Measuring the oscillometric method contribution to the measurement uncertainty of automated sphygmomanometers using a patient simulator

B A Rodrigues Filho\(^1\), R F Farias\(^1\) and W E dos Anjos\(^2\)

\(^1\)National Institute of Metrology, Quality and Technology – Inmetro, 50 Nossa Senhora das Graças Av., Xerêm, Duque de Caxias, RJ, Brazil
\(^2\)Weights and Measures Institute of São Paulo – IPEM-SP, 154 Muriaé St., Ipiranga, São Paulo, SP, Brazil

E-mail: bafilho@inmetro.gov.br

Abstract. The sphygmomanometer is a widely used device for non-invasive blood pressure measurement. Systematic measurement errors and uncertainties can affect measurements, consequently, impacting diagnosis or medication. In order to maintain the conformity of the instruments, sphygmomanometers are usually under control of legal metrology demanding periodical verifications. Automated sphygmomanometers are based on the oscillometric method, measuring small changes of arterial blood pressure occurring in the cuff. Once pressure working standards are unable to generate the oscillometric pulses, verifications are performed on the sphygmomanometer on its manometer mode, disregarding the contribution of the oscillometric mode to the uncertainties. The present study investigates the contribution of the oscillometric method to the expanded measurement uncertainty. We used a patient simulator in four sphygmomanometers available in the market for consumers. The results show that the contribution of the oscillometric mode to the expanded uncertainty can be significant, varying from 0.16 to 1.56 mmHg and from 0.12 to 1.55 mmHg, for 100 and 150 mmHg, respectively. We also observed different contributions to the uncertainty for systolic and diastolic blood pressure.

1. Introduction

The sphygmomanometer is the device used for non-invasive blood pressure (BP) monitoring, widely used in primary care and health care, by practitioners, physicians and doctors in order to diagnose hypertension or monitor patients for medication. It is a simple procedure conducted also by individuals at home to monitor their condition. However, systematic deviations due to measurement errors and uncertainties can affect the results, consequently, impacting the diagnosis. For example, a healthy patient may be treated as a hypertensive one or a hypertensive one may not receive the proper treatment. Literature shows that 32.95\% of healthy patients would be diagnosed as hypertensive for a + 5 mmHg measurement error associate to ± 5 mmHg uncertainty, considering the diastolic pressure [1].

Sphygmomanometers are usually under the legal metrology regulation due to their impact on health, demanding verifications according to national requirements. The International Organization of
Legal Metrology (OIML) issues international standards, used as a recommendation applied by members and associate countries. Consequently, the instrument is subjected to type approval, verification and surveillance, i.e. the legal metrology control activities [2].

Automated sphygmomanometers have an increasing percentage in the market when compared to aneroid devices and mercury-based ones, which are being discontinued due to the poisonous aspect of mercury.

The measurement of automated sphygmomanometers is based on the oscillometric method, where an algorithm developed by each manufacturer, using empirical data, is responsible to recognize the small changes of arterial blood pressure occurring in the cuff. Those oscillations are used to identify both systolic and diastolic pressure [3]. Consequently, the oscillometric-based devices rely on previous clinical investigations in order to validate the manufacturer methodology [4].

Although the sphygmomanometers are submitted to verification after being placed on the market, the periodic verification tests do not represent the real use of the instrument. Since a working pressure standard is unable to generate small oscillations in pressure, simulating the blood pressure measurement, automated sphygmomanometers have a “testing mode”, where the oscillometric algorithm is disabled, testing only the manometer, and not all the aspects of the instrument. Consequently, an import metrological aspect regarding the oscillometric algorithm is not being tested during metrological verifications.

Moreover, for diagnostic purposes, since BP is affected by external factors, such as anxiety, several measurements are usually carried out in order to mitigate these factors [5]. So, the number of measurements taken increases the correctness in categorization the patients as healthy or hypertensive according to the treatment threshold [6]. Consequently, the sphygmomanometer repeatability plays an important aspect in this BP measurement methodology.

In order to verify the contribution of the oscillometric method to the sphygmomanometer performance, the present study carries out a test using a patient simulator in order to measure the contribution of the oscillometric component to the expanded measurement uncertainty.

2. Methodology
In order to check the metrological accordance of sphygmomanometers in-use conditions, we randomly purchased four different brands easily found on the Brazilian market. Despite the wide selection of brands available, we chose only those manufacturers whose metrological assurance is under the metrological supervision process. All tested instruments have a type approval certificate issued by Inmetro, the National Metrology Institute in Brazil. Two instruments take measures from the wrist and two from the upper arm, representing the most common sphygmomanometers found on the market for consumers. Sample characteristics are shown in table 1. For impartibility and confidentiality, the manufacturers are not disclosed.

| Sphygmo. | Measurement Taken | Measuring Interval (mmHg) |
|----------|-------------------|--------------------------|
| 1        | Upper arm         | 30 – 280                 |
| 2        | Upper arm         | 0 – 299                  |
| 3        | Wrist             | 40 – 250                 |
| 4        | Wrist             | 30 – 280                 |

Both accuracy of the electromechanical transducer and repeatability were tested in order to check the behavior of the sample. The applied measurement procedure for the accuracy test is in accordance with the OIML Recommendation [7], for automated sphygmomanometers verification. The contribution of the oscillometric method is evaluated by the repeatability of sphygmomanometers using a Dynatech Nevada Inc., model Non-Invasive Blood Pressure Analyser Cuff Link, whose repeatability = 0.6 mmHg is appropriate to test automated sphygmomanometers [8-9]. The patient simulator is a device that simulates the oscillation of blood pressure enabling metrological testing of
oscillometric automated sphygmomanometers in conditions representing a real individual. Figure 1 shows the experimental set-up.

![Figure 1](image1.png)

**Figure 1.** Experimental set-up for upper arm (a) and wrist (b) sphygmomanometers. Devices are blurred for confidentiality.

The measurements were performed within the recommended environmental conditions which range from 15° to 25° C for temperature, and 20 % to 85 % for relative humidity [7]. The measurement uncertainty is computed for both manometer and oscillometric mode according to the procedure described by the ISO GUM [10].

### 3. Results

Table 2 shows the comparison of the expanded measurement uncertainty regarding manometer (U\text{mano.}) and the oscillometric contribution for systolic (U\text{Oscill.}) and diastolic (U\text{D\text{Oscill.}}) BP. As each sphygmomanometer (sphygmo.) presents different repeatability for systolic and diastolic blood pressure, using the patient simulator, we observed distinct expanded uncertainties for either systolic or diastolic BP. The individual contribution to the combined uncertainty, due to the repeatability of the oscillometric mode, is seen in figure 2.

**Table 2.** Expanded measurement uncertainty for manometer-only and the manometer plus oscillometric mode.

| Standard Value (mmHg) | Sphygmo. 1 (upper arm) | Sphygmo. 2 (upper arm) | Sphygmo. 3 (wrist) | Sphygmo. 4 (wrist) |
|-----------------------|------------------------|------------------------|-------------------|-------------------|
|                       | U\text{mano.} | U\text{Oscill.} | U\text{D\text{Oscill.}} | U\text{mano.} | U\text{Oscill.} | U\text{D\text{Oscill.}} | U\text{mano.} | U\text{Oscill.} | U\text{D\text{Oscill.}} |
| 50.00                 | 0.59        | -          | 0.67          | 0.84        | -          | 0.91          | 0.59        | -          | 0.66          | 0.16        | -          | 0.33          |
| 80.00                 | 0.92        | 0.96       | 0.97          | 0.84        | 0.89       | 0.88          | 0.59        | 0.67       | 0.62          | 0.16        | 0.16       | 0.16          |
| 100.00                | 0.84        | -          | 0.90          | 0.84        | -          | 0.84          | 0.59        | -          | 0.59          | 0.16        | -          | 1.56          |
| 120.00                | 0.59        | 0.69       | -             | 0.84        | 0.89       | -             | 0.59        | 0.73       | -             | 0.16        | 0.16       | -             |
| 150.00                | 0.59        | 1.16       | 1.15          | 0.59        | 0.69       | 0.65          | 0.59        | 0.65       | 0.74          | 0.12        | 0.12       | 1.55          |
| 200.00                | 0.59        | 0.88       | -             | 0.84        | 0.95       | -             | 0.59        | 0.87       | -             | 0.11        | 0.11       | -             |
The contribution due to the oscillometric method is important, especially for the sphygmomanometer 4, where the expanded uncertainty for diastolic BP = 100 and 150 mmHg varies from 0.16 to 1.56 mmHg and from 0.12 to 1.55 mmHg, respectively. Sphygmomanometer 1 presents a similar behavior for BP=150 mmHg, where the expanded uncertainty varies from 0.59 to 1.16 mmHg for systolic BP and from 0.59 to 1.15 mmHg for diastolic BP. For the sphygmomanometer 1 to 4, we also observed an increasing contribution of the oscillometric component in the higher BP points, for both systolic and diastolic BP, as observed in figure 2.

Based on the contribution of the uncertainties due to the repeatability of the oscillometric mode and expanded uncertainty we conclude that expanded uncertainty is independent of the measurement taken location (wrist or upper arm), for the tested sphygmomanometers. For example, the sphygmomanometer 4 presented the smallest contributions to the uncertainty for systolic and the greatest ones for diastolic BP, according to figure 2.

Although the observed discrepancies, it is not possible to conclude which specific component of the programmed oscillometric mode contributes the most for the divergences, such as frequency of data acquisition, air inflate and release rate. A further investigation is necessary in order to rank the contribution of each of those components individually, however, the oscillometric program is kept confidential by manufacturers.

4. Conclusion

The sphygmomanometer is the device used for non-invasive blood pressure measurement, and more specifically, to control hypertension. A proper measurement is a vital aspect for proper diagnosis and use of medication. Consequently, the present study showed the contribution of the oscillometric method to the expanded measurement uncertainty.

This study revealed that all expanded uncertainties of tested devices, considering systolic and diastolic pressure, were influenced by the oscillometric contribution, especially for sphygmomanometers 1 and 4. We also concluded that the contribution of the oscillometric method is not impacted by the measurement location (wrist or upper arm).

Acknowledgments

The authors acknowledge the support of FAPESP (grant 2017/50173-0), which enabled us to carry out this research.
References

[1] Rodrigues Filho B A, Farias R F and dos Anjos W 2018 Evaluating the impact of measurement uncertainty in blood pressure measurement on hypertension diagnosis *Blood Press. Monit.* **23** 141-7

[2] Klenovsky P 2006 Legal metrological control over measuring instruments in use: current situation *OIML Bulletin* **XLVII** 22–33

[3] Amoore J N 2012 Oscillometric sphygmomanometers: a critical appraisal of current technology. [Review] *Blood Press. Monit.* **17** 80–8

[4] ISO 2013 *ISO 81060-2:2013(en)* Non-invasive Sphygmomanometers — Part 2: Clinical Investigation of Automated Measurement Type

[5] Padial L R, Fragoso A S, Moreno F J A, Arias M A, Castro A V and Roca G C R 2017 Blood pressure differences between one automatic measurement and the mean value of 3 automatic measurements. SPRINT trial *Med. Clin.-Barcelona* **149** 72–4

[6] Powers B J, Olsen M K, Smith V A, Woolson R F, Bosworth H B, Oddone E Z 2011 Measuring blood pressure for decision making and quality reporting: where and how many measures? *Ann. Intern. Med.* **154**(12) 781-8

[7] OIML 2002 *OIML 2002 R 16 - 2 Non-invasive Automated Sphygmomanometers* (International Organization of Legal Metrology)

[8] Farias R F and Neto J A G 2015 Evaluation of the repeatability of non-invasive blood pressure simulators *Proc. Metrologia 2015*

[9] Farias R F 2015 Evaluation of the Effectiveness of Legal Metrological Control of Automated Sphygmomanometers (Duque de Caxias, RJ: National Institute of Metrology, Quality and Technology - Inmetro)

[10] Joint Committee for Guides in Metrology 2008 *Guide to the Expression of Uncertainty in Measurement (GUM)* (Brookhaven National Laboratory)