

Metrology in Health

Good Practices Guide

Part II

Chapter I

Blood Pressure

Measuring Instruments

Metrology in Health – Good Practices Guide

Part II

Chapter I

Blood Pressure Measuring Instruments

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CHAPTER I

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PREFACE

In the health sector, measurements and measurement instruments play key roles in everyday lives. Several clinical decisions are based on the results of measurements and supported by the evidence. For various reasons, the results obtained from measurement systems may show variability that could lead to misdiagnosis and therefore incorrect treatments, compromising the accuracy of the measurement and the resources available.

In this context, this guide aims to provide general and specific concepts, applied to instruments and measuring systems, to be used as a consultation document and a guide to the implementation of best practices of *Metrology for Health*.

The structure of the second part of the Good Practice Guide - Metrology in Health is based on a dynamic platform, developed over several chapters, addressing the practical aspects applied to the handling and use of medical devices with measuring function.

It starts with a chapter on the theme of blood pressure measuring instruments, after which issues related to clinical thermometers and other measuring devices are addressed.

1. Sphygmomanometers

In clinical practice, many decisions relating to the diagnosis and treatment result from the analysis of blood pressure (BP) readings. The measurement of this criterion is regularly performed by using measuring instruments, known as sphygmomanometers.

Therefore, the correct BP measurement is of the utmost importance in the daily practice of health. It is a widely evaluated clinical parameter for the diagnosis and monitoring of an individual's health status. Several studies have shown that small variations in the BP may be clinically relevant, depending on the clinical condition of the patient (SCENIHR, 2009), (Dahlöf B, 2005), (Hansson L, 1998), (Yusuf S, 2008).

1.1 Characterization

In 1905, Russian surgeon Nikolai Korotkoff suggested the identification of systolic and diastolic BP by using the sphygmomanometer introduced by Riva-Rocci in 1896 (Shevchenko, *et al.*, 1996), (SCENIHR, 2009). According to the existing settings, systolic blood pressure is the maximum blood pressure in the arteries caused by contraction of the heart ventricles, while the diastolic blood pressure is the minimum blood pressure in the arteries, which occurs in the filling phase and relaxation of the ventricles (Peura, 1998), (Geddes, 1991).

According to the measuring method, sphygmomanometers can be either manual and automatic (Figure 1). Regardless of the type, the measurement result of BP should be shown in kilopascals (kPa) or millimetres of mercury (mmHg).

Detailed information will be presented in the following items.

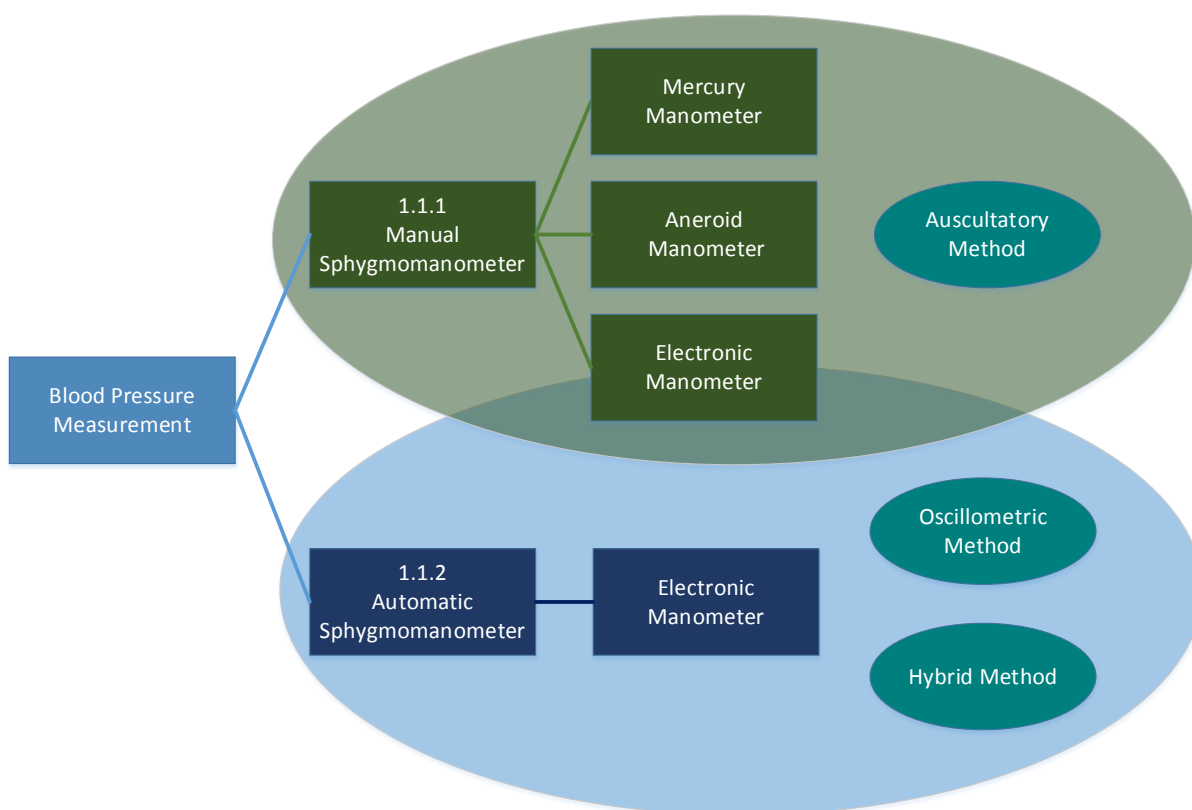


Figure 1: Blood pressure measuring instruments

1.1.1 Manual Sphygmomanometer

Manual sphygmomanometers are instruments that measure BP by the auscultatory method, based on the auscultation of the sounds of the individual's artery (SCENIHR, 2009), (OIML R 16-1, 2002).

Manual sphygmomanometers consist of:

- A rubber cuff, which when inflated allows it to press the artery of the arm;
- An air pump, also referred to as a bulb, with a valve, which serves to inflate and deflate the cuff;
- Mercury, aneroid or electronic manometer, which is the pressure measuring instrument.

Measurement process

The measurement process begins with placing the cuff on the patient's arm, inflating it at a pressure that obstructs the bloodstream in the brachial artery (a pressure higher than the systolic BP). After this first step, the deflation process begins. When the systolic BP is reached, the first Korotkoff sounds can be heard by using a stethoscope. This sound is caused by the turbulent flow of blood in the artery (SCENIHR, 2009). During the deflating process, the sound continues to be heard, gradually decreasing in intensity, until the same pressure is reached in the cuff and in the artery. This pressure,

from which sounds are no longer heard, should be considered as the diastolic BP (SCENIHR, 2009), (Peura, 1998) (Shevchenko, *et al.*, 1996).

The auscultatory method has limitations, mainly the influence of the hearing sensitivity of the person doing the measuring. In addition, in individuals with irregular heart beat (arrhythmias or tachycardia), an incorrect interpretation of sounds may lead to errors in BP measurement.

Mercury column, aneroid and electronic manometer

In the early days of BP measurements, the widespread use of mercury column manometer sphygmomanometers led to the pressure measurement being expressed in units of millimetres of mercury, mmHg.

In clinical validation, these instruments are still considered by several authors (Shah AS, 2012), (SCENIHR, 2009) as the benchmark in the measurement of non-invasive BP, characterized by high measurement accuracy. However, in view of the harmful effects of mercury, and in accordance with current EU Regulation no. 847/2012 of the Commission, of 19 September 2012 (UE, 2012), there are restrictions on the use of mercury sphygmomanometers, and steps have been taken to restrict the clinical use of these instruments (Shimek, 2011).

Consequently, considering the current legislation (Decree-Law no. 76/2008 of 28 April and Directive 2007/51/CE), the commercialization of instruments containing mercury is prohibited. However, this legislation is only applicable to new instruments and does not restrict the use of the existing instruments until the end of their lifetime.




Therefore, considering the current regulatory framework, sphygmomanometers with mercury manometers have been progressively replaced by sphygmomanometers with aneroid or electronic manometers.

Aneroid manometer sphygmomanometers are instruments in which the detected pressure is transferred to a gauge pointer (analogue display) (MHRA, 2013), through a mechanical system and an elastic expansion chamber.

In manual sphygmomanometers with electronic manometer, the pressure is indicated on a digital device, requiring electrical power for its operation (SCENIHR, 2009). Table 1 shows the various types of manual sphygmomanometers and their main characteristics.

Table 1: Types of manual Sphygmomanometers

Source: Adapted from (MHRA, 2013), (SCENIHR, 2009).

Mercury manometer sphygmomanometer	Instruments that use a mercury column manometer, an inflatable cuff and an inflation pump (bulb).	
Aneroid manometer sphygmomanometer	Instruments that use a scale and pointer manometer, called an aneroid, an inflatable cuff and an inflation pump (bulb).	
Electronic manometer sphygmomanometer	Instruments with an electronic indicator and a pressure sensor. The cuff is manually inflated using an inflation pump (bulb).	

1.1.2 Automatic Sphygmomanometer

Automatic sphygmomanometers, in their simplest version, and because of their low cost and ease of use, are usually marketed for use in the daily monitoring of BP by the general population.

In recent years, these measuring instruments have evolved with the introduction of multiple modules. Nowadays, in different healthcare establishments, professionals are increasingly turning to automatic multi-parameter instruments for measuring BP (Table 2).

In accordance with the international guidelines, namely OIML R 16-2: 2002 and IEC 80601-2-30: 2013, automatic sphygmomanometers consist of:

- A pneumatic system, which includes a cuff, air pump, valves, tubes and connectors;

- An electronic manometer with electromechanical pressure transducer, which transforms pressure signals into electrical signals;
- A digital display device.

Measurement methods

These measuring instruments (automatic sphygmomanometers) use the oscillometric method and the mixed method for the measurement of BP (MHRA, 2013).

The **oscillometric method** is a non-invasive method, which measures the amplitude of the pressure oscillations created by the expansion of the artery walls each time the blood flows.

In instruments based on this method, the inflation and deflation of the cuffs are obtained automatically. After the cuff pressure increases above the systolic BP, it decreases at a constant rate. During deflation, the cuff pressure measurement signal begins to oscillate, with an increasing amplitude from the systolic pressure, reaching the maximum oscillation when it reaches the mean BP (SCENIHR, 2009). As the cuff inflation pressure continues to decrease, the amplitude of the oscillations will decrease proportionally until the cuff is completely empty. There is no well-defined break point in the oscillations of the signal, which continue to decrease even below the diastolic pressure level. According to Robert Peura (Peura, 1998), sphygmomanometers using the oscillometric method use specific algorithms, developed by the manufacturers, for the determination of diastolic BP.

The main advantage of instruments with oscillometric methods is how easy they are to operate, even for home use.

After placing the cuff on the arm, the entire process is automatic until the end of the measurement with the respective BP reading shown on the digital display device.

However, the oscillometric method has some drawbacks: the measured pressure oscillation signal in the cuff depends on the pressure in the artery wall and the heart rate, so any variation in its state can induce measurement errors. In addition, the BP reading is calculated by mathematical algorithms adjusted to a specific group of individuals, considered to have normal heart rates. For this reason, the oscillometric method poses limitations in individuals with arrhythmias, tachycardia, diabetes, among other health conditions that involve an irregular heartbeat (SCENIHR, 2009).

The **hybrid method** combines both auscultatory and oscillometric measurement methods.




Currently, there are instruments that combine the two methods of measurement by incorporating a microphone in the cuff, applying algorithms to obtain the pressure reading through sound.

These instruments, which are available on the market, use the auscultatory method to validate the measurement result obtained by oscillometry, and also identify objects in the acquired signal (SCENIHR, 2009), (MHRA, 2013). The main limitation of this method is related to noise and incorrect positioning of the microphone in the cuff (SCENIHR, 2009).

It is important to consider that all these instruments have their limitations and advantages, so the choice of a measuring instrument should always call into consideration the various factors that influence and determine the measurement accuracy, as well as the clinical measurement process itself.

Table 2: Automatic sphygmomanometers typology

Source: Adapted from (MHRA, 2013), (SCENIHR, 2009).

Electronic manometer Sphygmomanometers	Instrument equipped with an electronic monitor, pressure sensor and electrically activated pump that inflates a cuff placed on the wrist, finger or arm. These measuring instruments are the most commonly used at home.	
	Instrument that offers the possibility to automatically measure blood pressure, heart rate, oxygen saturation (SpO2) and body temperature. It may include the BP record over time, with the possibility of an alarm.	
	These measuring instruments are usually used in clinical environments, and are called "Non-Invasive BP Monitors" (MHRA, 2013). Instrument with the same characteristics as the previous ones, but performing several cycles of BP monitoring automatically, at predetermined intervals. It indicates the results of non-invasive and invasive BP measurement, heart rate, oxygen saturation (SpO2), body temperature and monitors the ECG cycle. These measuring instruments are usually referred to as "Vital Signs Monitors" and are used in clinical environments.	

1.2 Technical and Metrological Requirements

The definition of the technical and metrological requirements of measuring instruments is essential for the characterization of the instrument and for the measurement process.

Health establishments should develop processes and procedures to ensure methodologies for monitoring the measuring instruments in accordance with applicable metrological requirements.

In accordance with the recommendations of the International Organization for Legal Metrology, namely OIML R 16-1: 2002 and OIML R 16-2: 2002, and the International Electrotechnical Commission's standards IEC 80601-2-30: 2013, the requirements that a measurement instrument should meet are: general requirements; metrological requirements; technical requirements and safety requirements.

Annex 1 to this document provides detailed information on the essential requirements for all sphygmomanometers.

Conformity assessment

Pursuant to Decree-Law no. 145/2009 of 17 June and Order No. 136/96 of 3 May, only the instruments that meet the essential requirements, have been subject to a compliance evaluation and respect the reciprocal compatibility between manufacturers, may be placed on the market.

In this context, all manual and automatic sphygmomanometers meeting the essential requirements set out in Annex 1 to this document must display the CE marking, affixed by the manufacturer.

Additional and complementary information on the main parameters to consider is available for consultation in Annex 1.

1.3 Traceability and Metrological Compliance

The BP measurement, widely used by the general community, requires high attention to its proper execution as well as in the metrological conditions of the measuring instrument, the manometer. Among other sources, the error and uncertainty associated with BP measurement depend on the conditions of the pressure gauge, a key instrument for assuring the quality of the measurements.

Considering the universe of sphygmomanometers in health facilities, priorities are often defined according to the critical use of the various instruments. Therefore, the services should prepare a calibration plan for the sphygmomanometers (see example in Table 3) and define its periodicity,

according to the history of the instrument, scope of use, manufacturer's guidelines and criticality of use of each sphygmomanometer.

In accordance with the performance of the instrument and the implemented evaluation criteria, the initially defined calibration period may be altered if duly substantiated.

In addition to this information, consultation of the Best Practices Guide is recommended - Part I (IPQ, 2015).

Table 3: Calibration plan example

Instrument	Brand	Serial number	Inventory number	Calibration period	Last calibration date
Aneroid sphygmomanometer					
Automatic sphygmomanometer					
Multi-Parameter Vital Signs Monitor					

1.3.1 Validation of the Calibration Certificate/Test Report

For the approval of the condition of use of a measuring instrument the Maximum Permissible Measurement Error (MPME) is defined, applying it to the following equation:

$$|E| + |U| \leq \text{MPME} \quad (\text{Equation 1})$$

where E corresponds to the measurement error and U to the expanded uncertainty of the measurement. Therefore, after calibration or testing (by an entity whose competence is recognized) for an instrument to be accepted and considered to be in conformity for use, the sum of the absolute value of the error and the uncertainty must be less than or equal to the MPME. This condition is usually the acceptance criterion defined by the owner of the instrument. This parameter can also be established by reference documentation (such as the manufacturer's instructions).

However, it should be noted that the value to be considered as MPME must always be justified by the person in charge of the instrument/organisation.

It is recommended that the maximum permissible measurement errors of the BP parameters be established prior to the use of the instrument. For reference purposes, OIML R 16-1: 2002 is a current medium (Annex 1).

For the assessment of the measurement error and uncertainty consultation of the Best Practices Guide - Part I (IPQ, 2015), as well as other applicable documents, is suggested.

It should also be noted that the identification of the sphygmomanometer's metrological condition must be easily accessible and available to everyone who uses it for clinical measurements. For this purpose, and in addition to the respective calibration labels affixed to the instrument (Figure 3), it is recommended to use electronic platforms to share information on the metrological status of the measuring instruments in use.

1.4 Maintenance

With the objective of reducing and eliminating faults, maintenance is reflected in all preventive or corrective activities necessary for the correct operation of the instruments and all their accessories.

According to Portuguese standard NP EN 13306: 2010, preventive maintenance aims to prevent the occurrence of failures, increasing the time between them (MTBF - *mean time between failures*) and, consequently, increasing the reliability and operational availability of the instruments. In this regard, inspections, cleaning and replacement of parts subject to wear and tear are relevant and imperative in the context of best practices. Visual inspection, cleaning and "zero point" adjustment (when applicable) are requirements that should be performed on a daily basis. In addition to the above, the annual plans should consider cuff, inflation bulbs and sphygmomanometer valves replacement, as well as availability of parts subject to wear and tear. However, in order to define the appropriate periodicity of maintenance for each sphygmomanometer, the instrument's use, its location and the criticality of the results obtained should always be analysed.

It should also be noted that, among other things, preventive maintenance operations should always comply with the actions described by the instrument manufacturer, applying the normative reference NP EN ISO 13460: 2009.

It is recommended that all information on maintenance interventions be properly filed and that the condition of the instrument be known to the users, as well as any reported malfunction.



Figure 2: NIBP monitor with its calibration and maintenance labels

1.5 Best Usage Practices

Blood pressure measurement is influenced by several factors, such as the condition of the instrument and its limitations, handling, measurement procedure, user behaviour or inherent variability of the BP (Table 4).

Table 4: Impact factors for measuring Blood Pressure

Measurement Instrument	<p>It is important to ensure that the instrument:</p> <ul style="list-style-type: none">• Shows adequate metrological traceability as well as the inherent maintenance operations.• Is suitable for the user in question.
Handling and measurement procedure	<p>It is important that the health professional has specific training in the use of the instrument.</p> <ul style="list-style-type: none">• The health professional should ensure:<ul style="list-style-type: none">- a suitable environment for measurement;

	<ul style="list-style-type: none">- appropriate cuff size;- BP measurement of both arms ¹;• In the case of measurements based on the auscultatory method, it is also important that the health professional is trained in the collection and detection of Korotkoff sounds.
User behaviour	The user should be in a comfortable position, sitting down, with both arms on a table or lying down, and wait a few seconds before the measurement. The user should not speak during the reading.

It is important to always carry out at least two measurements, with a maximum difference of one minute between the two, to reduce the errors caused by anxiety and to obtain more significant readings. If the difference between the two measurements is greater than 10 mmHg, the first measurement should not be considered and a new measurement should be carried out (British Hypertension Society, 2006).

For instruments using the auscultatory method, the measurement should be carried out according to the following approach:

1. Confirm that the arm is relaxed, not tensed, and that the cuff is placed correctly, approximately at the level of the heart (British Hypertension Society, 2006), (OIML R 16-1:2002);
2. Use the correct size cuff, which should cover at least 80% of the upper arm and have an arm circumference to cuff width ratio of approximately 0.40 (Table 5).
3. Confirm that the initial reading, before inflation, is 0 mmHg (OIML R 16-1, 2002). If not, contact technical support;
4. Inflate the pressure cuff up to approximately 30 mmHg above the systolic pressure value, obtained by palpation (O'Brien. E, 2005), (British Hypertension Society, 2006);
5. Deflate the instrument between 2 and 3 mmHg/s. A rate greater than 3 mmHg/s induces a reading error and a reading of less than 2 mmHg/s makes the measurement uncomfortable for the user, as the cuff will compress the arm for a longer period (O'Brien. E, 2005);
6. Measure the diastolic pressure when the sound disappears (O'Brien. E, 2005).

¹ The first BP measurement must be done in both arms, since there are differences in BP value exceeding 10 mmHg. This difference is more pronounced in the elderly. Subsequent BP measurements should be performed on the arm with the higher reading (Thomas P., 2005).

Table 5: Dimension of the pressure cuff

Source: (British Hypertension Society, 2006).

Cuff indication	Width (cm)	Length (cm)	Arm's circumference (cm)
Child/Small adult	10-12	18-24	< 23
Average adult	12-13	23-35	< 33
Large adult	12-16	35-40	< 50
Thigh cuff, adult	20	42	< 53

In the case of sphygmomanometers that operate according to the oscillometric method, only items 1 to 3 of the previous list should be considered.

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Annex I

Main requirements of sphygmomanometers

Parameters		Manual Sphygmomanometers OIML R 16-1: 2002	Automatic Sphygmomanometers OIML R 16-2:2002 and IEC 80601-2-30:2013
General requirements	Measurement Unit	millimetre of mercury (mmHg) or kilopascal (kPa)	
	Identification of the measuring instrument	Clear and readable identification of manufacturer and instrument (make, model, serial no. and inventory no.)	
	Manufacturer's directions	Circumference diameter Indication according to the dimensions of the arm as well as the correct placement of the cuff and the way of use.	Indication of the correct position and appropriate cuff circumference, for the limb; Indication of the mode of use and instrument specifications.
	Maximum Permissible Measurement Error	Conditions with room temperature(t) between 15 °C and 25 °C and relative humidity (hr) between 20 % and 80 %: ± 0,5 kPa (± 4 mmHg), for sphygmomanometers already in use ± 0,4 kPa (± 3 mmHg), for sphygmomanometers used for the first time or in variable t and high hr (> 85 %) conditions	
Metrological Requirements	Measurement interval	0 kPa to 35 kPa or 0 mmHg to 260 mmHg	According to OIML R 16-2: 2002, the measuring range must be specified by the manufacturer. According to IEC 80601-2-30: 2013, automatic sphygmomanometers must have a measuring range of: <u>Diastolic pressure:</u> 5,3 kPa (40 mmHg) to 17,3 kPa (130 mmHg) in adults and 2,7 kPa (20 mmHg) to 8,0 kPa

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		(60 mmHg) in the neonatal module. <u>Systolic pressure:</u> 8,0 kPa (60 mmHg) to 30,7 kPa (230 mmHg) in adults and 5,3 kPa (40 mmHg) to 14,7 kPa (110 mmHg) in the neonatal module.
	Resolution	0.2 kPa or 2 mmHg 0,1 kPa or 1 mmHg
Technical Require	Pressure reduction rate	Deflation rate of deflation valves: 0,3 kPa/s to 0,4 kPa/s or 2 mmHg/s to 3 mmHg/s
	Rapid deflation of the pneumatic system	With the valve fully open, the deflation time, from 35 kPa to 2 kPa (260 mmHg to 15 mmHg), should not exceed 10 s. With the valve fully open, the deflation time, from 35 kPa to 2 kPa (260 mmHg to 15 mmHg), should not exceed 10 s. In the case of instruments with neonatal and paediatric modules, the deflation time, from 20 kPa to 0,7 kPa (150 mmHg to 5 mmHg), should not exceed 5 s.
	Cuff Dimension	Width: 40 % of the arm's circumference at the cuff's application midpoint. Height: 80 % (preferably 100 %) of the arm's circumference at the cuff's application midpoint.
	Air leakage	Air leakage must not exceed a deflation rate of 0,5 kPa/min (4 mmHg/min). Air leakage must not exceed a deflation rate of 0,8 kPa/min (6 mmHg/min).
	Electrical safety	In accordance with the normative reference IEC 60601-1:2015.
ents	Mechanical safety	Avoid using the instrument on uneven or sharp surfaces that could cause damage.

Annex 2

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