor analysis of variance has shown that the parameters have significant effect. The variables affecting the performance sequentially are the pressure, model, temperature and the operator. Based on IEC 81060-1, type A &D are complied and type B, C, and E are not complied to the standard. The GRGR&R using the ANOVA method, the total GR&R based on % Combination Variance is 67.87% and % Study Variance is 82.38. The most significant sphygmomanometer dial model that affected the treatment is model C. This study indicates that based on IEC 81060-1 or by the GR&R, there are potential measurement consistency and accuracy issues, so the manufacturer requires some investigation and corrective action.

Keywords: aneroid; deviation; GR&R; pressure; sphygmomanometers; storage; temperature.

1. Introduction

The aneroid Sphygmomanometer is commonly used for the measurement of blood pressure. In general, aneroid blood pressure monitors are smaller than mercury ones[1]. They are made up of a thin brass corrugated bellows inside and a dial gauge that typically rises to 300 mmHg. However, they are easily damaged and can lose calibration without being noticed[2]. It is essential to evaluate the intrinsic properties of pressure gauges used, such as resolution, repeatability, hysteresis, drifts, and effects of environmental[3].

Routine calibration is needed to verify the accuracy of the blood pressure devices. Scheduled maintenance and calibration may be initiated by the manufacturer's supervisors or legal measures[4]. Thus, testing the Sphygmomanometer's accuracy in measuring static pressure is a crucial component of the verification process. The inaccuracy of the pressure measurement must be calculated in pressure increments of no more than 3 mmHg across the whole measuring range[5], and this pressure measurement should be applied to the Sphygmomanometer gauge.

The Sphygmomanometer gauge commonly used the Bourdon gauge; its twisted elastic tube connected to a needle. As the pressure within the tube increases, it aims to become straight, altering the position of the needle through a gear mechanism[6]. On some models, the gauge does not return to zero after deflating the cuff [7]. In this study, it's not just a deflated cuff but also stored in different temperatures. Pressure and temperature measurements are made for safety, control, and compensation[8]. Temperature and pressure readings are crucial for understanding, alerting, and reducing the chances of hazardous situations arising from physical changes in the gas or related equipment like compressors and pumps.

It should be noted that gas property follows the Ideal Gas Law. The four gas variables are: pressure (P), volume (V), number of moles of gas (n), and temperature (T). Lastly, the constant in the equation shown below is R, known as the gas constant[9,10]. Thus, if the pressure increases, so does the temperature, likewise, the if temperature rises, so does the pressure.

$$P.V = n.R.T \tag{1}$$

The manufacturer should consider the material properties of the Sphygmomanometer dial. The materials used in constructing the Sphygmomanometer dial may have temperature-dependent properties, affecting their performance and longevity. Modern alternatives like solid-state pressure transducers are designed to operate over a wide temperature range (-20 to +60°C) and are fully compensated, which helps maintain accuracy despite temperature fluctuations[11]. Hence, the manufacturer should keep their environment temperature condition. Since uncontrolled factory environments can introduce significant thermal variability, affecting the accuracy of measurements[4].

1.1. Conformity by SNI ISO 81060-1.2009

The international standard ISO 81060-1 outlines the specifications for the safety and fundamental functionality of non-automated sphygmomanometers and associated accessories, including the Sphygmomanometer dial, as well as explains the test methods to determine the accuracy. It states that the limit of error of the cuff pressure indication, the maximum at any point in the nominal measurement range for decreasing pressure must be less than or equal to ± 3 mmHg (± 0,4 kPa) or 2 %, whichever is larger[5]. Hence these error limits will be used to consider that the Sphygmomanometer dial model conforms to the Indonesian national standard adopted from the ISO as the same number[12].

1.2. Gauge Repeatability and Reproducibility (GR&R)

In quality management, GR&R analysis is the procedure used to assess the accuracy of a gauging device by making sure its measurements are consistent and reproducible[13-15]. This analysis will be used to verify that the output is the same value as the input and that the exact measurements are made over a specific period under the same operating conditions several measurements are taken to confirm the performance of the gauge[16,17].

Table 1: Acceptance Criteria % Contribution Variance

%R&R	Decision
<1 %	It's considered to be an acceptable measurement system
≥ 1% and ≤9%	It may be acceptable depending on the application and cost factor, but try to improve it
≥9%	It's considered to be unacceptable and should be improved

Table 2: Acceptance Criteria % Study Variance

%R&R	Decision
Under 10	Generally considered to be an acceptable measurement system
10 to 30	It may be acceptable for some applications.
Over 30	Considered to be unacceptable

Repeatability and Reproducibility are qualified measurement systems that include the measurement system analysis (MSA)[18-20]. In this study, the ANOVA method is used to examine which sources of variation have a significant impact on the result[21]. There are two criteria to determine the acceptance of GR&R. The first is based on percentage Contribution Variance[22], as shown in Table 1. The second criteria is based on acceptable of percentage Study Variance, based on The Automotive Industry Action Group (AIAG), Measurement Systems Analysis (MSA) Manual, Table 2[23].

There are a few references that discuss this topic. Previous research has been investigating the impact of ambient temperature on quartz Bourdon-type pressure gauges' long-term drift at high pressure settings[3]. Some researchers conduct studies on temperature effects on measurement devices such as general devices, such as gas sensing[24,25], submerged thermocouple[26], industrial contact thermometer [27], thermal pretreatment[28], and those are not for medical purposes. The other researcher researched the impact of temperature effect for medical devices, the study is for the chemical and comfortable purpose[29,30], or mostly to analyze the material properties[31]. Hence, in this paper, we will elaborate on the effect of temperature storage on medical devices' performance not for usage but the performance of medical devices especially the Sphygmomanometer dial performance manufacturing process.

Many institutions could design and conduct experiments to assess variations that arise from the operator, the individual components, and their interactions of their product. In this study, Gage Repeatability and Reproducibility (GR&R) analysis is applied, which involves collecting repeated measurements from multiple operators. This method enables the identification of the two primary sources of measurement variation—repeatability and reproducibility—and provides valuable insights into the factors influencing the sphygmomanometer manufacturing process.

2. Method

The setup of the measurement in this paper is shown in Figure 1. Five different Sphygmomanometer dials were placed inside the chamber. The dials were kept in the chamber with five different temperature settings which are -20, 10, 20, 40, and 70ºC, at constant relative humidity which is 85%, which represents the harsh environmental circumstances that products frequently encounter, particularly in tropical and coastal areas[32]. The pressure was given to the dial step by step at in interval of 30 mmHg from the low pressure to the high pressure, and vice versa, after 1 hour of storage. Three operators will do the measurement for each Sphygmomanometer dial.

The local manufacturer provided the Sphygmomanometer dials as the object of this study. The chamber specification in this study range is -4ºC to 80ºC. The pressure generator in this study uses a manual pressure generator, and the metal vessel volume is 500 ml. Statistical analysis is used to perform the result, and obtain the regression model, the % contribution variance criteria, and the % of study variance. Minitab is one of the tools used in this analyzing process, and graphing by Matlab is also used.

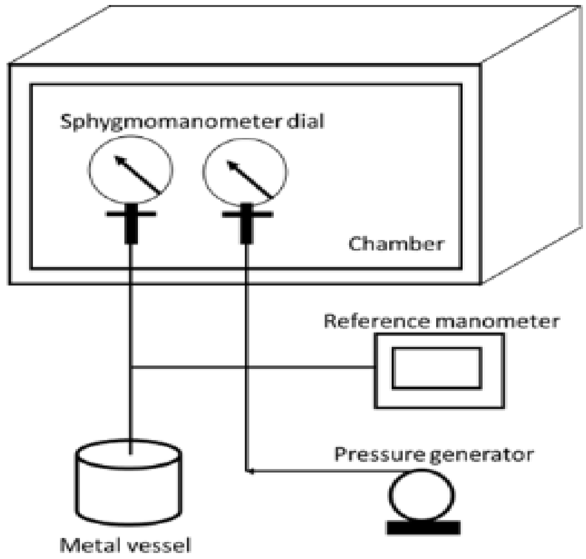

Fig. 1: Measurement setup

3. Result and Discussion

The result of five different models of sphygmomanometer dial after the temperature storage is shown on Figure 2, with the error bar included. Model A shows that at 10ºC there is no deviation effect. The average of the deviation for all temperatures is 0.35 ± 0.25 mmHg for model A. Model B, he averages deviation for all temperatures is 1.3 ± 0.37 mmHg, and at all temperature treatments, the deviation starts to increase at180 to 270 mmHg. However, at lower pressure, the deviation is not as high as at high pressure. These phenomena also happened to models C and model E, even though model D seems identical. However, the deviation at 40ºC is lower compared to the other temperatures. Although all the dials used the same material as their raw material, the deviation result differs after temperature storage. The possible cause is due to the manufacturing process of each Sphygmomanometer dial.

In terms of material explicitly used steel, increased heat led to the development of their pearlite phase, which lowered the total hardness value[33]. Hence it affected the material inside the Sphygmomanometer dial at a low temperature, which caused an increase in the hardness number and made the dial deviation lower.

At -20ºC, the zero point has shifted from the “ 0 ” on the dial marking, these phenomena did not happen at other temperatures, on models C and E (Figure 2.e). This phenomenon is called incorrect zero, and the gauge commonly does not return to “0” after the deflated cuff. However, in this study, it happened before it had been deflated. In this case, we suspect that pressure might be trapped inside the metal vessel, since all the dials are stored the same way during the temperature storage treatment. In the first deviation, models A and E have the lower deviate value.

In the second measurement, the inflation started from the high to the low pressure (decrease). The result is shown in Figure 3 with the error bar. Dial model A has the lowest pressure deviation compared to others. However, at -20ºC, the zero point has shifted to 0.33 mmHg. This value came from the average value of three times measurement, and the last measurement gave the higher contribution of the derivation. In this measurement, at 180 – 270 mmHg the deviation is higher than that of low pressure or at 300 mmHg for almost all dial models. As this dial works as a mechanical mechanism, it possesses a built-in natural resonant frequency. The system would oscillate with a significantly larger amplitude if the higher forces were applied at its resonant frequency. That is why the deviation is high at higher pressure compared to the low pressure[34]. Model A has the lowest deviation compared to the other dial model, in this measurement.

A Poisson Regression analysis was conducted to assess the influence of the variables pressure and temperature for each model on the deviation variable. The regression model for deviation at the first measurement from low to high pressure using in the exponential equation (e^Y) for each model of the dial is listed from equation 2 to 6. The R-sq of this equation model is 49.88% by p 0.000, and AIC (Akaike Information Criterion) value is 1901.97.

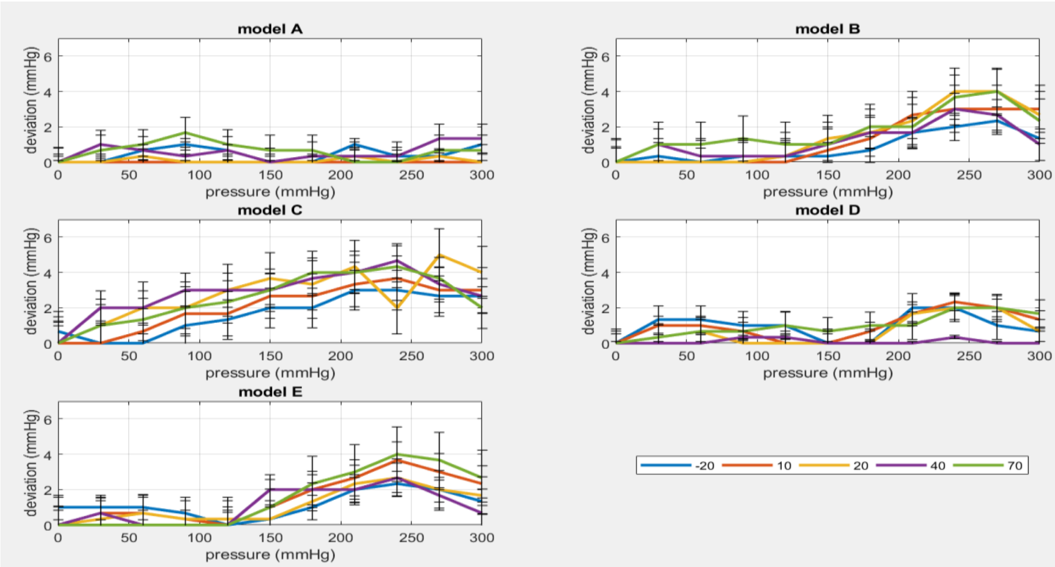

Fig. 2: Comparison of 5 different models deviation during pressurization from low to high

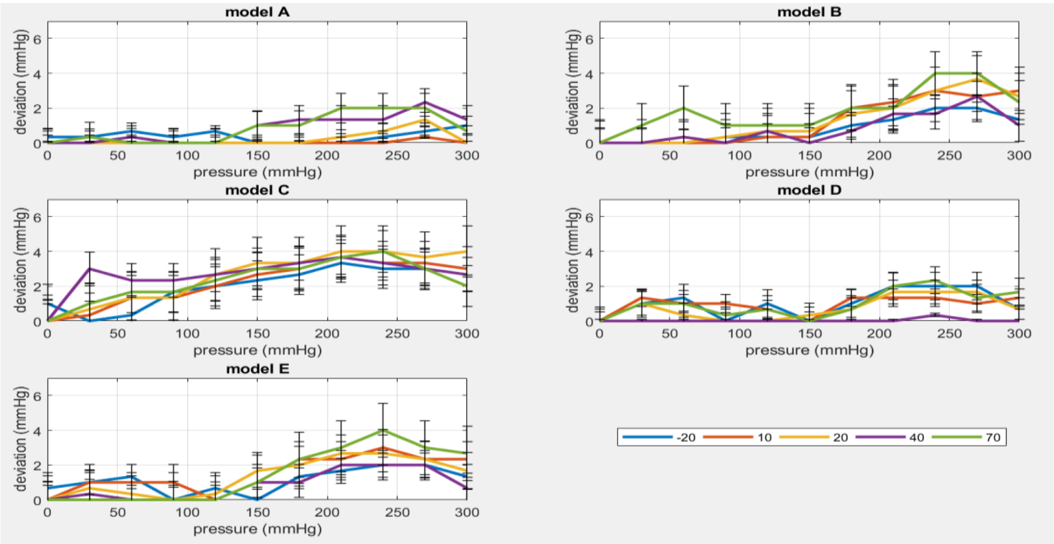

Fig. 3: Comparison of 5 different models deviation during pressurization from high to low

$$Deviation_{(modelA)} = e^{0.0061press+0.0039temp-2.22} \quad (2)$$

$$Deviation_{(modelB)} = e^{0.0061press+0.0039temp-0.91} \quad (3)$$

$$Deviation_{(modelC)} = e^{0.0061press+0.0039temp-0.30} \quad (4)$$

$$Deviation_{(modelD)} = e^{0.0061press+0.0039temp-1.49} \quad (5)$$

$$Deviation_{(modelE)} = e^{0.0061press+0.0039temp-0.95} \quad (6)$$

The regression model for the second measurement from high to low pressure for each model of the dial is listed from equation 7 to 11. The R-sq of this equation model is 49.24 % by p 0.000, and AIC value is 1880.99. In this model regression, the interaction between the operator is not included since the AIC value for regression model with interaction is almost the same as without interaction, which is 1905.1 and 1884.2.

$$Deviation_{1(modelA)} = e^{0.0063press+0.0031temp-1.96} \quad (7)$$

$$Deviation_{1(modelB)} = e^{0.0063press+0.0031temp-1.002} \quad (8)$$

$$Deviation_{1(modelC)} = e^{0.0063press+0.0031temp-0.36} \quad (9)$$

$$Deviation_{1(modelD)} = e^{0.0063press+0.0031temp-1.49} \quad (10)$$

$$Deviation_{1(modelE)} = e^{0.0063press+0.0031temp-0.98} \quad (11)$$

Based on the equation above we can conclude that all model assumes that pressure and temperature increase deviation by the same rate, and the only difference is the constant C, which shifts the entire curve up or down.

Constant determines how big the deviation starts, before pressure and temperature effects are added. The comparation of the deviation of each model from the equation for the first and second measurement (low to high and high to low pressure) shows in Figure 4. In the first group of equation, the temperature coefficient is 0.0039, it means that the measurement is more sensitive to temperature The second group equations change the way the models respond to pressure and temperature. By slightly increasing the pressure coefficient, the second equation makes all models react more strongly as pressure rises, especially at higher pressure levels. At the same time, the reduced temperature coefficient means that temperature now plays a smaller role in shaping the deviation curves. As a result, the differences between temperatures become less pronounced, and the models behave more consistently across a range of thermal conditions. Although each model's baseline value shifts due to changes in the constant term, their relative positions remain the same.

Overall, these adjustments create a system that is more sensitive to pressure but less influenced by temperature. This makes second group equation particularly useful in situations where pressure is the main factor affecting measurement accuracy. The reduced temperature sensitivity also helps stabilize the models in environments where temperature varies or is difficult to control. In practical terms, the revised formulas provide a clearer picture of how deviations grow with pressure while minimizing unnecessary fluctuations caused by temperature changes.

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Based on this study the environmental conditions such as high relative humidity (85%), elevated pressure, and high temperature have a measurable impact on the accuracy of pressure readings in sensitive equipment. Specifically, high humidity is associated with decreased pressure readings[35], posing challenges in tropical and oceanic climates. Similarly, high pressure can cause changes in sensor sensitivity[36], potentially affecting calibration consistency. Moreover, exposure to high temperatures leads to pressure drift (PD)[37], which undermines measurement stability over time. These effects underscore the importance of incorporating robust calibration and

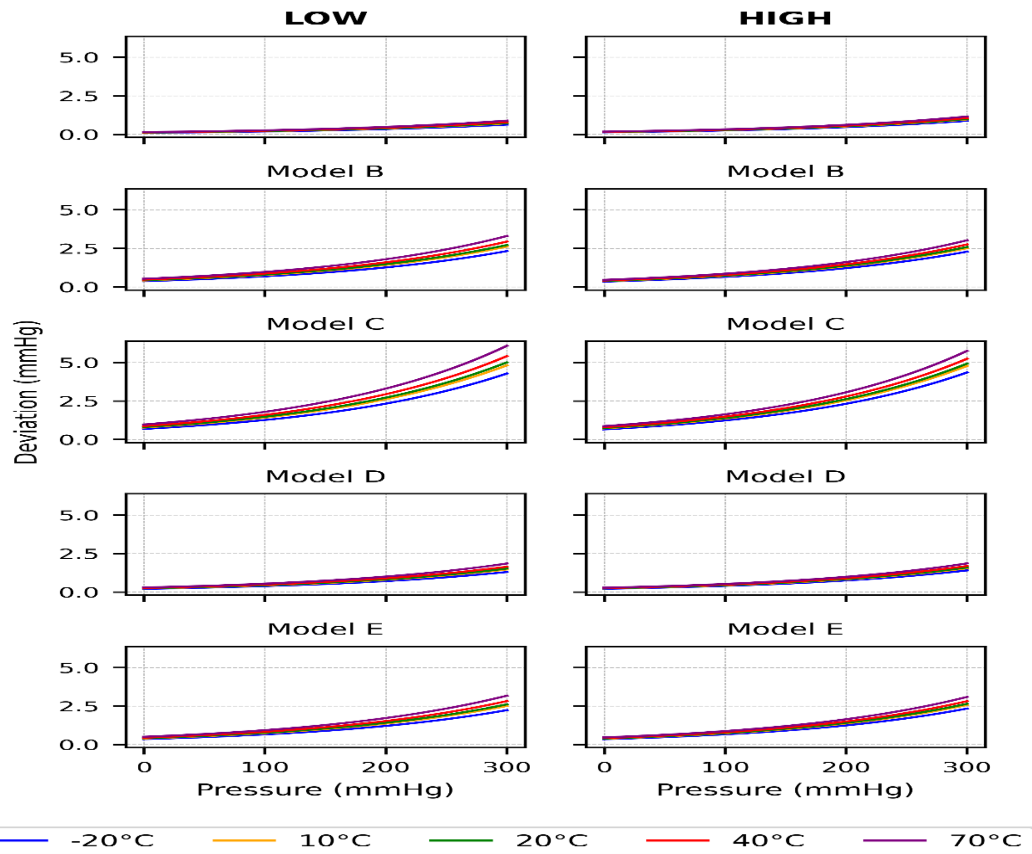

Fig. 4: Regression line from the equation for dial model A, B, C, D and E by measurement start from low to high pressure

Cite: W. Ardiatna et al., "Evaluation of Sphygmomanometer Dial Performance Across Variable Temperatures and Pressure Conditions". Evergreen, 13 (01) 364-372 (2026). https://doi.org/10.5109/7411071.

compensation strategies to ensure reliable performance in demanding environments.

3.1. Analysis based on ISO 81060-1

The performance analysis based on ISO 81060-1 shows that Sphygmomanometer dial model A and D are considered to conform to the standard requirement. The maximum deviation values of models A and D are 2.33 mmHg. Since the maximum deviation at any point in the nominal measurement range for increasing and decreasing pressure is more than ± 3 mmHg ± 0,4 kPa) or 2 %. Hence, the standard does not comply with Sphygmomanometer models B, C and E which have maximum deviation values 4, 5, and 4 mmHg. However, since this paper emphasizes the manufacturing process of the sphygmomanometer dial, hence the GR&R analysis needs to be done.

3.2. The GR&R analysis

Two-way ANOVA with interaction of model and operator will be showed in Table 3. This calculation is used as based of the ANOVA method for the GR&R analysis. The interaction between operators and models is important for the assessment of the reliability of the measurement systems. Since the model and the operator interaction P value is 0.666 (≥0.005), it is mean that the interaction is not significant between the models and the operators. And this statement is aligning with the statement from the model regression.

The GR&R analysis result based on the ANOVA model for the percentage of Contribution Variance (CV) is shown in Table 4. The result shows that the Total GR&R is ≥ 9 %, so it's considered to be unacceptable and should be improved. The Operator variance component is zero, therefore the reproducibility in this study is zero and interactions are not included.

The total GR&R %Study Variation (SV) is 82.38, based on Table 5. We can summarize that the percentage is above 30 %. It is considered unacceptable. Hence, the manufacturer's measurement system needs more effort to improve the result. The higher number of % CV and %SV may result from significant shifts in the performance of the apparatus or differences in the technique of the operator as well as the conditions in the lab.

The total GR&R based on this study shows that the values are above the requirement. It indicates potential measurement consistency and accuracy issues that require further investigation and corrective action. The first step involves assessing the stability of the measurement system by collecting data over a period of time, plotting the results on an X-bar chart, and analyzing them to confirm that the process remains within statistical control. Since the Sphygmomanometer dial is the most essential part of the aneroid Sphygmomanometer, the accuracy of this gauge is very important to minimize the error reading during blood pressure checking or monitoring.

Figure 5 shows that the dial model C deviation means the value is higher, compared to another Sphygmomanometer dial model, by all operators, the average is 2.36 mmHg. However, the dial models A, B, D, and E average deviation by all operators are within the requirement by the standard, 0.4, 1.25, 0.75, and 1.25 mmHg. Hence, the most significant Sphygmomanometer dial model that affected the temperature treatment is model C by p.0000.

Table 3: Two-way ANOVA with Interaction

Source	DF	SS	MS	F	P
model	4	719,21	179,802	215,293	0,000
operator	2	1,80	0,902	1,080	0,384
model* operator	8	6,68	0,835	0,729	0,666
Repeatability	1635	1872,10	1,145		
Total	1649	2599,79			

Table 4: Result of the % Contribution Variance

Source	VarComb	%Contribution (of VarComb)
Total Gauge R&R	1.14351	67.87
Repeatability	1.14351	67.87
Reproducibility	0.00000	0.00
operator	0.00000	0.00
Part-to Part	0.54139	32.13
Total Variation	1.68490	100

Table 5: Result of the % Study Variance

Source	SttDev (SD)	Study Var (6xSD)	%Study Var (%SV)
Total Gauge R&R	1.06935	6.41609	82.38
Repeatability	1.06935	6.41609	82.38
Reproducibility	0.00000	0.00000	0.00
operator	0.00000	0.00000	0.00
Part-to Part	0.73579	4.41476	58.69
Total Variation	1.29804	7.78822	100

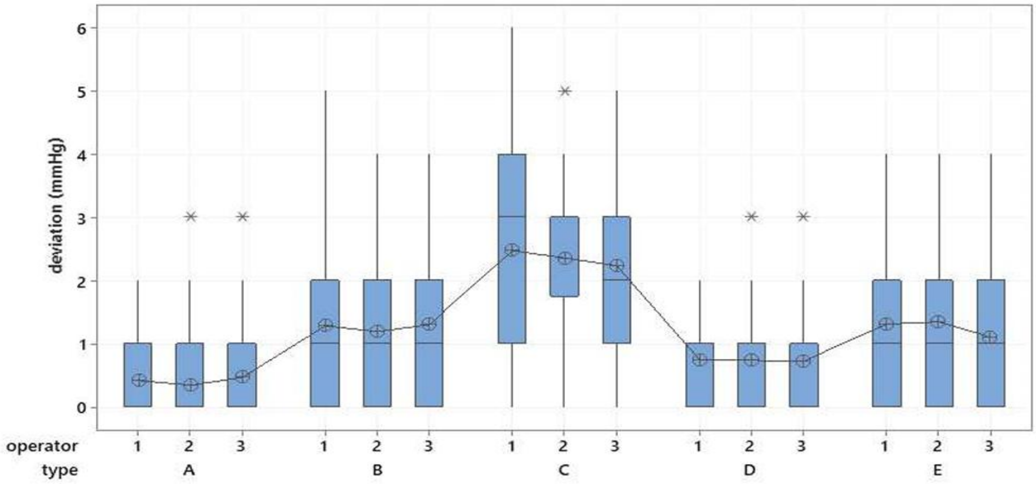

Fig. 5: Comparison of models A, B, C, D and E

4. Conclusion

The results show that, according to IEC 81060-1, sphygmomanometer types A and D meet the standard requirements, whereas types B, C, and E do not. The GR&R analysis using the ANOVA method indicates that the total GR&R is 67.87% for %Contribution Variance and for %Study Variance is 82.38%. Among all models, dial type C has the greatest impact on measurement variation. These findings suggest that, based on both IEC 81060-1 and the GR&R results, there are potential issues with measurement consistency and accuracy. Therefore, further investigation and corrective actions are recommended. The first step should be to evaluate the stability of the measurement system by collecting data over time, plotting the results on an X-bar control chart, and analyzing them to ensure the process remains statistically under control.

Acknowledgements

The authors gratefully acknowledge the valuable support provided by the National Research and Innovation Agency (BRIN) Republic of Indonesia, for contributions to this joint research collaboration. This joint effort was further supported by the Indonesia Endowment Fund for Education (LPDP) through the RIIM-4 Grant Program (Contract No. B-3837/II.7.5/FR.06.00/11/2023).

Nomenclature

P	pressure (kPa)
V	volume (L)
n	the number of moles
R	universal gas constant (kPa·L)/(mol·K).
T	Temperature (K)
CV	Contribution Variance (%)
SV	Study Variation (%)
R^2	coefficient of determination
AIC	Akaike Information Criterion

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