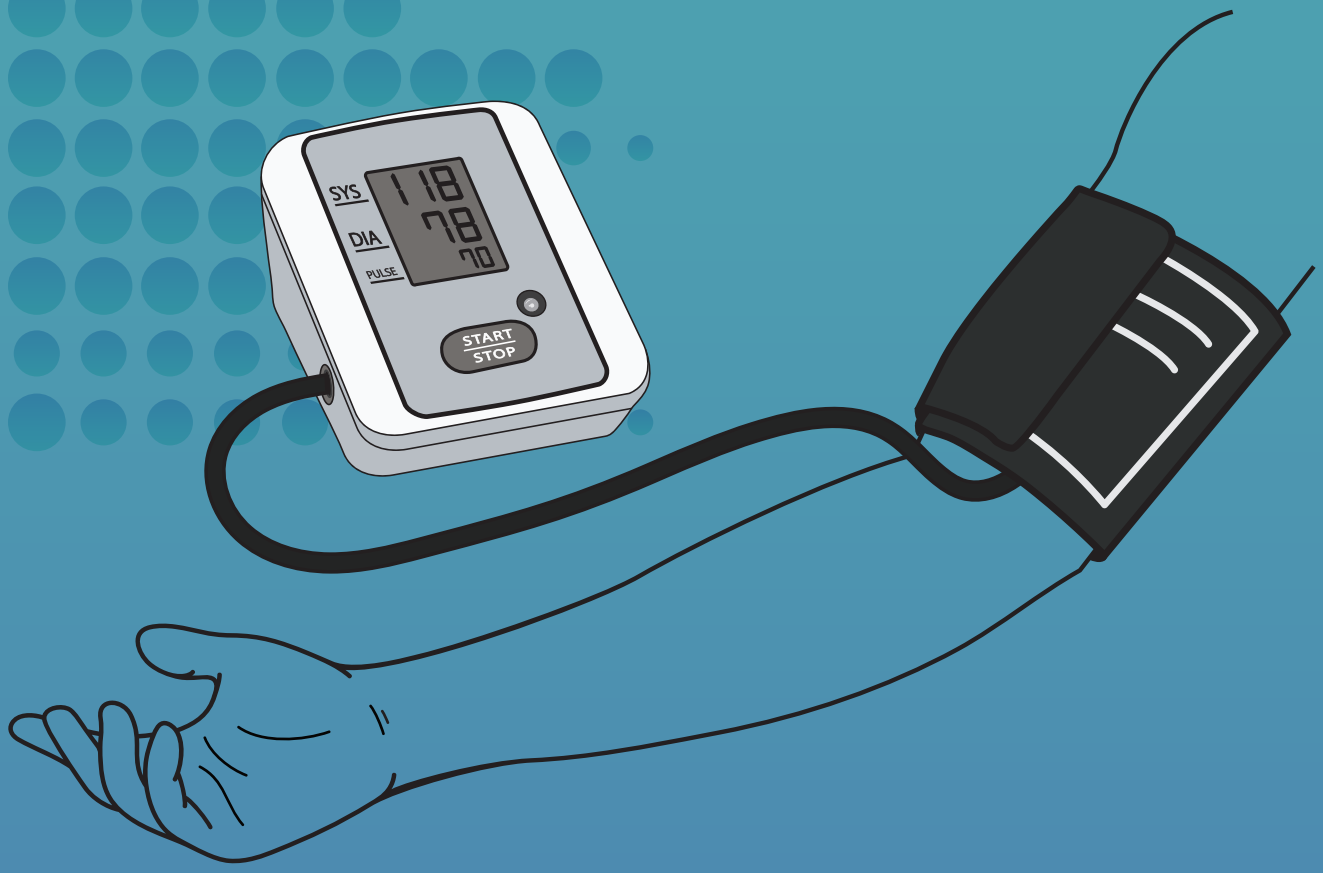
World Health Organization

WHO TECHNICAL SPECIFICATIONS FOR AUTOMATED NON-INVASIVE BLOOD PRESSURE MEASURING DEVICES WITH CUFF

WHO MEDICAL DEVICE TECHNICAL SERIES



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WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff

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Contents

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The document updates WHO's 2005 guidance on blood pressure measuring devices (BPMDs) *(1)*. It also responds to concern about the lack of accurate, good-quality devices, especially in low-and middle-income countries (LMIC), which was expressed at a workshop on blood pressure (BP) measurement during the 4th WHO Global Forum on Medical Devices held in India on 13–15 December 2018.

Laura Patricia López Meneses, a WHO consultant, drafted the document, which was discussed at an expert consultation on technical specifications for automated non-invasive BPMDs with cuff, that took place in Geneva, Switzerland, from 25–26 June 2019. The meeting further discussed the scope and content of this publication and steps for implementation. The document then underwent external review. The technical experts who participated in the consultation, and provided technical review to the document, were: Aletta E Schutte (North-West University, South African Medical Research Council, South Africa; University of New South Wales; The George Institute for Global Health, Australia; International Society of Hypertension), Tammy Brady (Johns Hopkins University, USA), Margaret Farrell (Resolve to Save Lives an initiative of Vital Strategies, USA), Norm Campbell (University of Calgary, Canada), Mulugeta Mideksa (Biomedical Engineer, Ethiopia), Marc Jaffe (Resolve to Save Lives an initiative of Vital Strategies and Kaiser Permanente, USA), Oommen John (The George Institute for Global Health, India), Mohammad Ameel (WHO Collaborating Centre for Priority Medical Devices and Health Technology Policy, Ministry of Health and Family Welfare, India) and Laura Alejandra Velez (WHO Operations Support and Logistics). All participants declared any conflicts of interest, which were reviewed by the WHO compliance unit.

After the expert consultation, a second draft was prepared with input from WHO consultants: George Schmidt, Eunice Lorenzo and Jennifer de Francesco, with organizational support and compilation by Valeria Montant, WHO intern.

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The publication was edited by Elisabeth Heseltine. Designed by L'IV Com Sàrl.

Acronyms and abbreviations

ANSI	American National Standards Institute
BP	Blood Pressure
BPMD	Blood Pressure Measuring Device
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
LED	light-emitting diode
LMIC	low- and middle-income countries
MAP	Mean Arterial Pressure
UNDP	United Nations Development Programme
WHO	World Health Organization

Glossary

Accuracy: The closeness of a determined value of a physical dimension to the real value. Ability to perform without making errors.

Aneroid sphygmomanometer: A manual BPMD with a manometer, composed of an inflation bulb for controlling the air pressure within the cuff that is attached to the manometer by tubing. The manometer head contains mechanical parts that convert the cuff pressure into readings.

Arterial BP: The pressure exerted in the arteries in the systemic circulation. Depends on the cardiac output, arterial elasticity, blood viscosity and peripheral vascular resistance.

Auscultatory technique: BP measurement technique used with a manual sphygmomanometer. Systolic and diastolic BP is detected from Korotkoff sounds using a stethoscope or microphone positioned over a compressed artery during cuff deflation.

Automated BPMD: A device that estimates BP after automatic inflation and deflation of the cuff and displays the values on an electronic display. The semi-automated device requires manual inflation.

Brachial artery: A major artery in the upper arm, which is compressed by the BP cuff during BP measurement.

Calibration: Steps taken to ensure that a BPMD measures BP accurately. This is typically done by testing the device against a gold standard. When an aneroid sphygmomanometer does not provide accurate BP reading, the device can be adjusted (calibrated) to produce accurate measurements. Automated BPMDs that are inaccurate should be sent to the manufacturer for repair.

Diastolic BP: The pressure in blood vessels when the heart rests between beats.

Eclampsia: Seizures resulting from high BP in a pregnant woman. This is a complication of pre-eclampsia.

Korotkoff sounds: Sounds emitted from a fully compressed artery as it becomes un-occluded during BP cuff deflation. These sounds are indicative of arterial flow and are used to determine BP.

Manual BPMD: Device for estimating arterial BP using the auscultatory technique. Systolic and diastolic BP is detected from Korotkoff sounds using a stethoscope or microphone positioned over a compressed artery during cuff deflation.

Mercury sphygmomanometer: Manual device for measuring BP, composed of an inflation bulb for controlling the air pressure in the cuff which is attached to a measuring unit and a mercury-infused glass column which displays BP (values in mm Hg). No longer recommended by WHO for clinical use, due to the need to phase-out mercury in health facilities.

Oscillometric technique: BP measurement technique used with automated or electronic BPMDs. Cuff deflation +/- inflation is initiated by the device which detects arterial oscillations, or variations in intracuff pressure caused by changes in pulse volume induced by the heartbeat at different applied pressures. The maximal oscillation during either inflation or deflation (device specific) corresponds to the mean arterial pressure and is used to calculate the systolic and diastolic BP using proprietary algorithms.

Pre-eclampsia: A condition that may develop during pregnancy, characterized by high BP (hypertension), proteinuria and edema.

Semi-automated BPMD: Device that operates by manual cuff inflation and electronic cuff deflation. BP is estimated as with other electronic devices. This device is energy-efficient because the cuff is inflated manually with a bulb.

Sphygmomanometer: Medical device for measuring arterial BP compromised of a cuff, an inflation bulb with release valve and a manometer (typically either a mercury column or an aneroid dial).

Spot-check BPMD: An electronic BPMD with an electrical pump that inflates the upper arm cuff and a digital display that shows the BP measurement. This device is typically designed to provide continuous BP monitoring in a hospital setting but could also be used to provide "spot checks" of BP (i.e. intermittent resting BP measurements).

Systolic BP: The maximal pressure in the aorta when the heart contracts and ejects blood from the left ventricle.

Validation: A term used to indicate the process by which devices are tested for accuracy. A "validated device" is one that has undergone rigorous, standardized testing against a gold standard to ensure that the device produces accurate measurements.

Executive summary

Hypertension is the leading modifiable risk factor for serious diseases such as cardiovascular disease (stroke and ischaemic heart disease), pre-eclampsia and eclampsia (a major killer of pregnant women and a cause of poor fetal growth and stillbirth) and chronic kidney disease. Globally, over one billion people have hypertension, with a higher prevalence in LMIC. Accurate BP measurement is essential to identify and properly manage individuals with hypertension, a silent killer with few symptoms.

Lack of access to accurate, affordable BP devices is a significant barrier to proper medical care, particularly in low-resource settings. Manual BP measurement is gradually being replaced by automated measurement because of environmental concerns about mercury, poor calibration and improper measurement with aneroid devices in clinical practice and the superior consistent accuracy of validated automated devices. There is, however, frequent concern about the accuracy of automated devices that have not been validated.

The document updates WHO's 2005 guidance on blood pressure measuring devices (BPMDs). It also responds to concern about the lack of accurate, good-quality devices, especially in low-and middle-income countries (LMIC) through technical consultation and expert review.

The focus of the publication is on automated non-invasive BPMDs with cuff, including characteristics, regulatory requirements and standards, calibration as well as maintenance. It also provides guidance on procurement, decontamination and decommissioning. Additional elements on accurate measurement of BP and training for personnel are included.

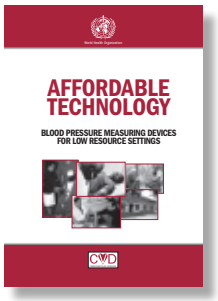
1 Introduction

This document describes the performance and technical aspects of automated non-invasive BPMDs, which are essential for optimal diagnosis and treatment of hypertension, particularly in LMICs. It also outlines the importance of measuring BP and identifies the barriers to access of accurate and affordable BPMDs.

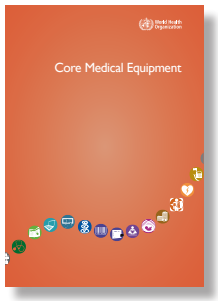
The scope of this document is on non-invasive upper arm BPMD with cuff, using oscillometric method, which is the preferred option to measure BP. Nevertheless, this document also mentions the manual BPMD aneroid for where automated is not available and mercury, only for callibration. It also describe other cuffless innovative technologies but further evidence for recommendation is needed. The document thus complies with WHO guidance to countries regarding phasing out mercury-containing sphygmomanometers in the health care sector in the context of the Minamata Convention on Mercury (see Annex 1). This version replaces the 2005 WHO publication on affordable technology blood pressure measuring devices for low-resource settings *(1)*.

The document is based on evidence and data on the predictive value of non-invasive upper-arm BP measurements. It includes discussion and comparison of alternative devices and standards to build consensus for shaping the global market. It is intended for regulators, policy-makers, programme managers, biomedical engineers, BP device manufacturers and industries, procurement officers and health care providers. It should assist procurement agencies and regulatory authorities to prepare policy, management and supply accordingly. Manufacturers should comply with the technical specifications outlined as minimum requirements to ensure safety and efficiency. Health workers, academics and the general population may benefit from this resource, as it may improve their understanding of BP devices and their capacity to measure BP accurately.

The following WHO publications are complementary to the body of this technical guidance and specification document:



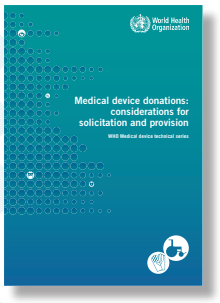
Affordable technology blood pressure measuring devices for low-resource settings
2003
https://apps.who.int/iris/handle/10665/43115



Core medical equipment
2011
http://apps.who.int/medicinedocs/documents/s22062en/s22062en.pdf

Procurement process resource guide
2011
https://www.who.int/medical_devices/publications/procurement_guide/en/

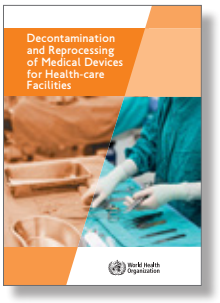
Phasing out mercury thermometers and sphygmomanometers in health care
2015
https://apps.who.int/iris/bitstream/handle/10665/259448/9789241508339-eng.pdf?sequence=1



Medical device donations: considerations for solicitation and provision

2016

https://www.who.int/medical_devices/management_use/manage_donations/en/



Decontamination and reprocessing of medical devices for health-care facilities

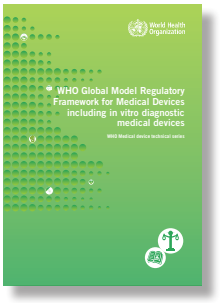
2016

https://www.who.int/infection-prevention/publications/decontamination/en/

WHO compendium of innovative health technologies for low-resource settings

2016–2017

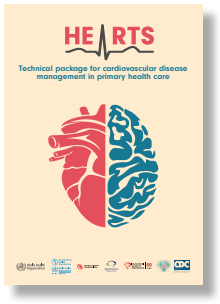
https://www.who.int/medical_devices/publications/compendium_2016_2017/en/



WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices

2017

https://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/



HEARTS Technical Package

2018

https://www.who.int/cardiovascular_diseases/hearts/en/

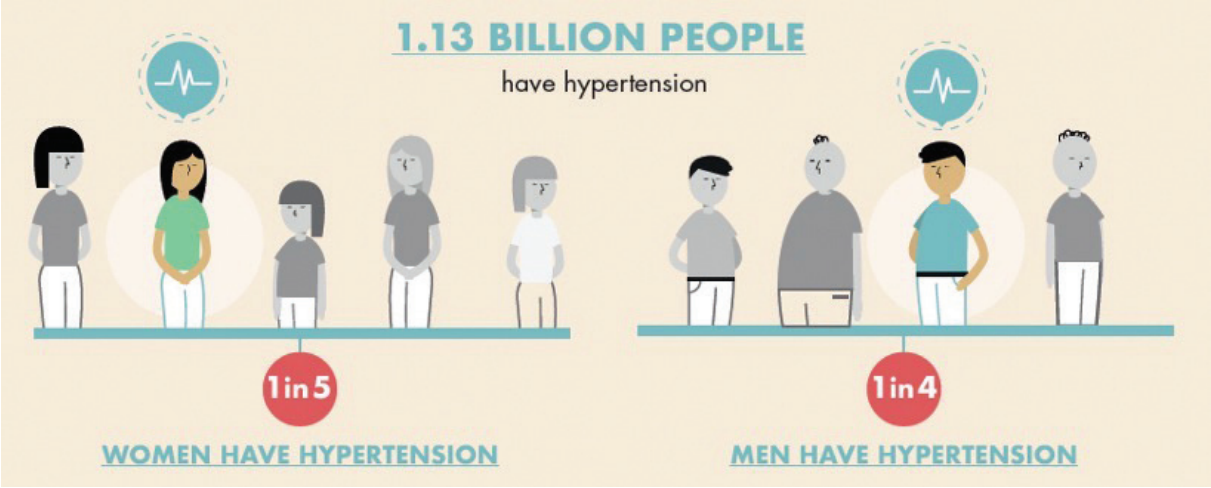
Decommissioning medical devices

2019

https://apps.who.int/iris/bitstream/handle/10665/330095/9789241517041-eng.pdf?sequence=1&isAllowed=y

2
Global burden of hypertension

In 2015, the global prevalence of hypertension was estimated to be more than 1.1 billion *(2)* (Fig.1). The highest prevalence of raised BP among people aged ≥ 18 years was in low-income countries (28.4%) and middle-income countries (25.5%). In 2017, the Global Burden of Disease study found that raised systolic BP was the leading modifiable risk factor for death globally, with 10.4 million deaths annually attributed to this cause *(3)*.



Sources: WHO.

Fig. 1. Global prevalence of hypertension

Hypertension is a leading risk factor for cardiovascular disease, including coronary artery disease, heart failure, chronic kidney disease, stroke, heart attack, dementia, peripheral vascular disease, fetal and maternal death and premature death.

2.1 BP measurement

BP is created by the combination of the force from the heart as blood is pumped into circulation against arterial walls, the blood volume and the elasticity of the muscular arteries. BP is an essential indicator of physiological and functional status. It can be affected by changes in blood volume, the pumping efficiency of the heart and peripheral vascular resistance *(4)*. BP is highly variable, changing with each beat of the heart, and is affected by the physical environment (e.g. temperature), stimulation such as noise, physical and mental activity, exogenous substances (e.g. diet, drugs, alcohol) and disease. Most people have a daily twofold variation between the lowest and the highest BP. To assess an individual's usual BP when screening for hypertension, the variables that cause rapid changes in BP must be standardized by controlling the environment and patient factors before measurement to reduce variation and improve reproducibility.

A rapid, substantial, sustained increase in BP can directly damage blood vessels, although most damage occurs over a long period through atherosclerosis, when even small increases in BP within the normal range cause damage. The greater the increase in usual BP, the more cardiac and blood vessel damage and the

higher the risk. Individuals are considered to have hypertension when their BP is sustained above a certain threshold, such as 130/80 or 140/90 mm Hg.

Critical components of BP assessment include use of an accurate device and an appropriate setting along with proper preparation of the subject and consistent use of a recommended standardized measurement technique. Accurate BP measurement is essential to identify hypertension and to guide treatment decisions, including when to start medication and when to adjust the dose. Inaccurate BP measurement can result in diagnostic errors and incorrect decision-making and risk assessment.

2.2 The need for good quality BPMDs

Selection of an accurate, validated BPMD is important for assessing BP as these devices will provide accurate and reproducible measurements. Accurate BP measurements are essential to manage hypertension, as imprecise measurement can significantly affect diagnosis and treatment. In one study, the diagnostic classification of > 50% of people changed when their BP was measured with a standardized method rather than a usual clinical method *(5)*.

Upper extremity automatic oscillometric BP measurement is preferred, auscultatory BP measurement during routine clinic visits, partly due to environmental apprehension about mercury *(6)*, the suboptimal accuracy of aneroid devices in usual clinical care and concern for observer error with the auscultatory method, which includes visual and auditory defects and terminal digit preference. Independently of where BP is measured (outpatient clinic, hospital, home) or how (manual, automated), the primary requirement is that the measurement device be safe and accurate *(7)*.

Several barriers to accurate BP measurement have been identified, particularly in LMICs. These include poor access to inexpensive devices; difficulty in maintaining devices; challenges in ensuring a consistent power source, including concern for damage to the environment from the batteries of electronic devices and their cost for replacement; limited awareness of the problems associated with auscultatory BP devices and the hazard of mercury; and lack of training of health workers *(1)*. Practical issues are being raised in LMICs regarding the choice of validated BP devices, ensuring appropriate use and education on the importance of device validation and regular calibration and maintenance.

3
Non-invasive BPMDs with cuff

BP can be measured either invasively (directly) or noninvasively (indirectly). Screening, diagnosis and treatment of hypertension are done solely with non-invasive devices, whereas invasive monitoring is used in a hospital setting for cardiovascular monitoring to allow quicker assessment of both hyper- and hypotension. Invasive methods should be used only in specialized health care settings. The present document refers only to non-invasive or indirect methods, in which external pressure on the upper arm is used to assess BP. Fig. 2 illustrates the two main methods of BP measurement and their subcategories.

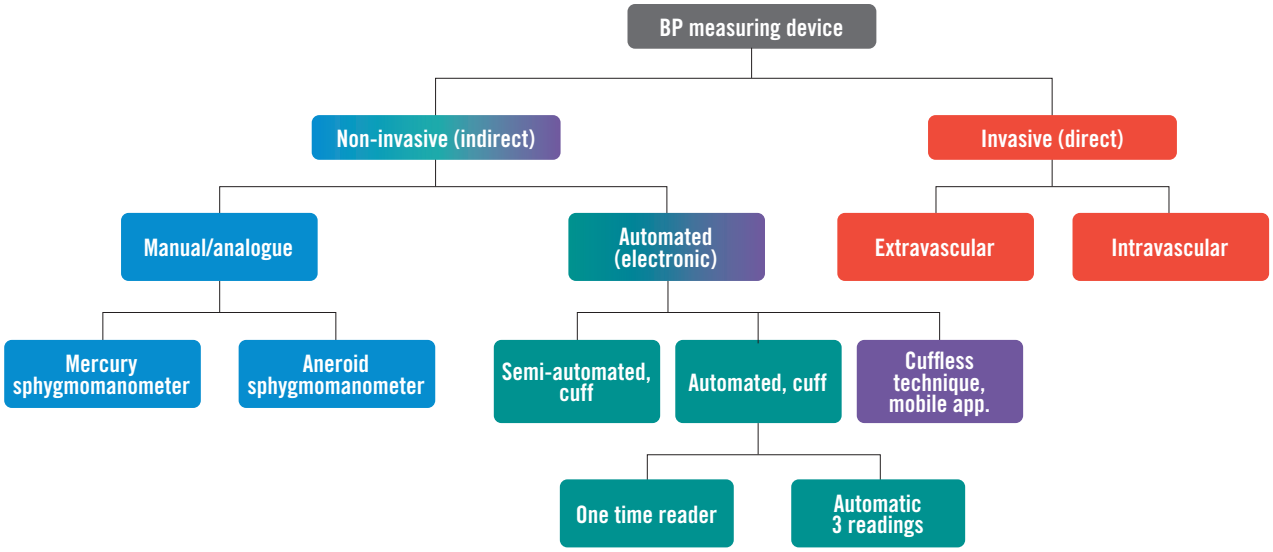


Fig. 2. Main means for measuring BP

The scope of this publication will only focus on semi-automated and automated non-invasive BPMDs with cuff.

For non-invasive BP measurement there is a vast range of medical devices that use different technology to display the results. Each type has advantages and disadvantages, which makes them less or more suitable for certain use and level of care. Table 1 lists the advantages and disadvantages of various devices.

Table 1. Subcategories of non-invasive BPMDs and their advantages and disadvantages

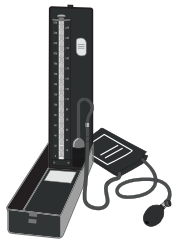
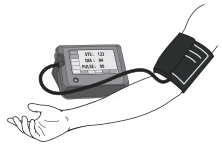
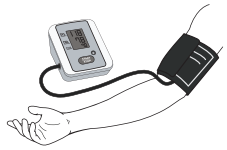
	Manual / analogue		Electronic / automated			
Type	**Mercury sphygmomanometer**	**Aneroid sphygmomanometer**	**Semi-automated, cuff**	**Automated, cuff**		**Cuffless technique, mobile app.**
Illustration						
Recommend?	No longer, because of toxicity of mercury	Not recommended because requires frequent recalibration and observer training and retraining	Only accuracy validated automated BPMDs are recommended for clinical use			Not suitable or recommended for clinical use because of lack of universal standards for validating the accuracy of BP measurements
Reference on publication	Annex 6. Technical specifications and use of manual non-invasive BPMDs		Chapter 3. Automated non-invasive BPMDs			Chapter 5. Innovation and research
Brief description	Pressure cuff, hand pump, mercury column, stethoscope	Pressure cuff, hand pump, aneroid (mechanical transducer), stethoscope	Pressure cuff, hand pump to inflate cuff, automated deflation and determination of BP	Pressure cuff automatically inflates and deflates to determine one BP	Pressure cuff automatically inflates and deflates to determine multiple BP after a predetermined period of rest and with a predetermined pause between repeated measurements. All measurements ± an average of measurements is displayed.	E.g. tonometry, pulse transit time, ultrasound or magnetic method, tissue characteristic methods, machine-learning methods, heart rate variation and heartrate power spectrum ratio, photoplethysmography, heart rate and smartphone technology
Method of BP estimation	Detection of Korotkoff sounds through a stethoscope for auscultation.		Two possible methods: Most common: Detection of arterial flow (oscillometry), in which pulses sensed through the cuff are filtered, amplified, processed and applied to an algorithm to estimate systolic and diastolic BP. Least common: Detection of Korotkoff sounds by the device with a pressure transducer (auscultatory), which are then used to estimate BP			Variable

Table 1. Subcategories of non-invasive BPMDs and their advantages and disadvantages (continued)

	Manual / analogue		Electronic / automated		
Type	**Mercury sphygmomanometer**	**Aneroid sphygmomanometer**	**Semi-automated, cuff**	**Automated, cuff**	**Cuffless technique, mobile app.**
Advantages	• Often referred to as gold standard or reference • No need for calibration, inexpensive, does not require electricity	• Inexpensive and portable • Does not require electricity	• Portable • Easy to use • Fewer observer errors • Minimal observer bias or terminal digit preference • Good for screening • Home use • Saves time and clinical resources • Less expertise and training required when used in the absence of a health care provider • Calibration not required		• Can measure during motion or continuously (beat-to-beat) • Easy measurement without discomfort due to inflation, no limb size limitations (e.g. obese patients)
Disadvantages	• Risk of noise interference • Expertise and retraining required to avoid observer error • Requires manual dexterity to ensure proper cuff deflation rate • Risk of observer bias and terminal digit preference • Requires excellent hearing and vision		• Requires access to a continuous power source (electricity or battery) • Requires validation by standard protocol (some are validated only for adults) • Manufacturer variation due to proprietary algorithm for estimation • Some are inaccurate • Cost and longevity of device • Integrity of cuff and tubing essential to maintain accuracy over time • Must be replaced periodically because of mechanical failure		• Generally poor accuracy; more trials are needed • No current accuracy validation standards; devices need to be tested to ensure accuracy.
	Mercury is an environmental hazard	• Requires regular calibration (at least every 6 months) • A device can lose calibration (become inaccurate) when it is jostled or bumped, leading to false readings • Often inaccurate in clinical practice if no routine accuracy testing	Requires manual inflation of cuff, which can lead to false measurements if cuff not fully inflated	Many are not suitable for patients with atrial fibrillation	

Sources: References *(1, 8, 9)*.

The market for electronic/automated BPMDs has grown in the past few years, contributing to a larger variety which makes specification of the different types of devices much more significant. Fig. 3 shows the various types of electronic BPMD available *(8)*.

Automated (spot-check) device	Spot-check NIBP monitor	Automatic-cycling NIBP monitor	Multi-parameter monitors	Ambulatory BP monitor	Wrist device	Finger device
Electronic battery powered monitor, pressure sensor, electrical pump, digital display and upper arm cuff. May display pulse rate, memory.	More sophisticated than automated, for routine clinical assessment. May measure other vital signs using upper-arm cuff. Main and battery powered.	Similar to spot-check NIBP, automatic-cycling, facility to record, bed side monitoring. May measure other vital signs using upper arm cuff. Alarms. DC and AC.	For use in critical care wards and operating theatres; monitors a wide range of vital signs, including BP (with upper arm cuff). Ethernet or Wi-Fi.	Same as automated, it is all attached to patient´s belt. Records patient´s BP at different intervals over 24-hour period using upper arm cuff, and stores data.	Electronic battery powered. Function similar to automated, pump attached to a wrist cuff.	Electronic monitor finger cuff or device attached to finger. Could use different techniques.

Source: Reference *(8)*.

Fig. 3. Electronic BPMDs

Not all the variety of external pressure cuffs that are available, such as wrist and finger devices, are suitable for clinical use, because they have not been validated for accuracy. Other non-invasive methods for measuring BP are beyond the scope of this document.

4

Automated non-invasive BPMDs with cuff

This section presents the characteristics of electronic BP devices designed for use on the upper arm. Automated and semi-automated oscillometric devices are easier for health care workers to use than manual devices, and they avoid potential observer error due to variations in user technique and hearing acuity in listening for Korotkoff sounds *(10, 11)* (see Glossary).

4.1 Description

Electronic BP devices are used to measure and display arterial BP by automated and semi-automated inflation and deflation of a cuff applied to an extremity. The cuff is usually positioned on the upper arm for even compression of the brachial artery, which is the standard location for BP measurement *(12)*. In some electronic devices, the cuff is placed over the radial artery on the wrist; however, these devices may give inaccurate measurements, particularly if the arm is not kept at heart level during measurement and if the radial artery is not evenly compressed *(13)*. In addition, as systolic and diastolic pressure vary substantially in different parts of the arterial tree, a radial BP measurement may not be equivalent to a brachial artery measurement *(14)*. Therefore, most guidelines do not recommend their use. Similarly, devices for measuring BP in a digital artery are no longer recommended because their accuracy is critically affected by the position of the limb and peripheral vasoconstriction *(15)*.

Electronic devices can provide BP measurements on demand by the clinician (immediately after pushing a button with automated devices) or after pre-set intervals without a clinician present (several minutes after pushing a button with fully automated devices). One of the main benefits of automated devices is reduced human error *(15)*. Additionally, most such units display other physiological indicators, such as the pulse rate or heart rate, adding to their clinical usefulness. Some automatic BPMDs have auditory and visual alarms that are activated if a patient's BP or pulse rate drops below or exceeds the limits established by the user or clinician.

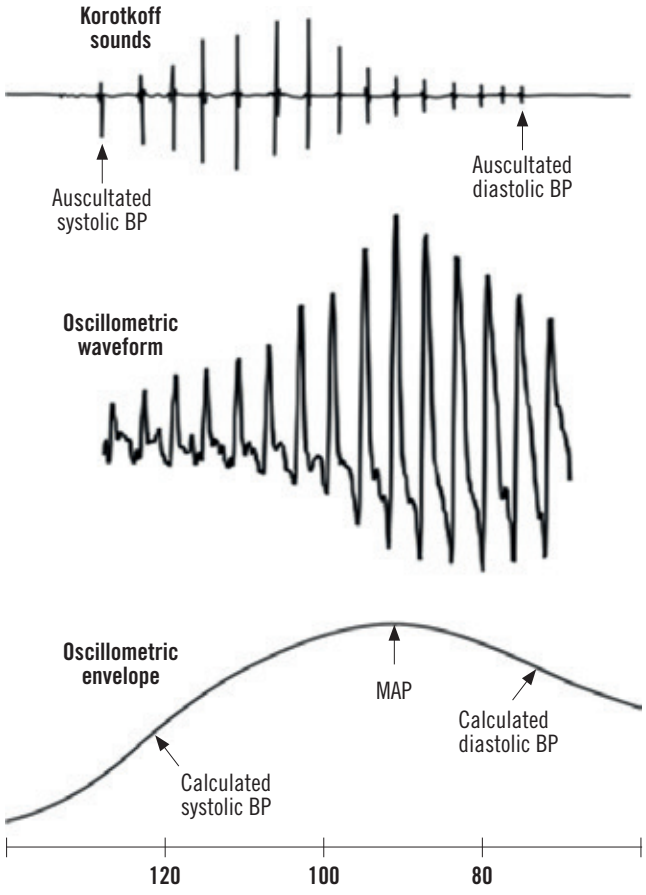
Regulatory agencies, such as the Medicines and Healthcare Products Regulatory Agency in the United Kingdom, recognize that some automated BP devices may not give reliable results for patients with heart arrhythmia, pre-eclampsia or certain vascular diseases. It is therefore recommended that calibrated, non-mercury devices that do not rely on oscillometry be available in all clinical areas *(8)*.

4.2 Measurement principles

Most automated, or electronic, devices on the market utilize the *oscillometric technique* for BP measurement. With this technique, BP is estimated from oscillations detected during inflation or deflation of the BPMD's cuff using proprietary algorithms that vary among manufacturers. This technique does not include Korotkoff sounds; instead, the cuff occludes an artery (typically the brachial artery) and acts as a transducer to detect the small variations in intracuff pressures that occur with changes in heartbeat-induced pulse volume at different cuff pressures. The maximal oscillation during cuff inflation or deflation corresponds to the mean arterial pressure (MAP). This measured value (the MAP) is used to estimate systolic and diastolic BP with the previously mentioned algorithms. In these devices, a microprocessor inflates and slowly deflates a cuff *(16)*.

Some automated devices estimate BP using Korotkoff sounds. These devices contain a microphone that is positioned against the compressed artery to detect Korotkoff sounds, which determine both systolic and diastolic pressure. Unlike the automated devices that measure the MAP and use that value to calculate the systolic BP and diastolic BP, these devices estimate BP from Korotkoff sounds and use those values to calculate the MAP. MAP measures are shown on an electronic display *(15)*, which may be a liquid crystal, light-emitting diode (LED) that produces either a numerical display, or a simulated pointer of an aneroid gauge. A disadvantage of these devices is that they require electrical power.

Fig. 4 contrasts manual BP measurement (with auscultation of Korotkoff sounds) to automated oscillometric measurement from a mathematical oscillometric waveform envelope derived from proprietary algorithms.



MAP, mean arterial pressure.
Source: Reference *(17)*.

Fig. 4. Comparison of auscultatory and oscillometric techniques for measuring BP

Ultrasonic techniques (Doppler ultrasound) are based on the Doppler phenomenon, which is variation in the frequency of sound waves with the speed of the sound transmitter in relation to the sound receiver. These devices depend on the shift in sound waves when they encounter red blood cells. When the ultrasound strikes an immobile structure such as a compressed arterial wall, the ultrasound frequency is rejected unchanged. If a moving structure (pulsating artery) is encountered, however, the frequency is altered up or down (Doppler effect), and this is detectable as an audible alteration in sound *(18)*.

4.3 Regulatory requirements and standards

Resolution WHA 67.20, adopted in 2014, calls for strengthening of regulatory systems for medical products. The resolution states that "effective regulatory systems are an essential component of health system strengthening and contribute to better health outcomes" *(19)*. Every medical device must comply with complex regulations and procedures, strict specifications and safe clinical performance. As BPMDs are considered "life-critical", they must be safe and effective for use in clinical practice *(20)*.

"Standards" are defined generically as technical specifications adopted by a recognized standardization body for repeated or continuous application. Application of standards is voluntary, but their wide use with respect to medical devices ensures that the sector is uniform. For example, in the European Union, harmonized standards are a specific set of standards that allow a presumption of conformity with the essential or general requirements in European regulatory documents (directives and regulations) that foresee CE marking of products. In this context, manufacturers are not obliged to use the harmonized standards, but, if they do, they must comply with the requirement of being covered by that standard. In other counties, use of specific standards may be required at a regulatory level *(21)*.

A different but complementary definition of a standard in the medical device domain is that of the International Organization for Standardization (ISO):

> Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose.

Medical device standards allow manufacturers, laboratories, biomedical engineers, technical personnel, clinicians, patients and others to inspect and assess equipment and devices to ensure quality and usability *(22)*. Some institutions dedicated to regulation and standardization are: The International Electrotechnical Commission (IEC), the ISO, the American National Standards Institute (ANSI), the Canadian Standards Authority, the European Committee for Standardization and the European Committee for Electrotechnical Standardization.

Medical devices must be manufactured within a robust quality management system that delineates a systematic approach to ensure continuous quality. Such a system includes standard operating procedures, documentation, design and manufacturing controls and third-party assessments. Maintenance of a quality management system requires appropriate human resources and their management, infrastructure, timely and appropriate procurement, stock management, maintenance and rigorous pre- and in-service training. Another crucial stage of the life cycle of devices is following them up on the market, in real time and in real-life use. Post-market surveillance is an obligation for manufacturers in order to investigate and act on any adverse event, product failure or error. The most relevant sources of information for post-market surveillance are complaints made by users. Manufacturers should analyse the cause and determine whether the risk–benefit ratio is maintained. If malfunction or deterioration in the characteristics and/or performance of the device leads to or might have led to death, such incidents must be reported by the manufacturer to the competent authorities in a "vigilance reporting system". Corrective actions in the field, such as recall or changes to the product (including labelling), are notified by manufacturers in a field safety notice to the national regulatory agency or authority, which should conduct its own market surveillance and oversee any investigation of incidents and complaints by

the manufacturer. WHO guidance on quality management systems and post-market surveillance for medical devices can be found in the WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices *(20)*.

Several international reference standards are applicable to different stages of the life cycle of medical devices. Non-exhaustive lists of applicable standards are given below *(23)*. The standards may not be required in all countries, or countries may define the equivalent standards.

Standards applicable to general quality systems for medical devices, and specific for non invasive BPMD:

- EN ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2012, Medical devices – Application of risk management to medical devices
- ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice
- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- IEC 80601-2-30:2018 Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 16142-1:2016, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
- ISO 81060-2; 2018 protocol, "single universal standard" replacing all other previous standards/protocols

Standards applicable to automated non invasive BPMD:

- ISO 81060-2:2018(E) Non-invasive sphygmomanometer standard – Part 2: Clinical investigation of intermittent automated measurement type
- ISO/IEEE 11073-10407:2010 (Part 10407: Device specialization – Blood pressure monitor)
- IEC 80601-2-30:2009 (Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers)
- DS/EN 1060-3 Non-invasive sphygmomanometers – Part 3: Electro-mechanical blood pressure measuring system

4.4 Accuracy

The "pursuit of accuracy" for BPMDs has a long history. In 1918, Dr F.A. Faught made the despairing statement that "the market is flooded with instruments of all descriptions for estimating BP, so that it is important that the prospective purchaser should be able to separate the good from the bad." Serious efforts to distinguish the "good from the bad" to avoid inaccurate measurements began only in the 1980s, with work to standardize validation of BPMDs *(24)*. More than 100 years since Dr Faught's statement, inaccurate, untested BPMDs remain available. As the accuracy of these devices is fundamental to health care quality and safety and scientific research, electronic devices should be validated both technically and clinically. Validation is typically conducted by determining the mean difference in results between the device tested and a control standard for a given number of tests. The control standard BP is typically obtained with a manual device by two independent observers, who simultaneously determine the systolic and diastolic BP of each person with a double-headed stethoscope. Accuracy validation testing should be conducted independently by institutions that are certified or identified as capable by relevant regulatory entities and should be based on standard validation protocols. Practical issues have been raised in LMICs with regards to phasing out mercury devices, choosing appropriate BP devices, identifying inexpensive devices that have been validated, providing periodic training for health care professionals and checking devices regularly for accuracy.

Standardized protocols for validating the clinical accuracy of non-invasive BPMDs have been available since 1987, some of which were developed by standards bodies and others by professional organizations:

- Association for the Advancement of Medical Instrumentation (USA), 1987, 1992 and 2002
- British Hypertension Society, 1990, 1993
- German Hypertension League (Deutsche Hochdruckliga), 1999
- European Society of Hypertension, 2002, 2010
- ISO, 2009
- American National Standards Institute, Association for the Advancement of Medical Instrumentation and International Organization for Standardization, 2009, 2013
- Association for the Advancement of Medical Instrumentation, European Society of Hypertension and International Organization for Standardization, 2018

The protocols differ notably with a key difference being the number of individuals required for testing. In 2018, experts from the European Society of Hypertension, the Association for the Advancement of Medical Instrumentation and ISO published an endorsement of the ISO 81060-2; 2018 protocol, calling it the "single universal standard" and stating that it "will replace all other previous standards/protocols" *(25)*. Table 2 shows the key aspects of the universal validation protocol and main parameters published by the European Society of Hypertension Working Group on Blood Pressure Monitoring, as well as the British Hypertension Society *(26)*. Annex 3 reproduces the consensus document.

Table 2. Main parameters considered in validation protocols

Item	Universal standard	British Hypertension Society	European Society of Hypertension
Number of participants	85	85	33
Test cross-cuff range	Requirement for testing each cuff	No requirement for testing each cuff	No requirement for testing each cuff
Reference measurement	Any sphygmomanometer, with maximum error ± 1 mm Hg Can also use invasive devices	Mercury sphygmomanometer	Mercury sphygmomanometer
Pass criteria or value	Mean overall difference ± 5 mm Hg, standard deviation within 8 mm Hg Mean difference among patients based on mean difference in BP and standard deviation	Proportion of BP measurements (test reference) overall and among patients within 5, 10 and 15 mm Hg	Proportion of BP measurements (test reference) overall and among patients falling within 5, 10 and 15 mm Hg

Additional specifications are outlined for special populations such as children and pregnant women as well as for devices, such as ambulatory monitors and devices to be used during exercise stress testing.

Table 3 shows the key aspects of the universal validation standard *(27)*.

Table 3. Requirements for various parameters of the universal validation standard

Parameter	Requirement
Efficacy measure	Threshold for accepting accuracy of BP measurement at estimated probability of tolerable error (≤ 10 mm Hg) ≥ 85%
Sample size	≥ 85 participants
Participating populations	A general population study: participants aged ≥ 12 years. Special populations (age < 3 years; age 3 to 11 years; pregnant women; arm circumference > 42 cm; atrial fibrillation; others may be added). Pregnant women: N = 45 (15 normotensive, 15 gestational hypertensions, 15 pre-eclampsia). Children aged 3–12 years. 35 participants can be included and analysed together with 50 older participants; results reported separately.
Cuff sizes	Minimum number of participants per cuff size, depending on number of test device cuffs. Requirement for arm circumference distribution according to range of use of test device.
Reference BP	Mercury sphygmomanometers or accurate non-mercury devices.
Data collection	Sequential BP measurements on the same arm are preferred.
Pass criteria	Average difference in BP and standard deviation criteria 1 and 2 of universal method. Absolute differences in BP ≤ 5, 10 and 15 mm Hg and scatterplots presented.

Source: Reference *(27)*.

The most accurate electronic BPMDs with cuff are those that have undergone rigorous validation testing and passed the new universal standard validation protocol and those that offer a variety of cuff sizes to accommodate a range of mid-upper arm circumferences.

Certain websites provide information on validated non-invasive BPMDs, such as the STRIDE website (www.stridebp.org), the British and Irish Hypertension Society (www.bihsoc.org/bp-monitos), and Hypertension Canada (www.hypertension.ca/bpdevices). These sites are described in detail in Annex 5.

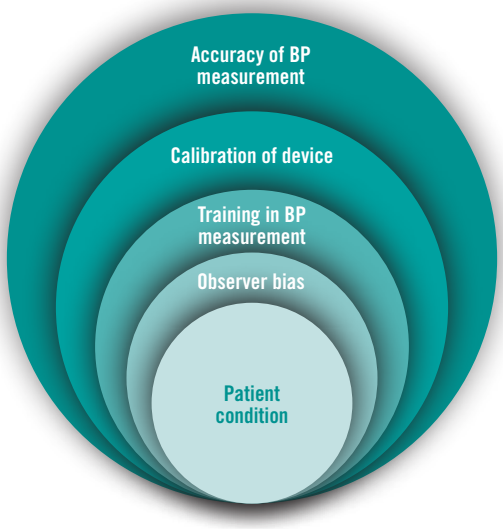
4.5 Calibration

Even accuracy validated automated BPMDs can lose accuracy over time with regular use, usually related to the wear and tear of the cuff and tubing. Because of this, the accuracy of devices must be assessed regularly for effective hypertension management. This can be done by visually inspecting the parts and comparing the measurements obtained with the device against those obtained with a gold standard device and method. If the cuff or tubing have lost integrity, or the results of the comparison differ by an unacceptable amount, the device may need repair or replacement. Devices should be checked regularly in accordance with the manufacturer's user and maintenance manuals. Accuracy should usually be assessed by technical professionals at the institution, the manufacturer (during warranty or in a service contract) or by an approved service centre at the interval prescribed by the manufacturer or as established in the medical equipment management programme.

The frequency of accuracy-checks must be in accordance with the recommendation of the manufacturer, which depends on the type of technology. The usual interval is once every 1 or 2 years. Nevertheless, experience indicates that, if an electronic BPMD is used frequently every day in clinical practice, the integrity of the cuff and tubing and the adequacy of the power source should be checked at least once a month *(28)* by users or clinical engineers. A more technical check could be performed by an authorized laboratory (metrological testing in order to guarantee accurate measurements by the national calibration or metrology centre in the country), which will measure and calibrate the electronic device against a reference manometer, such as

an electronic sensor with a high accuracy of ± 0.1 mm Hg, and compared with a well-maintained mercury sphygmomanometer with a rated accuracy of only ± 3 mm Hg.

It is important to remember that the accuracy of the device is just one of the factors necessary for an accurate measurement (Fig. 5). The United Nations Development Programme (UNDP) GEF Global Healthcare Waste Project provides guidance on maintaining and calibrating non-mercury clinical thermometers and sphygmomanometers *(29)*.



Source: Reference *(29)*.

Fig. 5. Factors in the accuracy of BP measurement

Annex 4 provides further information on laboratory testing of auscultative sphygmomanometers, including aneroid mechanical dial and face gauges, shock-resistant gearless gauges, digital auscultative sphygmomanometers and automated or semi-automated electronic sphygmomanometers with an auscultative or calibration check mode.

4.6 Maintenance

Preventive maintenance reduces the risks associated with operation of medical devices, decreases the time during which a device cannot be used and contributes to improving diagnosis and therapy. The quality and safety of medical devices are ensured not only by acquisition of validated devices but also with a periodic preventive maintenance programme.

Most maintenance tasks are performed by technical clinical engineering personnel, although some easy, routine or defined tasks may be completed by users. This saves time for technical personnel and gives the user a sense of ownership *(30)*.

The following elements are necessary for a successful maintenance programme:

- skilled technical staff;
- an adequate number of good-quality tools;
- calibrated test equipment;
- proper forecasting of accessories and spare parts;
- user's instructions, troubleshooting and service manuals; and
- a computerized health technology management system (if possible).

Routine maintenance of electronic BPMD should comprise cleaning and disinfecting the exterior of the device; maintaining any quantitative measurement that is out of the specification according to the manufacturer's instructions; and replacing tubing, electrical safety hoses, connectors, cuffs and batteries as necessary.

The following is an example of a procedure for preventive maintenance of an electronic non-invasive BPMD *(31)*. The suggested interval for preventive maintenance is at least every 12 months, according to the manufacturer's recommendations or according to the internal plan for maintaining medical equipment. The protocol takes approximately 0.5 h to complete. The following equipment is needed:

- analyzer (acceptance),
- pressure meter (0–500 mm Hg),
- stopwatch or watch with a second hand,
- limb simulator,
- inflation bulb, tubing and T-connector and
- non-invasive BP simulator (optional).

Tables 4 and 5 list the procedures for qualitative and quantitative tasks for "acceptance" and scheduled inspections or both.

Table 4. Qualitative tasks according to the kind of inspection

Quantitative tasks	Acceptance inspection	Scheduled inspection	Both kind of inspection
Chassis and housing			●
Mount and fasteners			●
Casters and brakes			●
AC plug			●
Line cord			●
Strain reliefs			●
Circuit breaker and fuse			●
Tubes and hoses			●
Fittings and connectors			●
Transducers (non-oscillometric units)			●
Controls and switches			●
Battery and charger	●		
Battery		●	
Time and date settings			●
Cybersecurity			●
User calibration			●
Alarms			●
Labelling			●
Accessories	●		

Table 5. Quantitative tasks according to the kind of inspection

Quantitative tasks	Acceptance inspection	Scheduled inspection	Both kind of inspection
Grounding resistance	●		
Touch leakage current	●		
Air leakage			●
Static pressure accuracy			●
Maximum pressure			●
Heart rate			●

4.7 Accessories and consumables

An inventory of the parts required for maintenance must be available at health facilities to ensure that devices can be used. Depending on the device, they may include: rubber tubing, hoses, connectors, various sizes of single-use and reusable cuffs and rechargeable batteries.

Transducers and power are also important in LMIC. Some may have difficulty in accessing an ample battery supply and the necessary maintenance. Electronic transducers can be inserted into semi-automatic devices, in which cuff inflation is manual and energy is provided by solar charges to the transducer itself *(1)*. Electronic indicators or warning systems should be included to indicate whether the power is adequate

4.8 Guidance on procurement

WHO *(32)* asserts that "Procurement is a vital element of equitable access to health care", which can be defined as "the acquisition of property, plant and/or equipment, goods, works or services through purchase, hire, lease, rental or exchange". Procurement includes

> all actions from planning and forecasting, identification of needs, sourcing and solicitation of offers, evaluation of offers, review and award of contracts, contracting and all phases of contract administration until delivery of the goods, the end of a contract, or the useful life of an asset.

Technical specifications, including the minimal requirements for ensuring the quality and safety of the devices, must be defined during tender to ensure that managers and procurement personnel purchase appropriate products. The specifications should always be aligned with the context. A request for supplementary information can also aid decision-making, including:

- time from receipt of contract or purchase order to delivery;
- method of shipment;
- shipping route;
- international commercial terms: general terms and any special terms and/or conditions that will appear on the contract and/or the purchase order;
- shipment and delivery costs, if applicable;
- weight and dimension of shipment;
- quotation valid until (a period or a specific date must be indicated);
- payment terms;
- evidence of ISO validation of the manufacturer and the safety and quality of the product;
- warranty for at least 2 years from the start of operation of the device;
- letter stating that the equipment will not be discontinued within the next 5 years;
- proof that the manufacturer has a qualified distributor in the country in which the device is sold;
- operation and service manuals in the language of the country acquiring the material;
- regulatory approvals and clearances (e.g. US FDA, CE or from local authority or another stringent regulatory authority);
- proof of registration in the country of import; and
- certificate of free sale in the country of origin.

Once a tender is awarded, the following information is required to facilitate customs clearance, if applicable: :

- delivery date;
- copy of the certificate of origin;
- copy of the certificate of conformity with safety and quality standards;
- commercial invoice; and
- final transport documents (waybill).

Countries that have not previously regulated medical devices are beginning to prepare legislation, and aspects of regulation are becoming increasingly common. Often, the device manufacturer, the make and the model of devices must be registered for them to be imported. If there is no registered product or manufacturer, an importer may collaborate with the ministry of health to apply for an import waiver. Such waivers are, however, usually issued only for individual shipments. It is therefore important to ensure that manufacturers apply to the local regulatory authority to be registered for future procurements. In some countries, registration can take 1–3 years; so, the earlier a manufacturer applies, the better.

4.8.1 International commercial terms

Standard international commercial terms, widely known as "incoterms", have been trademarked by the International Chamber of Commerce. Incoterms are defined terms that are widely used in global commercial transactions, and their use is encouraged by trade councils, courts and international lawyers, as they are based on international commercial law and simplify the movement of goods. For international procurement, incoterms delineate the tasks of sellers and buyers with respect to transaction obligations (e.g. transport and delivery) and with whom lie the risks and costs at every step, including the point at which the responsibility shifts from seller to buyer. Use of incoterms also helps to clarify, for example, who pays customs clearance charges, import duties and taxes and final delivery costs. As the terms themselves are widely known and accepted, they are regularly used in purchase orders and sales contracts. They are not themselves contractual and do not determine prices or currency rates or override any local law.

At the time of publication, the current incoterms were those for 2010. The International Chamber of Commerce has, however, started to draft incoterms for 2020. For further information on incoterm rules and guidance, see https://iccwbo.org/resources-for-business/incoterms-rules/.

4.8.2 Nomenclature

The generic nomenclature of medical devices is used to identify them and related health products. It is used at all levels: manufacturing, regulation, procurement and use in hospitals (i.e. for stock management and post-market feedback). The benefits of the adoption of a global or universal nomenclature system are reflected in terms of *(33, 34)*:

- safety and risk: facilitating registration for market approval by regulatory authorities, supporting patient and operator safety by tracking devices along their life cycle, technological surveillance;
- furthering universal health coverage: lists of medical devices with standard codes facilitate efficient, reliable exchange of information;
- financial sustainability and access: by facilitating procurement, the supply chain, planning and budgeting, logistics and customs and tax clearance;
- asset management: by improving the availability, inventory, maintenance, monitoring and evaluation of medical devices; and
- improving aid, emergency assistance and donations: by standardizing delivery for emergency and development programmes and donations.

The classification and nomenclature of automated BPMDs are presented in Table 6.

Table 6. Classification and nomenclature of automated BPMDs

Generic name	Automatic blood pressure monitor
Specific type or variation (optional)	Automatic electronic, sphygmomanometer
GMDN name ©	Automatic-inflation electronic sphygmomanometer, non-portable
GMDN code ©	16-173
GMDN category ©	Automatic, electronic, oscillometric
UMDNS name ©	Sphygmomanometer, electronic, automatic, auscultatory. Sphygmomanometer, electronic, automatic, oscillometric monitors
UMDNS code ©	18325, 18326, 25209
Alternative names (optional)	Non-invasive BP monitors; auscultatory sphygmomanometers; oscillometric sphygmomanometers; oscillotonometers, spot check monitors; spot checking; recorder, sphygmomanometer, automatic
Keywords (optional)	Automatic electronic sphygmomanometers, non-invasive. Digital automatic non-invasive blood pressure monitor
WHO Code	It should be noted that in 2019, some Member States requested WHO to work on a standardized international nomenclature so in future updates to this publication, a WHO nomenclature that will be freely available, will be added to these technical specifications.

4.8.3 Donations

Donations of medical equipment can help bridge inequity between the global health care innovation community and users in resource-limited settings. If poorly executed, however, donations can become a burden for recipients and waste enormous amounts of money, human resources and time. Donations must be assessed as part of standard procurement. The only difference is the initial financial transaction, with the cost borne by the donor. Factors that ensure a successful donation include a partnership between the donor and the recipient, understanding and appreciation of the recipient's difficulties and an inventory to identify gaps in priority medical equipment, so that procurement is not blind. Recipients can then better plan for:

- short- and longer-term integration of new equipment;
- requirements for infrastructure to support the donations;
- necessary accessories, spare parts and consumables;
- capacity-building programmes for users and clinical engineering staff; and
- tracking and monitoring of donations to identify issues in safety (post-market surveillance) and quantification of the impact.

For more information, refer to WHO's Medical device donations: considerations for solicitation and provision *(35)*.

4.8.4 Other relevant considerations

Availability of funding: BPMDs are essential in all health care settings. Adequate funds from domestic budgets must be allocated to ensure the availability of good-quality BPMDs in all health facilities. Funding is also required throughout the life cycle of the device. In addition to the price, other costs, such as local infrastructure (i.e. access to electricity, a battery supply or another power source), access to health facilities, private health services, reimbursement, maintenance, validation, calibration and decommissioning should be considered.

Additional potential hazards: The batteries for electronic devices may be a hazard. The main risks are acid leakage, fire and explosion. Health workers should be trained in managing rechargeable batteries, corrective action when acid is in contact with a person's skin or eyes and fire prevention.

Installation: In general, there are no specific requirements for installing BPMDs. Some devices may have to be mounted on a wall so that staff can easily observe the results displayed. It might also be necessary to consider extending tubing to reach patients' arms more easily.

Some devices can transfer recorded information to another device (i.e. mobile phone, electronic medical record). Providers should provide the technical specifications for this kind of link.

List of validated devices: As indicated above, some agencies publish lists of validated devices on their websites. Such lists can be useful for patients and physicians by providing comprehensive, unbiased bases for selecting a BPMD. Annex 5 details some of these online resources.

It is recommended that countries work with certified bodies, regulatory agencies, professional societies and institutes to draw up a national list of validated BPMDs.

4.9 Decontamination

Health care-associated infections are common, and they not only have a significant impact on morbidity and mortality but also present an economic burden to health care facilities and countries. Within larger programmes for infection prevention and control, decontamination of instruments and medical devices are critical to prevent health care-associated infections.

A manual entitled Decontamination and Reprocessing of Medical Devices for Health-Care Facilities *(36)* outlines the decontamination life cycle, which includes cleaning, disinfection and sterilization. It describes specific methods for decontaminating and reprocessing medical devices. The manufacturer's instructions should also be considered.

Cleaning is the first step in reprocessing a device after use, involving removal of visible organic and inorganic material from objects and surfaces manually or mechanically, usually with water and detergents, enzymatic products or chlorine-diluted solutions. BPMDs should be cleaned according to the clinical practice, for example after each patient or daily. Reusable cuffs should be cleaned and disinfected, as they are a potential source of infection. The manufacturer's protocols for cleaning and disinfecting should be followed, as they may account for the characteristics of the cuff material. The substance to be used to clean the cuffs might be mild enzymatic detergent, distilled water, cool water, mild soap, detergent–disinfectant, ethanol, soap, warm water or bleach, and the instructions will clarify whether the equipment should be brushed, sterilized, machine-washed (with the cycle), machine-dried or dried in air.

Over the past decade, single-patient cuffs have become more common, as they prevent nosocomial infections. The cost–effectiveness of such cuffs with regards to the incidence and cost of health care-associated infections should be evaluated, as well as the environmental impact.

4.10 Decommissioning

Decommissioning is usually understood as “retirement” of equipment from active service. In health care, equipment is not only withdrawn from service but must be properly decontaminated and rendered both unusable and safe for the environment. The manufacturer is responsible for providing details of disposal, including environmental concerns and recycling or structural requirements. The owner or the responsible health authority is obliged to understand and follow the decommissioning procedures.

Common reasons for decommissioning a medical device are that it is unserviceable, obsolescent, unsafe, costly to use and repair, superfluous, inoperable or that a replacement has been scheduled.

For decommissioning, the device must be properly identified, with authorization for disposition and sanitized. All patient health information and software must be deleted such that it is forensically unrecoverable.

Additional information on decommissioning medical devices, including the conditions to reuse or discard a medical device, is presented in WHO’s 2019 guidance on decommissioning medical devices, as part of the WHO Medical Device Technical Series *(37)*.

4.11 Technical specifications of automated non-invasive BPMDs with cuff

The technical specifications for procurement of electronic BPMDs with cuff are listed below.

TECHNICAL SPECIFICATIONS OF AUTOMATED NON-INVASIVE BP MEASURING DEVICES WITH CUFF (Including information on the following where relevant or appropriate)		
i	Version No.	1
ii	Date of initial version	1 December 2019
iii	Date of last modification	1 December 2019
iv	Date of publication	31 December 2019
v	Completed or submitted by	WHO working group
Name, category or coding		
1	WHO category or code	To be determined
2	Generic name	Electronic blood pressure monitor
3	Specific type or variation (optional)	Electronic (automated, semi-automated) sphygmomanometer
4	GMDN name ©	Automatic-inflation electronic sphygmomanometer, non-portable
5	GMDN code ©	16173
6	GMDN category ©	Automatic, electronic, oscillometric
7	UMDNS name ©	Sphygmomanometers, electronic, automatic. Sphygmomanometers, electronic, automatic, oscillometric monitors
8	UMDNS code ©	18326, 25209
9	UNSPSC (optional) ©	
10	Alternative names (optional)	Non-invasive BP monitors; oscillometric sphygmomanometers; oscillotonometers; spot check monitors; spot checking; sphygmomanometer, automatic
11	Alternative codes (optional)	
12	Keywords (optional)	Automatic electronic sphygmomanometers non-invasive. Digital automatic non-invasive BP monitor
13	GMDN/UMDNS definition (optional) ©	An electrically powered device designed to non-invasively measure BP, with a self-contained software program to regulate automatic arm-cuff inflation and measurement cycles. It typically displays current heart rate and mean arterial pressure in addition to systolic and diastolic BP; it may have memory to store values and may sound an alarm if BP exceeds pre-set limits. This device is not designed to be portable and is typically used at the bedside.
Purpose of use		
14	Clinical or other	Physical examination; diagnosis of hypertension; monitor, measure and display arterial blood pressure
15	Level of use (if relevant)	Ambulatory care centre, health centre, district hospital, provincial hospital, specialized hospital, home
16	Clinical department or ward (if relevant)	All areas
17	Overview of functional requirements	The main unit includes controls and displays numerical data for BP. It also includes appropriate attached cuffs (probes, and sensors, depending on their configuration) that allow sequential, periodic and/or simultaneous measurements.
Technical characteristics		
18	Detailed requirements	Measurement ranges: systolic (mm Hg), 60–250, 290 preferred for adults, 30–160 for children and 20–120 for neonates. Diastolic (mm Hg), 30–180 adults, 10–150 paediatric, 10100 neonate. Mean arterial pressure (mm Hg), 30–250 adults, 30–160 children, 30–110 neonates. Pulse (beats per min), 30–150 adult and children, 30–180 neonates. Inflation pressure (mm Hg) 150–260 adults, 85–140 neonates; adjustable or automatically set preferred. Auto deflate pressure (mm Hg), 300 adults, 150 neonates. Measurement interval, min: User selectable: ≥ 5 choices. Cuff sizes: neonatal, paediatric, adult, large adult, thigh. Measurement time (s) ≤ 60, user selectable. Automatic 0 required. Display may include tabular and/or graphic trends (user preference). Equipment alarms required: cuff leak, cuff disconnect, failure to take successful reading, low-battery notice. Equipment alarms preferred: hose leak, inflation or deflation error. Sphygmomanometer should automatically deflate if the cuff pressure reaches 300 mm Hg for an adult and 150 mm Hg for a neonate.
19	Displayed parameters	The unit should display the following numerical values: systolic pressure, diastolic pressure, pulse rate and mean arterial pressure. Other parameters are optional. The unit should alert the operator, either visually or audibly.

TECHNICAL SPECIFICATIONS OF AUTOMATED NON-INVASIVE BP MEASURING DEVICES WITH CUFF (Including information on the following where relevant or appropriate)		
20	User adjustable settings	Inflation pressure should be adjustable or automatically set according to a previous or current pressure reading or individual requirements. Time between automatic BP measurement cycles should be selectable from at least five values over a range of 1 to 60 min. Set alarm volume and limits within the specified measurement ranges.
Physical and chemical characteristics		
21	Components (if relevant)	Rubber tubes to be detachable from other parts, allowing periodic cutting of decayed ends. Gauge body to include clip for mounting on cuff. Tube length to be > 30 cm. Different cuff sizes available (small or neonate, medium or paediatric, large or adult and extra-large or large adult). Cuff material to be removable and washable.
22	Mobility, portability (if relevant)	Wall, portable, table-top, mobile stand
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electricity, water and/or gas (if relevant)	AC: 120/240, 50/60 Hz DC: Rechargeable battery (for at least 1 h of operation, single-use or rechargeable)
Accessories, consumables, spare parts, other components		
25	Accessories (if relevant)	Mobile stand
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables and reagents (if relevant)	Single-use cuffs in the following sizes: neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). The sizes of the cuffs depend on the manufacturer but should not deviate by ± 5 cm from the stated sizes. Batteries
28	Spare parts (if relevant)	Rubber tube (length > 30 cm), reusable cuffs in the following sizes: neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). The sizes of the cuffs depend on the manufacturer but should not deviate by ± 5 cm from the stated sizes. Tubing, valve
29	Other components (if relevant)	Protective case
Packaging		
30	Sterility status on delivery (if relevant)	Single-use cuffs must be delivered sterile.
31	Shelf life (if relevant)	Minimum shelf life for single-use cuffs must be 1 year from the date of reception.
32	Transport and storage (if relevant)	Storage environment humidity: 10–95% relative humidity. Storage environment temperature: –20 to 60 °C
33	Labelling (if relevant)	With the proper certification and validation requested, plus those required in each country
Environmental requirements		
34	Depend on context	Handling environment temperature: –20 to 60 °C
Installation		
35	Pre-installation requirements (if relevant)	Not applicable
36	Requirements for commissioning (if relevant)	Battery, uninterruptable power source, appropriate cuffs
37	Training of users (if relevant)	All users (physicians nurses, other medical staff) shall have initial training in operation. Biomedical or clinical engineer or technician, medical staff, manufacturer or servicer shall have initial training in operation and basic maintenance by manufacturer, and subsequently if necessary.
38	User care (if relevant)	Clean surface of device and wash reusable cuffs as stated by manufacturer.
Warranty and maintenance		
39	Warranty	2 years
40	Maintenance tasks	Cables and lead wires should be inspected periodically for breaks and cracks.
41	Type of service contract	Not applicable
42	Availability of spare parts after warranty	5 years after discontinuation by factory

TECHNICAL SPECIFICATIONS OF AUTOMATED NON-INVASIVE BP MEASURING DEVICES WITH CUFF (Including information on the following where relevant or appropriate)		
43	Availability of software and hardware upgrades	Software upgrade required and if available from factory
Documentation		
44	Documentation requirements	User, troubleshooting and service manuals must be available to the client, preferably in the national language(s) and/or in another language authorized by the national regulatory agency. Certificate of calibration and validation to be provided. List of equipment and procedures required for local calibration and routine maintenance to be provided List of important spares and accessories, with their part numbers and cost, to be provided. Contact details of manufacturer, supplier and local service agent to be provided.
Decommissioning		
45	Estimated life span	10 years
Safety and standards		
46	Risk classification	Depends on the country. Examples: Class A (Global Harmonization Task Force Rule 4); Class II (USA); Class I (Australia, Canada and Japan); Class IIa (European Union)
47	Regulatory approval or certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification, by regulatory agency (e.g. by a founding member of IMDRF-EU, USA, Canada, Australia, Japan). Else approved by local national regulatory agency.
48	International standards	Standards applicable to the product and to the manufacturing process are listed below. Compliance to the last available version of the international standard or to its local equivalent standard is recommended and proof of compliance must be provided. Non-exhaustive list of standards applicable to general quality systems for medical devices and specific for BPMD: • ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes • EN ISO 14971:2012, Medical devices – Application of risk management to medical devices • ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice • ISO 14971:2007, Medical devices – Application of risk management to medical devices • IEC 80601-2-30:2018 Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers • ISO 16142-1:2016, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards Non-exhaustive list of standards applicable to electronic BP devices: • AAMI/ESH/ISO 81060 Universal Standard for the Validation of Blood Pressure Measuring Devices Non-invasive phygmomanometers – Part 2: Clinical investigation of automated measurement type • ISO 81060-2:2018(E) Non-invasive sphygmomanometer standard Part 2: Clinical investigation of intermittent automated measurement type • ISO/IEEE 11073-10407:2010 (Part 10407: Device specialization – Blood pressure monitor) • IEC 80601-2-30:2009 (Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers) • DS/EN 1060-3 Non-invasive sphygmomanometers – Part 3: Electro-mechanical blood pressure measuring system
49	Regional and local standards	ANSI/AAMI SP10:2002 & ANSI/AAMI SP10:2002/A1:2003 (Manual, electronic or automated sphygmomanometers) DS/EN 1060-3 Non-invasive sphygmomanometers - Part 3: Electro-mechanical blood pressure measuring system GOST R 50267.30 Medical electrical equipment. Part 2. Particular requirements for safety of automatic cycling indirect blood pressure monitoring equipment JIS T 1115:2005 Non-invasive automated sphygmomanometers
50	Regulatory requirements	Compliance with (where applicable, but not limited to, and last available version): USA: CFR - Code of Federal Regulations, Title 21, Part 820 CFR - Code of Federal Regulations, Title 21, Part 870, Section 1130 / Non-invasive blood pressure measurement system Japan: MHLW Ordinance No. 16916156000 Aneroid sphygmomanometer European Commission: Council Directive 93/42/EEC of 14 June 1993 on Medical Devices Regulation (EU) 2017/745 of the European Parliament and the Council on Medical Devices

GMDN, General Medical Device Nomenclature; UMDNS, Universal Medical Device Nomenclature System; UNSPSC, United Nations Standard Products and Services Code.

5 Measuring BP

5.1 General standardized procedure for proper electronic BP measurements

When BP is measured in a clinic or at home, the environment should be standardized, and a quiet, relaxed, comfortable setting ensured, with the person seated quietly with their arm outstretched and supported. Stimuli in the area such as a television, use of a telephone or smartphone, a radio or loud conversations or noises should be avoided. The room temperature should, if possible, be neither hot nor cold (Fig. 6).

Source: Reference *(7)*.

Fig. 6. Instructions and recommendations for optimizing observer accuracy in clinical BP measurement

The following are specific instructions for proper electronic BP measurement *(1, 38, 39)*.

Step 1: Properly prepare the patient

① Ask the patient to empty their bladder and to abstain from caffeine, nicotine and exercise for 30 minutes before the BP measurement.

② Ask the patient to relax and to sit on a chair with their feet on the floor, legs uncrossed, back supported, ideally for at least 5 minutes.

③ Neither the patient nor the observer should talk, read or use electronic devices during the rest period or during the assessment.

Step 2: Use the proper technique for BP measurement

① Use a validated upper-arm, automated BPMD.

② Identify the appropriate size of cuff for the patient's mid-upper arm circumference. Many manufacturers mark cuffs to indicate proper fitting. A proper cuff should have:
– a bladder length 75–100% of the upper mid-arm circumference and
– a bladder width of 37–50% of the upper mid-arm circumference.

③ Position the cuff on the patient's bare upper arm (a light sleeve is acceptable) and centre it over the brachial artery (the centre is marked on most cuffs). The cuff should fit snugly on the arm, allowing no more than two fingers to fit between the distal part of the cuff and the skin. The distal part of the cuff should be positioned 1–2 cm above the cubital fossa.

④ Support the patient's arm (i.e. resting on a desk with a pillow or book to adjust arm height) so that the middle of the cuff is at heart level. The cuff should not be higher or lower than heart level.

Step 3. Activate the device as per the manufacturer's instructions

For semi-automated BPMDs (that require manual cuff inflation), ensure that the cuff is inflated to at least 30 mm Hg higher than disappearance of the radial or brachial pulse. Most devices will indicate an error if the inflation is inadequate.

① At the first visit, measure BP in both arms. If one arm has a consistently higher reading, use that arm for subsequent readings. If the difference between the two arms is >20 mm Hg for systolic pressure or >10 mm Hg for diastolic pressure on consecutive readings, the subject should be referred to a cardiovascular centre for further evaluation in order to exclude arterial disease.

② Take two or more readings in a seated position to assess usual BP for screening, diagnosis and treatment decisions. Assess standing BP to determine postural hypotension in people with newly diagnosed hypertension, those taking drugs and those who have symptoms of postural hypotension.

③ Separate repeated measurements by 1–2 minutes.

Step 4: Properly record accurate BP readings

① Electronic BPMDs automatically display the BP value.

② Note the most recent time any BP medication was taken before measurements, the subject's position (sitting, lying or standing), the arm (left or right), the cuff size and the attitude of the subject (e.g. anxious, relaxed).

Step 5: Average the readings

Average the last two seated readings obtained on at least two occasions to estimate the individual's BP.

Step 6: Provide BP readings to the patient

Give patients their systolic and diastolic readings both verbally and on their health record, and inform them whether their BP is hypertensive, prehypertensive, elevated or normal.

Some patients will have high BP readings when they are obtained in a health care setting but normal readings elsewhere ("white-coat hypertension"). Therefore, BP should be monitored at home to confirm a diagnosis. People with "white-coat hypertension" may have other cardiovascular risks, which should be monitored.

5.2 Specific advice for different settings

In a *clinical setting*, health care professionals who take BP measurements must have adequate initial training and periodic review of their performance *(40)*. In LMIC with poor access to biomedical engineering services, the following steps are suggested:

- Equip the clinic with independently validated upper-arm automated (electronic) BPMD(s) for routine use.
- Keep a limited number of auscultatory sphygmomanometers for confirmation of elevated readings, for device accuracy-checks or as alternatives for clinical conditions in which oscillometry is inappropriate (certain arrhythmias and in situations of technical failure of automatic devices). At least one health staff member should be trained in manual BP assessment.
- Consider use of semi-automatic devices (battery-powered with manual hand-bulb cuff inflation system) where battery supply and availability of electricity are limited.

BP measurement at home is used increasingly for management of hypertension. In some high-income countries, guidelines recommend BP measurement at home to confirm or complement clinical measurement *(41, 3, 5, 7)*. Before this is introduced broadly in LMICs, decision-makers may need to enforce regulations and implement WHO-recommended standards at health care facilities.

Home users should also be aware of the need for an accuracy validated BPMD and should know where and how to maintain the device and how to check the accuracy of their device. They should consider taking their BP monitor to a health care provider to ensure that it has been validated and learn the steps needed for making an accurate measurement (i.e. the same general procedure of emptying the bladder, resting, properly using an appropriately size of cuff, etc.). They should record their BP, the time of day when the measurement was obtained and the timing of any medication, to be reviewed by their health care provider. In general, at least 3 days of measuring BP twice in the morning and twice in the evening are required to obtain an accurate assessment of usual BP.

Phone applications and wearable devices, such as fitness trackers, state that they have the capability to measure BP, at home and elsewhere. These technologies are not considered to be medical devices and therefore are not validated by regulatory bodies. These devices are not currently recommended for clinical care or decision-making.

5.3 Sources of error

For an accurate BP measurement, health care personnel must understand the factors that can affect accuracy, contribute to variation among measurements and reduce misinterpretation of small, probably erroneous or misleading changes. Table 7 indicates the effect of some factors on BP measurements.

Table 7 Increases in blood pressure due to external factors

Factor	Increase in systolic BP (mm Hg)	Increase in diastolic BP (mm Hg)
Talking	4–19	5–14
Crossed legs	2–15	1–11
No back support	No significant effects	6
Arm unsupported	5	3–5
Cuff position lower than heart level	4–23	3–12
Oscillometric device	5–32	4–23
Distended urinary bladder	4–33	3–18
Recent caffeine intake	3–14	2–13
Recent smoking	3–25	2–18
Cuff over clothing	No significant effects	No significant effects
Cuff too small	2–11	2–7

Source: The table was based on data from reference *(42)*.

There are thus several potential sources of error with non-invasive BPMDs, which are associated with observer accuracy (device independent) and device accuracy (device dependent).

The requirements for accuracy that are independent of the device used, as described in section 4.2, include preparing the patient, ensuring the correct posture and using an appropriately sized cuff. An undersized cuff tends to result in an overestimate of BP, while an oversized cuff may result in an underestimate of BP *(1, 8)*. Wide-range, "one-size-fits-all" cuffs that may encompass a 22–42-cm arm may be practical in a very busy clinic, but the accuracy might be lower at either end of the cuff range *(43)*.

Observer-dependent sources of error include systematic error related to lack of concentration, poor patient preparation, incorrect cuff selection and placement, and suboptimal recording of obtained BP values. As an example, "terminal digit preference", an observer rounds off pressure readings to a preferred digit, which is usually zero. Doctors may have a 12-fold bias in favour of the terminal digit zero *(44)*. This is pertinent for all devices but may play a greater role in manual measurements. Another source of observer error is prejudice or bias, whereby the observer simply adjusts the pressure to meet his or her preconceived notion of what it should be. This usually occurs when an excess of pressures below the cut-off point for hypertension has been recorded, and it reflects the observer's reluctance to diagnose hypertension. This is most likely to occur when an arbitrary division between normal and high BP is applied, such as 140 and 90 mm Hg. An observer might tend to record a favourable measurement in a young healthy man with a borderline increase in pressure but categorize an obese, middle-aged man with a similar reading as hypertensive. Observer bias might also be present in over-reading BP to facilitate recruitment for a research project, such as a drug trial. Observer prejudice is a serious source of inaccuracy, as the error cannot usually be demonstrated.

Device-dependent sources of error can be removed by ensuring the requirements for accuracy, which include intact, functioning mechanical and electrical components. Cuffs and tubing should be intact and without leaks. Regular inspection of all devices and accuracy-checks of aneroid devices are essential parts of a preventive maintenance program.

5.4 Importance of training personnel

To assess BP accurately and reproducibly, a suitable environment, standardized patient preparation, and use of a standardized measurement technique are essential. Many studies show that BP is rarely assessed properly in clinical practice, resulting in measurement errors and/or confusion about the diagnosis, with downstream impacts on medication initiation and titration; and BP control that could affect hundreds of millions of people. Some health facilities have therefore established standardized BP measurement training programmes, some with certification requirements. Some use unobserved clinical audit to limit inaccuracies in BP measurement. Despite the clinical importance of accurate BP measurement, few health facilities require training.

Technical training of staff who measure BP is much easier when automated electronic BPMDs are used. Manual devices require the same training as automated ones plus they require additional skill of auscultation, which requires excellent vision and hearing and specialized equipment (a stethoscope). Automated devices are therefore preferred for use in routine clinical practice.

Staff who are appropriately trained and certified in measuring BP with an accuracy validated automated BPMD will improve the diagnosis and treatment of hundreds of millions of people with hypertension. Optimization of hypertension management will reduce death and disability from cardiovascular disease.

A comprehensive programme for training and certification in use of medical devices can ensure that the personnel of educational programmes and health care institutions are fully committed to safe and effective use of devices. WHO encourages authorities at all levels of health care to commit to creating and implementing training programmes in BP assessment. Training should be provided at the time of engagement of staff, with periodic training and certification, depending on the context, provided as part of a periodic training programme organized by technical staff, the head of service or the head nurse. Clinical competence should be reviewed at specific intervals.

The purpose of a training programme is to guarantee that staff and observers learn the following:

- Devices should be used in suitable locations in the facility to minimize the influence of environmental factors on patients' BP measurement (e.g. temperature, noise);
- Patients should be prepared for BP readings mentally and physically, by reducing stress, emptying their bowel or bladder, avoiding consumption of tobacco, caffeine or physical exercise close to the appointment time;
- The standardized procedure for accurate BP measurement (detailed in section 4.1)
- How to properly maintain the BPMD, including the understanding of:
  - accurate recording of readings in a clinical file and identification of readings that should be repeated;
  - the purpose and use of all components of the equipment (e.g. display, controls, indicators, alarms, accessories such as tubing and cuff, controls);
  - how to clean the device, including decontamination procedures;
  - how often the device must be calibrated (manual devices) or checked for accuracy and by whom
  - when devices should be replaced or repaired;
- How to report device-related adverse incidents;
- When alternative methods of assessing BP (e.g. manual auscultation with an aneroid device) should be used and how to access them; and
- Risks associated with misuse.

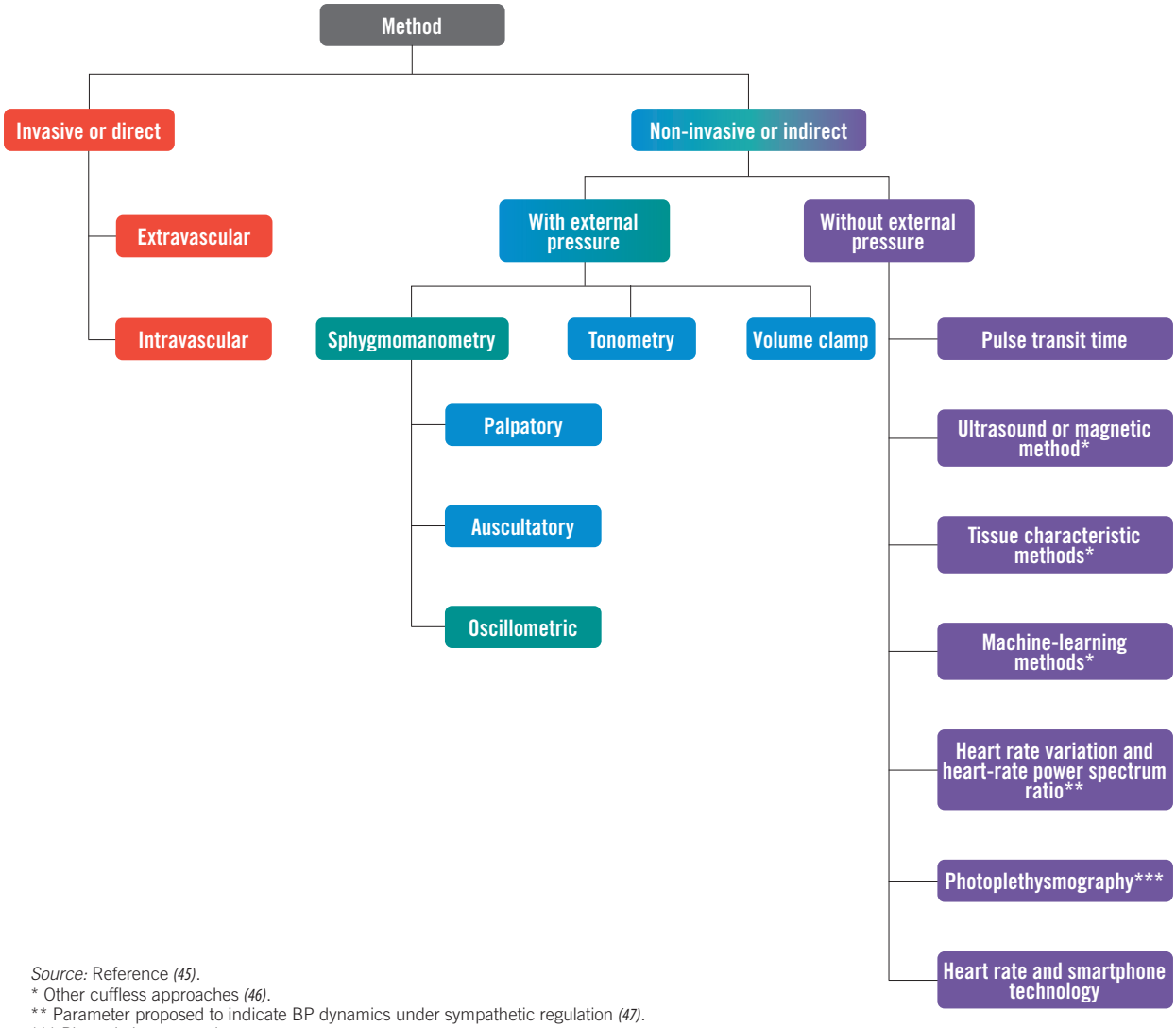
Medical devices are sometimes used improperly or not used to their full capacity because of a lack of training. Therefore, local governments should ensure that all staff members receive regular training. Periodic training in maintenance, accuracy-checks and replacement of devices could be provided through a centralized programme or in programmed visits to various locations.

The accuracy of a BP device is the key to obtaining a clinically valuable measurement. It has two components:

- **device accuracy (requiring validation) and**
- **observer accuracy (measurement technique).**

6 Innovation and research

Previous sections described non-invasive (indirect) electronic BPMDs in which external pressure is applied to the upper arm (in blue on the diagram below). There are, however, many more devices for estimating BP (purple). At the time of publication, there was inadequate evidence on the accuracy of these devices; they may be considered in future revisions. The various methods for measuring BP can be categorized according to their invasiveness and may be further classified according to the method used to estimate BP (Fig. 7).



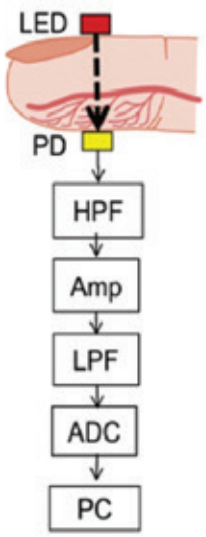
Source: Reference *(45)*.
* Other cuffless approaches *(46)*.
** Parameter proposed to indicate BP dynamics under sympathetic regulation *(47)*.
*** Photoplethysmography *(48)*.

Fig. 7. Classification of BPMDs

Various innovations have been introduced for BP measurement, such as novel BP estimation sensors, mobile apps and wearable devices *(49, 50)*. New developments include central aortic BP measurement, ultra-thin microchip sensors, advanced mathematical methods of signal analysis based on artificial neural networks and cuffless systems for estimating BP (Fig. 8). Cuffless devices require only one sensor for photoplethysmogram, and the algorithm ensures comfortable, continuous, flexible measurement of BP in various settings *(48)*.

None of these mobile phone technologies have been validated, they are not regulated, and there is no unified, standard system to evaluate their accuracy, performance or use. Thus, these emerging technologies cannot yet be recommended for clinical use.

An LED emits light with a wavelength of 940 nm, which penetrates the finger and arrives at the photo detector. The photo detector detects changes in blood flow that corresponds to natural pulsation of the blood flow. Baseline fluctuation is removed by a high-pass filter with a cut-off frequency of 0.3 Hz, and noise is removed by a low-pass filter with a cut-off frequency of 30 Hz. The output signal is digitized at a sampling frequency of 200 Hz and a resolution of 12 bytes.



LED, light emission diode; PD, photo detector; HPF, high-pass filter; Amp, amplificator; LPF, low-pass filter; ADC, analog-digital converter; PC, personal computer.
Source: Reference *(48)*.

Fig. 8. Cuffless BPMD

According to the validation guideline of the Institute of Electrical and Electronics Engineers (IEEE 1708-2014), the device shows a comparable BP to that measured simultaneously by auscultatory and electronic oscillometric techniques. The device has not yet met the requirement for pre-calibration with a conventional BPMD, which limits its routine use.

The accuracy, reproducibility and reliability of such new systems have not yet been established. An effective regulatory system must be in place to ensure independent validation of the accuracy of BPMDs.

Mobile phone apps to measure BP are still at an early stage of research and development. They are not regulated, and there is no established validation protocol to determine accuracy. Potential inaccuracy is a major constraint for clinical use. Development has also been constrained by the requirement that accessory devices or integrated hardware be built into a device.

Mobile phone apps (Fig.9) with features to track medical data, enhance medical adherence, link BP data to broader electronic medical records and clinical decisions, however, present promising opportunities which may improve the diagnosis and treatment of hypertension. The way in which new, non-validated devices are flooding the markets is underestimated, and their potential inaccuracy contributes to failures in clinical decisions on hypertension treatment.

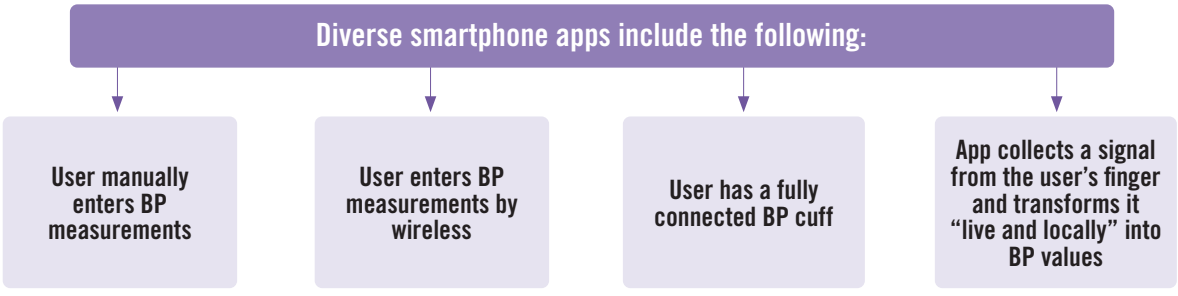


Fig. 9. Options proposed for smartphone apps for measuring BP

Given the versatility and low cost of developing such devices, it is expected that a number of apps will become available that aid in the treatment of hypertension. They might include medication reminders and health coaching according to the time, location or missed logging of an event, or they might accumulate personal data to facilitate continuous health monitoring and telemedicine *(51, 52)*.

Although strict validation standards are set for evaluating manual and electronic (automated and semi-automated) BPMDs, there is no universal standard for assessing the accuracy of BP estimates from mobile apps. Therefore, these devices are not suitable for clinical use.

7 Conclusions

Hypertension is a global health challenge that must be tackled on many fronts. As it is the largest modifiable risk factor for cardiovascular disease, appropriate devices to screen for hypertension and measure BP are important to ensure that hypertension is accurately diagnosed and treated. Devices validated for accuracy by international protocols are essential, and non-validated devices must not be marketed or purchased. As hypertension is more prevalent in LMICs, these countries must make procurement of accurate BPMDs a priority to combat the growing public health crisis of hypertension. Validated devices with upper arm cuffs should be available in all settings. Regulatory agencies must have the capacity to ensure that devices intended for measuring BP are appropriately and rigorously tested and validated and properly labelled, in accordance with international standards, before they are commercialized.

BPMD technology should be spread globally, with broad, regular training and re-training of providers to accurately measure BP. Providing standardized BP measurement certification with ongoing assessments and re-training to ensure competence will result in accurate BP readings, appropriate diagnosis and better management of hypertension. As manual BPMD are being phased out because of environmental concerns, need for frequent calibration to maintain accuracy, and the increased risk for observer error and inaccurate BP measurements with aneroid, use of validated automatic devices is preferred and recommended, as they may produce more accurate and consistent measurements on a global scale. Even with automatic BPMD, the importance of trained health care professionals and standardized methods to diagnose and treat hypertension must be emphasized.

In view of the growing number of innovations and devices, this document provides evidence for the accuracy and use of aneroid, semi-automatic and automatic BPMDs. As new technology becomes available, its implications, impact and viability in the global clinical setting must be assessed. More appropriately trained health care professionals as well as validated and affordable BPMDs could reduce the risks for disability and mortality for hundreds of millions of people living with hypertension. WHO invites everyone to engage in the battle against hypertension by increasing screening, treatment and access throughout the world.

Key messages

In order to increase access to accurate BP measurement and monitoring, the experts and WHO secretariat who participated in the meeting in June 2019 (Annex 2) proposed the following messages.

Member States, governments

1. Member States are encouraged to strengthen their regulatory capacity to ensure that only certified accurate, validated BPMD are marketed and to identify institutions in which independent validation can be conducted.
   a. Member States should enforce quality assurance by mandating manufacturers to clearly state on packaging whether their BPMD has passed validation testing for accuracy.
   b. Non-validated BPMDs should not be marketed, purchased or used for clinical diagnosis.

2. Appropriate resources should be maintained for use of manual auscultatory BPMD only for special clinical or testing purposes.

3. Governments, health and scientific communities and BPMD manufacturers should ensure the availability of affordable accurate, validated automatic BPMDs in low-resource settings with or without a reliable electricity supply.

4. LMICs are encouraged to acquire, allocate and use validated BPMDs.

5. Important to have trained professionals (clinical engineering and other technical professionals) to appropriately select, validate and maintain BPMDs.

Manufacturers

1. Electronic BPMD (automated and semi-automated) should undergo independent validation testing with a rigorous international protocol (e.g. ISO 81060-2; 2018). Compliance with this should be indicated on the label.

2. Manufacturers should specify the range of arm circumferences for which the device or cuff size is intended and clearly mark the cuffs for the arms for which they are intended to be used.

Health care institutions and professionals

1. Validated automatic BPMDs with appropriately sized upper-arm cuffs should be used in routine clinical and community screening.

2. Certification courses and annual training and re-training of health care professionals should be required to ensure accurate BP measurement. Training should include patient preparation, cuff selection and BP measurement technique. In order to minimize additional training for manual BP measurements, preferably automated non-invasive BPMDs should be used.

3. Health care facilities in which manual BPMDs containing mercury cannot yet be replaced by validated electronic BPMDs should inform their communities about the hazards of mercury and develop procedures for safe operation of the devices, search for ways to replace them for non-mercury ones, preferably automated, and do proper decommissioning.

References

1. WHO, Affordable technology blood pressure measuring devices for low-resource settings, Geneva, 2005.
2. WHO, "Global Health Observatory (GHO) data," 2015. [Online]. Available: https://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence/en/.
3. GBD, "Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks for 195 countries and territories, 1990-2017: a systematic analys," 2018.
4. B. Filho Rodrigues, R. Farias and W. Dos Anjos, Evaluating the impact of measurement uncertainty in blood pressure measurement on hypertension diagnosis. Blood Press Monit, 23(3), 141-147, 2018.
5. N. Campbell, M. Myers and D. McKay, Usual measurement of blood pressure is it meaningful? Blood Press Monit. 4:71–6, 1999..
6. WHO, Replacement of mercury thermometers and sphygmomanometers in health care: technical guidance, 2015.
7. R. Padwal, N. Campbell, O. Schutte AE, M. Delles, A. Etyang, J. Cruisckshank, G. Stergiou, M. Rakotz, G. Wozniak, M. Jaffe, I. Benjamin, G. Parati and J. Sharman, "Optimizing observer performance of clinic blood pressure measurement: a position statement from the Lancet Commission on Hypertension Group," 2019.
8. U. MHRA, "Blood pressure measurement devices. Guidance for healthcare professionals on the use and management of blood pressure management devices.," Medicines and Healthcare Products Regulatory Agency, London, 2013.
9. Miyashita and Ellis, Primary hypertension and special aspects of hypertension in older children and adolescents., Health Ther, 2, 45-62., 2011.
10. ECRI, "Vital Signs Monitoring Systems," 2011.
11. ECRI, "Monitors, vital signs, device overview specifications – comparative data (Information is only available for subscribed members of ECRI)," Plymouth Meeting (PA), 2016.
12. G. Ogedegbe and T. Pickering, "Principles and techniques of blood pressure measurement. 28(4):571–86.," Cardiol Clin., 2010.
13. E. O'Brien, B. Waeber, G. Parati, J. Staessen and M. Myers, "Blood pressure measuring devices: recommendations of the European Society of Hypertension. 322(7285):531–6.," BMJ., 2001.
14. P. Muntner, D. Shimbo, R. Care, J. Charleston, T. Gallard and S. Misra, "Measurement of blood pressure in humans 73: e35–66.," American Heart Association. Hypertension., 2019.
15. NHBPEP, NHLBI and AHA, "working meeting on blood pressure measurement.," Bethesda (MD): National Institutes of Health, 2002.

16. W. JG., “Encyclopedia of medical devices and instrumentation.,” Jogn Wiley & Sons, New York City (NY), 1990.
17. J. Cohen, R. Padwal, M. Gutkin, B. Green, M. Bloch, F. Germino and e. al., “History and justification of a national blood pressure measurement validated device listing. Hypertension. 73(2):258–64.,” 2019.
18. J. Pineda Pardo, Automatic learning procedures for non-invasive blood pressure measurements. Blood pressure measuring. Chapter 2, Seville: University of Seville, 2009.
19. World Health Organization, “SIXTY-SEVENTH WORLD HEALTH ASSEMBLY WHA67.20 Regulatory system strengthening for medical products.,” Organization,.
20. World Health Organization, “WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices.,” Geneva:, 2017.
21. E. Commision, ““Blue Guide” on the implementation of EU product rules.,” Official journal of the European Union, Brussels, 26.7.2016.
22. einfochips, “A Definitive Guide to Medical Device Design and Development,” einfochips, [Online]. Available: https://www.einfochips.com/resources/publications/a-definitive-guide-to-medical-device-design-and-development/.
23. ISO, “Standards ISO,” [Online]. Available: https://www.iso.org/standards.html. [Accessed 20 02 2020].
24. E. O’Brien, G. Stergiou and M. Turner, “The quest for accuracy of blood pressure measuring devices. 20(7):1092–5.,” J Clin Hypertens., 2018.
25. G. Stergiou, P. Palatini, R. Asmar, J. P. Ioannidis, A. Lollias, P. Lacy, R. J. McManu, M. G. Myers, G. Parati, A. Shennan, J. Wang and E. Obrien, “Recommendations and Practical Guidance for performing and reporting validation studies according to the Universal Standard for the validation of blood pressure measuring devices,” AAMI/ESH/ISO, 2019.
26. G. Stergiou, P. Palatini, R. Asmar, J. Ioannidis, A. Lollias, P. Lacy, R. McManu, M. Myers, G. Parati, A. Shennan, J. Wang and E. Obrien, “on Blood Pressure Monitoring and Cardiovascular Variability. Improving the accuracy of blood pressure measurement,” ESH-IP, 2018.
27. G. Stergiou, B. Alpert, S. Mieke, J. Wang and E. O´Brien, “Validation Protocols for Blood Pressure Measuring Devices in the 21st century20:1096-1099.,” 2018.
28. M. Turner, C. Speechly and N. Bignell, Sphygmomanometer calibration--why, how and how often. 36:834-8., Aust Fam Physician, 2007.
29. United Nations Development Programme, Guidance on Maintening and calibrating non-mercury clinical thermometers and sphygmomanometers. GEF GLOBAL HEALTHCARE WASTE PROJECT, 2013.
30. World Health Organization, Medical equipment maintenance programme overview (WHO Medical device technical series), Geneva: World Health, 2011.
31. ECRI, Instructions of Preventive Maintenance, Procedure No. 454-20160810 for Sphygmomanometers (aneroid or mercury), 2016.
32. World Health Organization, Procurement process resource guide (WHO Medical device technical series)., Geneva, 2011.
33. World Health Organization, Nomenclature of medical devices., Geneva, 2017.
34. World Health Organization, Standardization of medical devices nomenclature: international classification, coding and nomenclature of medical devices., Geneva, 2019.

35. World Health Organization, Medical device donations: considerations for solicitation and provision, Geneva, 2016.

36. World Health Organization, Decontamination and reprocessing of medical devices for health-care facilities., Geneva, 2016.

37. World Health Organization, Decommissioning Medical Devices., Geneva, 2019.

38. P. K. Whelton, R. M. Carey, W. S. Aronow, D. E. Casey, K. J. Collins, C. Dennison Himmelfarb and J. T. Wright, PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults, ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA, 2018.

39. K. A. Nerenberg, K. B. Zarnke, A. A. Leung, K. Dasgupta, S. Butalia and K. McBrien, Hypertension Canada's 2018 Guidelines for Diagnosis, Risk Assessment, Prevention, and Treatment of Hypertension in Adults and Children, Hypertension, C., 2018.

40. Hypertension: The Clinical Management of Primary Hypertension in Adults: Update of Clinical Guidelines 18 and 34 [Internet]. NICE Clinical Guidelines, No. 127., London: Royal College of Physicians (UK): National Clinical Guideline Centre, 2011 Aug.

41. B. Williams, G. Mancia, W. Spiering, E. Rosei, M. Azizi, M. Burnier and I. Desormais, Guidelines for the management of arterial hypertension. The Task Force for the management of arterial hypertension, Rome: (ESC) (ESH), 2018.

42. N. Kallioinen, A. Hill, M. Horswill, H. Ward and M. Watson, Sources of inaccuracy in tehe measurement of adult patients´ resting blood pressure in clinical settings: a systematic review., Journal of Hypertension, 2017.

43. E. Sprague and R. S. Padwal, Adequacy of validation of wide-range cuffs used with home blood pressure monitors: a systematic review. Blood Press Monit, 23(5), 219-224., 2018.

44. G. Beevers, G. Y H Lip and E. O´Brien, Part II-Conventional sphygmomamanometry: technique of auscultatory blood pressure measurement. Clinical Revie: ABC of hypertension Blood pressure measurement., BMJ, 2001.

45. A. Meidert, Techniques for Non-Invasive Monitoring of Arterial Blood Pressure, 2018.

46. X. Ding, Z. N, G. Yang, R. Pettigrew, B. Lo, M. F, Y. Li, L. J and Y. Zhang, Continuous Blood Pressure Measurement from Invasive to Unobstrusive, 2016.

47. Y. Chen, L. Lei and J. Wang, Methods of blood pressure assessment used in milestone hypertension trials. 6:112-123., Pulse, 2018.

48. N. Watanabe, Y. K. Bando, T. Kawachi, H. Yamakita, K. Futatsuyama, Y. Honda and T. Murohara, Development and Validation of a Novel Cuff-Less Blood Pressure Monitoring Device., JACC Basic Transl Sci, 2(6), 631-642., 2017.

49. E. Goldberg and P. Levy, New approaches to evaluating and monitoring blood pressure., Curr Hypertens Rep 18:49., 2016.

50. R. Mukkamala, J. Hahn, O. Inan and e. al., Toward ubiquitous blood pressure monitoring via pulse transit time: theory and practice., IEEE Trans Biomed Eng 62:1879–901., 2015.

51. M. S. Key, "Features hypertension apps need to have based on an extensive review of medical literature," 2014.

52. N. Kizilova, "Review of emerging methods and techniques for arterial pressure and flow waves acquisition and analyses.," Int J Biosen Bioelectron., 2018.

Annex 1
Phasing out mercury

The WHO document, Decommissioning Medical Devices *(1)*, part of the WHO Medical Device Technical Series, includes devices containing mercury. Mercury evaporates readily into the atmosphere, which can result in breathing air containing elemental mercury vapours, which can have harmful effects on the nervous, digestive and immune systems and the lungs and kidneys. In the environment, mercury can be transformed by bacteria into methylmercury, which is toxic to the nervous system and developing foetuses. People are exposed to methylmercury by eating contaminated fish and shellfish. Mercury waste is therefore a global concern *(2)*.

The Sixty-Seventh World Health Assembly adopted resolution WHA67.11 for the protection of public health from exposure to mercury and mercury compounds by implementation of the Minamata Convention on Mercury *(3)*. The resolution encouraged Member States to

> address the health aspects of exposure to mercury and mercury compounds in the context of their health sector uses, and also the other negative health impacts that should be prevented or treated, by ensuring the sound management of mercury and mercury compounds throughout their life cycle.

The Convention established 2020 as the date for phasing out the manufacture, export or import of mercury-containing thermometers and sphygmomanometers, with possible exemptions up to 2030. An open-ended exemption was also granted to products for research, calibration of instruments and use as a reference standard. Further information is available in the WHO guidelines on phasing out mercury-containing thermometers and sphygmomanometers in health care *(4)*.

Discarded medical devices are a source of mercury in the atmosphere. The devices include sphygmomanometers, thermometers, dental amalgams and batteries. Care must be taken in handling devices that contain elemental mercury, from collecting and storing to transporting the devices and their disposal. Any mercury spill from broken devices should be removed immediately with proper procedures to avoid inhalation. Kits and guidelines for cleaning up spills of mercury in a proper, safe way are widely available, and responsible users and personnel should be trained in disposal. Mercury devices must not be placed in biohazard medical waste containers or sharps containers but should be collected for hazardous waste disposal or for designated recycling. An area for mercury waste should be determined in a health care facility before the waste is collected for disposal. Mercury waste must be sent to authorized facilities or to the suppliers, if applicable. An alternative is to send it to a disposal or storage site designated for hazardous industrial waste. For more information, see the WHO guidelines on safe management of wastes from health-care activities *(5)*.

European Union regulation 2017/852, Article 5 *(6)*, states that “the export, import and manufacturing in the Union of the mercury-added products (…) shall be prohibited. This prohibition is applicable to sphygmomanometers from 31st of December 2020 on.”

References

1. Decommissioning medical devices. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/bitstream/handle/10665/330095/9789241517041-eng.pdf?sequence=1&isAllowed=y).
2. Blood pressure measurement devices. Guidance for healthcare professionals on the use and management of blood pressure management devices. London: Medicines and Healthcare Products Regulatory Agency; 2013 (https://www.gov.uk/government/publications/blood-pressure-measurement-devices).
3. Minamata Convention on Mercury. Nairobi: United Nations Environment Programme; 2013 (www.mercuryconvention.org).
4. Replacement of mercury thermometers and sphygmomanometers in health care: technical guidance. Geneva: World Health Organization; 2015 (https://apps.who.int/iris/bitstream/handle/10665/259448/9789241508339-eng.pdf?sequence=1).
5. Chartier Y, Emmanuel J, Pieper U, Prüss A, Rushbrook P, Stringer R, et al. Safe management of wastes from health-care activities. Geneva: World Health Organization; 2014.
6. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008. Brussels: European Commission; 2017 (https://eur-lex.europa.eu/eli/reg/2017/852/oj).

Annex 2

Meeting participants – Consultation for technical specifications for automated non-invasive BPMD with cuff, 25–26 June, 2019

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Annex 3

Universal standard for the validation of blood pressure measuring devices

A Universal Standard for Validation of Blood Pressure Measuring Devices was developed by: The Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) in 2018.

It is named: ISO 81060-2:2018(en), Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type

History of validation protocols

Publication	Organization
1987, 1992, 2002	US Association for the Advancement of Medical Instrumentation (AAMI)3, 5
1990, 1993	British Hypertension Society (BHS)4, 6
1999	German Hypertension League (Deutsche Hochdruckliga) (DHL)7
2002, 2010	European Society of Hypertension International Protocol (ESH-IP)8, 9
2004	European Committee for Standardization (CEN)10
2009	International Organization for Standardization (ISO)11
2009, 2013	American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO)12, 13
2018	Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO)14.

Scope

This document specifies the requirements and methods for the clinical investigation of me equipment used for the intermittent non-invasive automated estimation of the arterial blood pressure by utilizing a cuff.

This document is applicable to all sphygmomanometers that sense or display pulsations, flow or sounds for the estimation, display or recording of blood pressure. These sphygmomanometers need not have automatic cuff inflation.

This document covers sphygmomanometers intended for use in all patient populations (e.g. all age and weight ranges), and all conditions of use (e.g. ambulatory blood pressure monitoring, stress testing blood pressure monitoring and blood pressure monitors for the home healthcare environment for self-measurement as well as use in a professional healthcare facility).

The AAMI, ESH, and ISO experts agreed to develop a single universally acceptable standard (AAMI/ESH/ISO), which will replace all previous protocols. This major international initiative has been undertaken to best serve the needs of patients with hypertension, a public interested in cardiovascular health, practicing physicians, scientific researchers, regulatory bodies, and manufacturers. There is an urgent need to influence regulatory authorities throughout the world to make it mandatory for all BP measuring devices to have undergone independent validation before approval for marketing. Efforts need to be intensified to improve the accuracy of BP measuring devices, further optimize the validation procedure, and ensure that objective and unbiased validation data become available.

References

A Universal Standard for Validation of Blood Pressure Measuring Devices, Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Collaboration Statement. https://www.ncbi.nlm.nih.gov/pubmed/29386350.

Validation protocols for blood pressure measuring devices in the 21st century. George S. Stergiou MD, PhD, FRCP, Bruce S. Alpert MD, Stephan Mieke PhD, Jiguang Wang MD, PhD, Eoin O'Brien MD, DSc, FRCP. First published:13 July 2018 https://doi.org/10.1111/jch.13294.

https://www.iso.org/obp/ui/#iso:std:iso:81060:-2:ed-3:v1:en

Annex 4
Procedures for laboratory and accuracy testing

Calibrating aneroid mechanical gauge sphygmomanometers

Accurate measurement is essential for managing hypertension, as imprecise measurements might significantly affect diagnosis and treatment. Aneroid sphygmomanometers (manual BPMD) are still used in health care institutions, and, in view of their sensitivity to mechanical shocks, they must be tested regularly for accuracy to determine whether they should be calibrated. This section describes the procedure in detail.

Aneroid sphygmomanometers may be portable, wall-mounted or mobile-mounted. Fig. A4.1 shows two common aneroid sphygmomanometers.

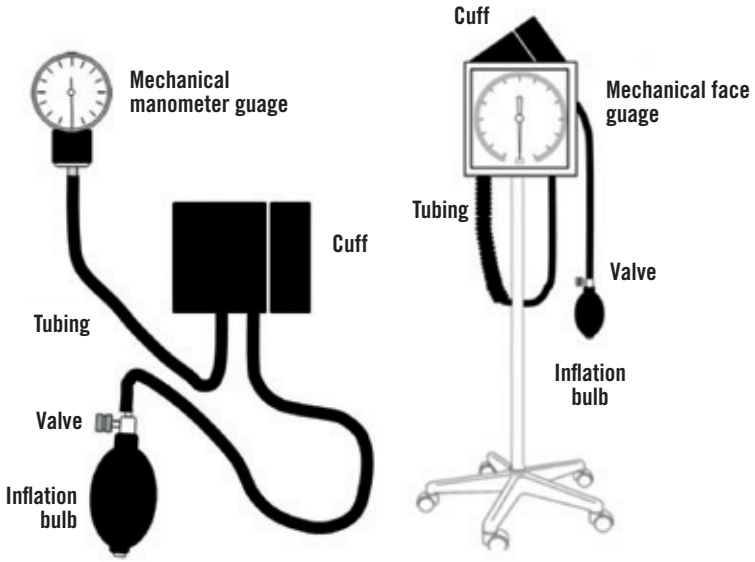


Fig. A4.1. Two common aneroid sphygmomanometers

The devices required to test the accuracy of an aneroid pressure gauge are a reference manometer, preferably electronic, which is traceable to a national standard; one or two "Y" or "T" connectors, with tubing and Luer fittings; and an inflation bulb with a valve or an adjustable manual syringe pump. Some tests recommend use of a cuff placed around a cylinder or adding a 500-mL vessel, such as a metal container, so that the tester can increase the pressure gradually and avoid suddenly exceeding the maximum gauge pressure.

Some tests suggest use of a mercury sphygmomanometer as the reference manometer, but, as explained above, these devices may not be available. A well-maintained mercury sphygmomanometer has a rated accuracy of ± 3 mm Hg, whereas the accuracy of typical reference electronic manometers is ± 0.1–1 mm Hg traceable to a national standard. Reference electronic manometers with high accuracy and an operating

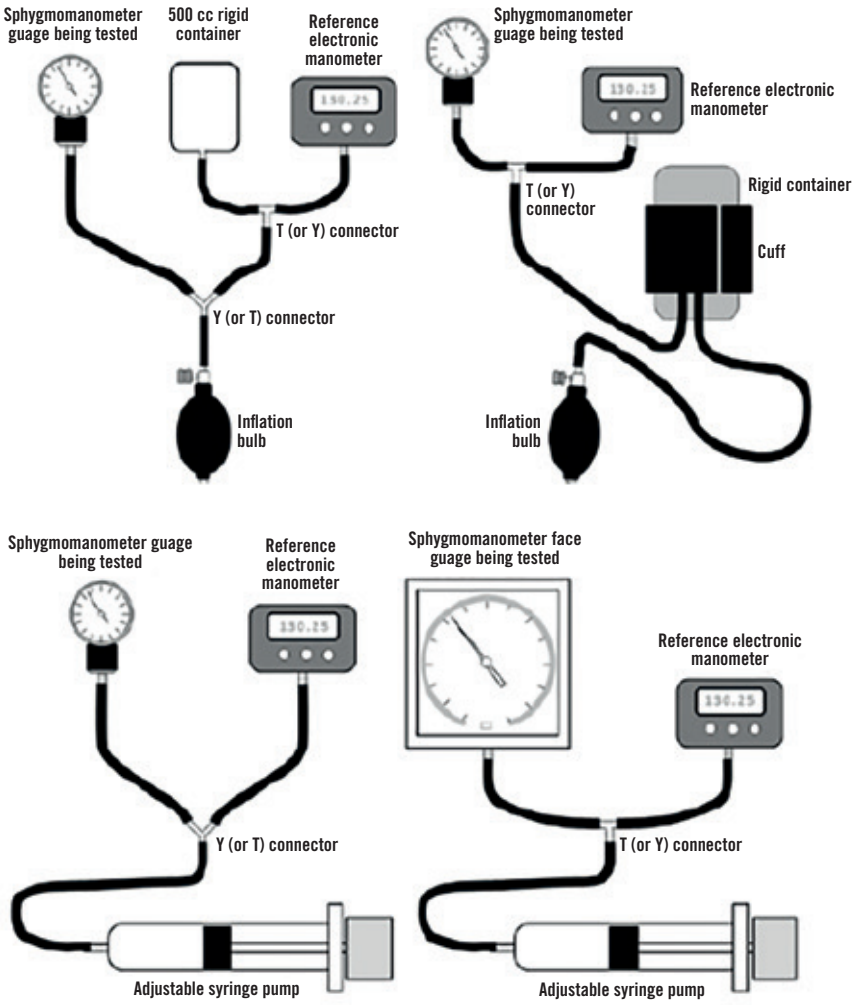


Fig. A4.2. Examples of equipment for accuracy tests for aneroid sphygmomanometer gauges

range of at least 0–300 mm Hg are commercially available. Fig. A4.2 shows examples of various accuracy test set-ups for aneroid sphygmomanometer gauges.

The procedure is as follows.

1. Connect the pressure gauge to be tested to the reference manometer with plastic Y or T connectors and plastic or rubber tubing to an inflation bulb or adjustable syringe pump. Addition of a 500-mL hard plastic or metal container or use of the cuff wrapped around a rigid cylinder (about 10 cm in diameter) is recommended if an adjustable manual syringe pump is not used.

2. Make sure the pointer is at 0 when no pressure is applied before beginning the test. Adjust the pointer if necessary.

3. Using the inflation bulb or syringe pump, pressurize the gauge to about 280 mm Hg, and close the valve. Observe whether the pressure is stable. If not, check the set-up for air leaks.

4. If the pressure is stable, increase the pressure to slightly above 300 mm Hg, and release the pressure no faster than 10 mm Hg per second.

5. Stop the pressure release at least every 50 mm Hg. Record both the reading on the gauge being tested and the reference manometer reading. For example, readings can be taken at 300, 250, 200, 160, 120,

100, 80, 60, 40 and 0 mm Hg. At a minimum, take readings at 300, 250, 200, 150, 100, 60 and 0 mm Hg. Ensure that the pointer returns to the 0 mark.

6. Compare the gauge readings with the correct value indicated by the reference manometer. If the gauge is accurate to within ± 3 mm Hg, the aneroid sphygmomanometer is of the required accuracy and acceptable for clinical use.

7. If one or more of the readings exceeds ± 3 mm Hg, determine whether the error is linear or nonlinear. An error is linear when the readings are consistently above or below the correct reading; an error is non-linear when the readings deviate by different amounts. Examples are given in Table A1.1. It is important to determine whether the error is linear or non-linear, as the method used to re-calibrate the instrument depends on the type of error.

Table A4.1. Examples of linear and non-linear errors

Example of linear error		
Reference manometer reading	Reading of aneroid guage being tested	Difference
40	46	+ 6
60	66	+ 6
80	86	+ 6
100	106	+ 6
120	126	+ 6
160	166	+ 6
200	206	+ 6
250	256	+ 6
300	306	+ 6

Example of non-linear error		
Reference manometer reading	Reading of aneroid guage being tested	Difference
40	31	-9
60	54	-6
80	77	-3
100	100	0
120	123	3
160	166	6
200	203	3
250	251	1
300	298	-2

Source: The table was based on data from reference *(42)*.

8. Follow the manufacturer's instructions to re-calibrate the instrument. Examples of typical re-calibration procedures for aneroid gauge dials are given below.

Example 1: Remove the retaining ring and glass from the gauge. Carefully remove the needle and dial face to reveal the bellows. Locate the concave triangle with a pin at its centre. To correct a linear error, move the pin towards the sides of the triangle, right or left. To correct a non-linear error, move the pin linearly within the triangle, up or down, with very small adjustments. Replace the dial face, needle, glass and retaining ring. Repeat the test to determine whether the accuracy is within ± 3 mm Hg as compared with the reference manometer. Repeat the adjustments until the required accuracy is achieved.

Example 2: Remove the glass, pointer and dial until you see the triangle with concave sides, on one side of which is a pin. To correct a linear error, bend the pin very slightly along the line of the triangle side. To correct a non-linear error, bend the pin very slightly away or towards the triangle. Replace the dial face, needle and glass. Repeat the test above to determine whether the accuracy is within ± 3 mm Hg as compared with the reference manometer. Repeat the adjustments until the required accuracy is achieved.

Example 3: Unscrew the bezel and remove the crystal, pointer and dial. Place a test dial and test pointer on the pinion and connect the gauge to the test set-up. Apply 320 mm Hg pressure to the gauge, and then release the pressure to 300 mm Hg. Place the calibration tool supplied by the manufacturer into the radius plate slot. If the reading is < 300 mm Hg, rotate the tool counter-clockwise until the gauge reaches 300. If the reading is > 300 mm Hg, rotate the tool clockwise until the gauge reaches 300 mm Hg. Release the pressure, and test for the 0 point. Rotate the dial if the pointer is off the 0 mark. Repeat the test at 300 mm Hg until the range is set. Replace the crystal and bezel and repeat the calibration test at different pressure intervals to ensure that the required accuracy is achieved.

Accuracy-checking electronic (digital, automated or semi-automated) sphygmomanometers with auscultative or calibration check modes

Most fully automated electronic sphygmomanometers cannot be tested or calibrated by the user but must be sent to the manufacturer or an approved service centre.

The procedures below are for electronic sphygmomanometers with a calibration check or test mode, whereby the pressure can be set manually or provided by an external source. This test can be used to compare the readings from the device against a reference manometer.

To test the accuracy of an electronic monitor, the devices required are a reference manometer (preferably an electronic manometer traceable to a national standard), one or two Y or T connectors with tubing and Luer fittings and an inflation bulb with a valve or an adjustable manual syringe pump, unless the pressure can be selected manually.

Fig. A4.3 shows an accuracy test set-up for a digital auscultatory sphygmomanometer in calibration check or test mode. The procedures for testing digital auscultatory sphygmomanometers with inflation bulbs, as shown below, are similar to those for mechanical aneroid sphygmomanometers described above.

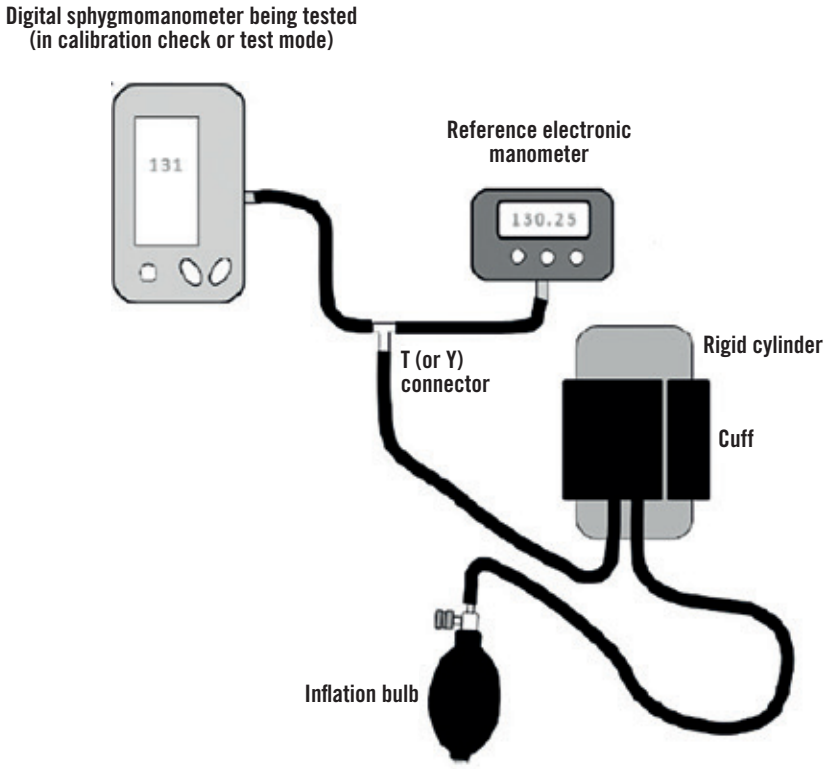


Fig. A4.3. Set-up for testing the accuracy of a digital auscultatory sphygmomanometer

Fig. A4.4 shows the set-up for testing electronic sphygmomanometers with an auscultative mode.

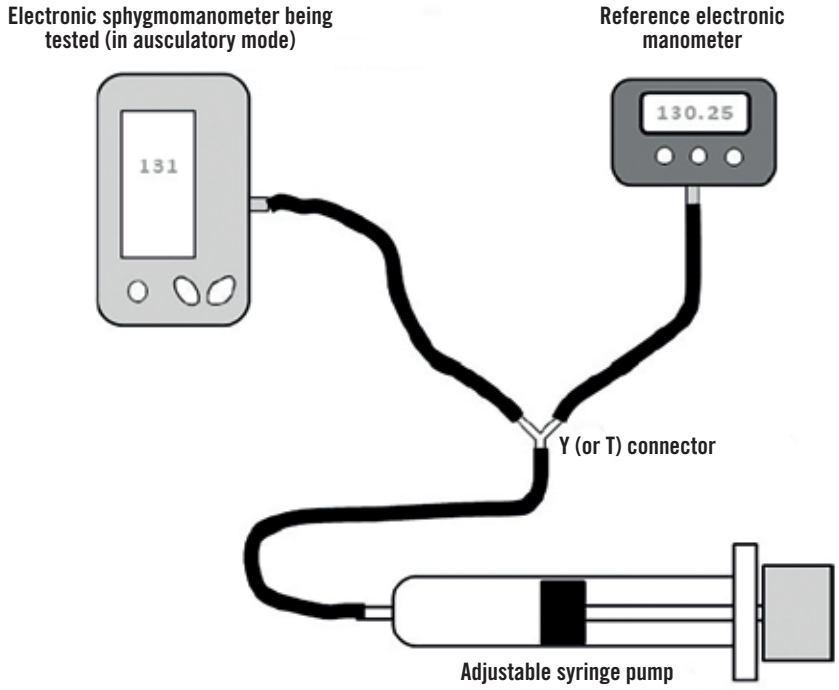


Fig. A4.4. Laboratory accuracy test set-up for some electronic sphygmomanometers

A typical procedure for electronic sphygmomanometers with auscultative modes is as follows.

- Temporarily seal the pressure release hole, which is usually at the back or side of the unit.
- Once the electronic sphygmomanometer is turned on and placed in auscultatory mode, the unit is allowed to pressurize until it stops.
- With the adjustable syringe pump, the pressure is adjusted to 300 or 280 mm Hg (± 2 mm Hg) from the readings on the reference manometer.
- The readings of the electronic sphygmomanometer are then recorded.
- The procedure is repeated in 20-mm Hg decrements down to 20 mm Hg, following the readings of the reference manometer.

Annex 5

Online resources from professional societies

Agency / Society	Description	Website
British and Irish Hypertension Society	The BIHS publishes the only independent, peer-reviewed list of blood pressure monitors that is not governed by commercial interest.	https://bihsoc.org/bp-monitors/
Hypertension Canada	Hypertension Canada's Blood Pressure Measurement Device Recommendation Program is designed to help you in your purchasing decisions by easily identifying devices that are validated in studies as accurate	https://hypertension.ca/bpdevices
French National Agency for the Safety of Medicines and Health Products	Since 2001, AFSSSAPS, today ANSM, has paid particular attention to the marketing of blood pressure measuring devices intended for the general public. Between 2001 and 2005, it carried out, as part of the national plan, a market control operation relating in particular to the procedures for the clinical evaluation of these devices.	https://www.ansm.sante.fr/Dossiers/Appareils-d-automesure-tensionnelle/Surveillance-du-marche-des-autotensiometres/(offset)/0
Japanese Society of Hypertension	It is of great importance to have products evaluated and validated in accordance with protocols set by organizations such as the British Hypertension Society (BHS), the Association for the Advancement of Medical Instrumentation (AAMI) and, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH).	http://www.jpnsh.jp/com_ac_wg1.html
STRIDEBP (cosponsored by the European Society of Hypertension and the International Society of Hypertension)	Is an international scientific non-profit organization founded by hypertension experts with the mission of improving the accuracy of blood pressure measurement and the diagnosis and management of hypertension. STRIDE BP provides international guidance and practice tools on the methodology and technology for accurate blood pressure evaluation according to the latest scientific evidence.	https://stridebp.org/bp-monitors
American Medical Association and American Heart Association	The 2017 hypertension guideline from the American College of Cardiology (ACC) and the American Heart Association (AHA) recommends that all BP monitors have peer-reviewed publications showing they have been tested using internationally accepted protocols for the validation of clinical accuracy. Yet it is not easy for patients and physicians to find out which BP monitors on the market meet that criterion, so the AMA is working with the AHA to create a validated device listing.	https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/iho-bp-self-measured-blood-pressure-monitoring_0.pdf
dabl Educational Trust	The purpose of the dabl®Educational Trust website is to produce regular reviews of blood pressure measuring devices to guide the would-be-purchaser through a complex market. As the majority of blood pressure measuring devices has not been independently validated, the devices listed on the website are representative, therefore, of only a fraction of the many devices available. It is hoped that manufacturers will wish to list devices for which validation is planned and that in time the devices listed will be representative of the market.	http://www.dableducational.org/sphygmomanometers/devices_1_clinical.html#ClinTable http://www.dableducational.org/sphygmomanometers/devices_2_sbpm.html#ArmTable

Annex 6

Technical specifications and use of aneroid manual blood pressure measuring devices with cuff

This section introduces manual BPMDs used by health care professionals to diagnose and treat hypertension. Although many topics that also apply to manual devices are covered in previous sections, particular aspects of manual devices are explained here. As this document encourages use of automated BP measurement, the following topics specific to manual devices are not included: accuracy, validation standards, accessories and consumables, guidance on procurement (except for changes in nomenclature), decontamination and decommissioning.

The manual, or auscultatory, BP measurement technique was first described by Korotkoff in early 1905 *(1)*, and many basic studies in BP research were performed with this technique *(2)*. One of the main qualities of auscultatory measurement is that the appearance of Korotkoff sounds indicates systolic pressure and the disappearance (or muffling) of sound indicates diastolic blood pressure *(3)*.

1. Description

There are two commonly used non-mercury sphygmomanometers for manual BP measurement *(4)*:

- an aneroid manometer with an analogue display (circular scale with a pointer) and
- an electrical pressure transducer (digital manual) with an analogue look but a digital display (described previously).

Arterial pressure is measured with a sphygmomanometer, as shown in Fig. A61, which consists of an inflatable pressure cuff, a manometer (usually a mechanical gauge, electronic display or mercury column), an inflating bulb (hand pump) to increase the pressure in the cuff, and a deflating valve *(5)*.

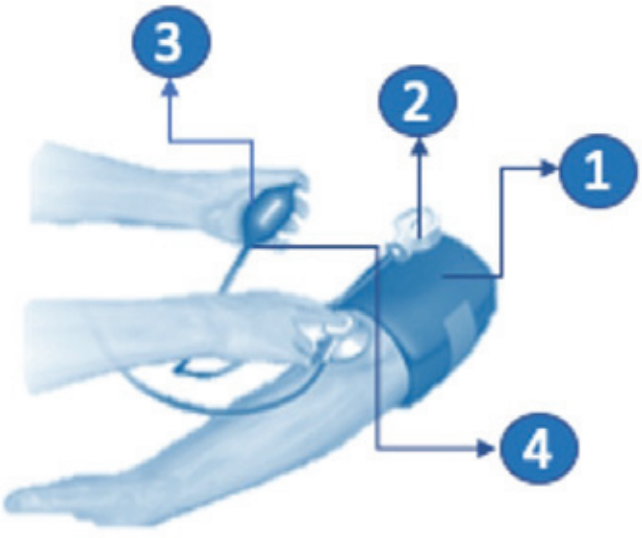
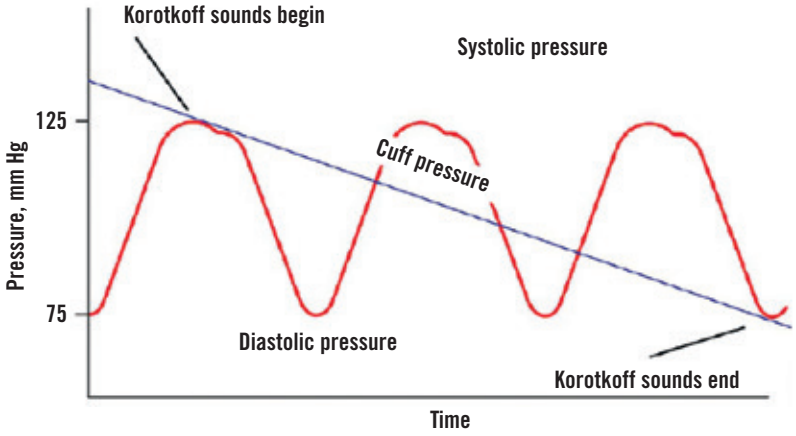


Fig. A6.1. Components of a sphygmomanometer

When an inflated air cuff compresses an artery, it closes it and stops the flow of blood. As the outside cuff pressure is gradually lowered, it eventually falls below that of the systolic pressure, and some blood forces its way through the artery during the brief period when the arterial BP is higher than the cuff pressure; however, the blood flow is not normal, resulting in turbulence that produces Korotkoff sounds. These sounds persist until the cuff pressure falls below the diastolic pressure and blood flow returns to normal (Fig. A6.2).



Source: Reference *(6)*.

Fig. A6.2. Korotkoff sounds

A stethoscope is used to listen to the Korotkoff sounds made by the blood flow in the arteries. Sounds occur in five phases as the cuff is deflated from the maximal occlusive pressure. There no are sounds until the cuff pressure is below the systolic pressure, when it creates turbulence and a sound is heard (Korotkoff 1, or systolic pressure). The sounds continue, with a slight change in character, until the cuff pressure is deflated below the diastolic pressure. At that point (Korotkoff 5, or diastolic pressure), no sound is heard. A manometer connected to the cuff is used to identify the pressure during the transitions from silence to sound to silence.

The auscultatory technique requires expertise acquired through training and practice. Other essential elements for accurate measurement by manual auscultation include very good auditory and visual acuity, manual dexterity to inflate and deflate the bulb, little ambient noise, a good-quality stethoscope and frequent re-training of the staff to maintain standardized technique *(7)*. Their hearing and accuracy should be reassessed regularly, at 6–12-month intervals. To carry out the BP measurement with a manual device, the following steps are suggested:

- Use a palpated estimate of the radial pulse obliteration pressure to determine maximal cuff inflation for BP measurement. Rapidly inflate the cuff 20–30 mm Hg above the pulse obliteration pressure to ensure proper determination of systolic pressure. (The pulse obliteration pressure is determined by palpating the radial pulse, rapidly inflating the sphygmomanometer, first to 60 mm Hg then in increments of 10 mm Hg until the pulse is no longer palpated.)
- Deflate the cuff pressure by 2–3 mm Hg per second and listen for Korotkoff sounds. The onset of two sequential tapping sounds is K1 and corresponds to the systolic BP. The point at which Korotkoff sounds disappear is K5 and corresponds to the diastolic BP. Occasionally, K5 will not be heard (sounds are heard to 0 mm Hg) or will be heard at a non-physiological level (e.g. 20 mm Hg). In such instances, the point at which the Korotkoff sound is muffled (K4) should be used as the diastolic pressure.
- Record systolic and diastolic pressure to the nearest even number. Do not round the number to the nearest 5 or 10 mm Hg.
- Ensure regular calibration assessment (every 6 months or according to the manufacturer's recommendations) of any aneroid sphygmomanometer (manual BPMD).

2. Measurement principles

As described above, the combination of a cuff, an inflation bulb with a release valve and a manometer is called a sphygmomanometer (Fig. A6.1), which is the equipment used in the auscultatory technique. The Korotkoff sounds in the artery can be detected by manual auscultation, as the manometer is used only to display pressure.

2.1 Mercury sphygmomanometer

For decades, the mercury sphygmomanometer was considered the gold standard and the first choice of device for BP measurement. Now, mercury is recognized as a substance producing significant adverse neurological and other health effects, with particular concerns expressed about its harmful effects on infants and unborn children. The global transport of mercury in the environment was a key reason for taking the decision that global action to address the problem of mercury pollution was required *(8)*,

> this leads to the Minamata Convention on Mercury, adopted in 2013 to protect human health and the environment from the adverse effects of mercury. Its core purpose is to "protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds."

The treaty specifies that some products containing mercury are excluded, such as products for research, calibration of instrumentation and as a reference standard.

2.2 Aneroid sphygmomanometer

Sphygmomanometers with aneroid (or mechanical) gauges and an elastic pressure-sensing element are common alternatives to mercury sphygmomanometers. They may be handheld, free-standing or wall-mounted. Important considerations *(4)* are:

- quality control of production and the technical design, which affect the reliability of a device to a greater extent than for mercury manometers;
- sensitivity to mechanical shocks; and
- the requirement for frequent calibration (usually every 6 months).

With regard to the second consideration, most aneroid manometers cannot withstand a fall from a typical table height. As this is unacceptable, the ISO/IEC Joint Working Group introduced requirements for the mechanical strength of portable and handheld aneroid manometers. With the exception of stationary non-automated sphygmomanometers, including aneroid types, all devices must function normally after a free fall from 25 cm. When they are labelled "shock resistant", they must withstand a fall from 1 meter without loss of performance.

3. Regulatory requirements and standards

The regulations and standards listed below were valid at the time of publication of this document. Any updates should be consulted. The lists are illustrative and non-exhaustive. The standards may not be required in all countries.

Standards applicable to general quality systems for medical devices:

- EN ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2012, Medical devices – Application of risk management to medical devices
- ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada and European Union)
- ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice
- ISO 14971:2007, Medical devices – Application of risk management to medical devices

- ISO 16142-1:2016, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

Standards applicable to manual BP devices:

- ISO 81060-1:2007, Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type
- ISO/IEEE 11073-10407:2010 (Part 10407: Device specialization -- Blood pressure monitor)
- BS EN 1060-2:1995 +A1:2009, Non-invasive sphygmomanometers: Supplementary requirements for mechanical sphygmomanometers

4. Calibration

Mercury devices must be inspected to ensure that the mercury column is intact, in the vertical position and that the mercury meniscus is centred at zero. Otherwise, no specific calibration is required.

Aneroid sphygmomanometers contain moving parts and lose accuracy relatively quickly. Therefore, calibration by technical experts every 6 months (or as recommended by the manufacturer) is necessary to ensure that accuracy is retained (9). More technical checks could be performed by an authorized laboratory (metrological testing to guarantee accuracy). Digital display BPMD can be calibrated against a reference manometer, such as an electronic manometer with an accuracy of ± 0.1 mm Hg or compared with a well-maintained mercury sphygmomanometer with a rated accuracy of only ± 3 mm Hg.

5. Maintenance

Maintenance routines for BPMDs should include all the following aspects.

For mercury sphygmomanometers, replacement of mercury columns is considered a high risk because of potential contact with mercury. Protective equipment and protocols should be followed to minimize risk. The tasks are:

- Clean and disinfect the exterior of the device.
- Lubricate casters and swivel wall mount.
- Inspect column integrity and zero-centred mercury meniscus.
- Replace tubing, hoses, connectors and cuffs as necessary.

For aneroid sphygmomanometers:

- Clean and disinfect the exterior of the device.
- Calibrate the device by technical experts.
- Replace tubing, hoses, connectors and cuffs as necessary.

An example of a procedure for preventive maintenance of a manual, non-invasive BPMD (aneroid or mercury sphygmomanometer) is shown in tables 8 and 9 below *(10)*. The suggested interval is every 6 months; the protocol takes 0.25 h. The test apparatus required is a pressure gauge or meter (not required for testing mercury sphygmomanometers, except for initial inspection or when the glass tube is replaced) and a stopwatch. The procedure includes qualitative and quantitative tasks for acceptance and scheduled inspections or both.

Table 8. Qualitative tasks to be performed according to the type of inspection
Manual non-invasive BP sphygmomanometers (aneroid or mercury)

Qualitative tasks	Acceptance inspection	Scheduled inspection	Both kinds of inspection
Chassis and housing			●
Mount and fasteners			●
Casters and brakes			●
AC plug (oscillometric and non-oscillometric units)			●
Line cord (oscillometric and non-oscillometric units)			●
Strain reliefs			●
Circuit breaker and fuse (oscillometric and non-oscillometric units)			●
Tubes, hoses and bulb			●
Fittings and connectors			●
Filters			●
Bleed valve			●
Indicators and displays			●
Zero pressure setting			●
Transducers (non-oscilometric units)			●
Controls and switches			●
Battery and charger (oscillometric and non-oscillometric units)			●
Battery (oscillometric and non-oscillometric units)			●
Labelling	●		
Alarms			●
Cuffs			●
Gauge and column			●
Accessories	●		

Table 9. Quantitative tasks to be performed according to the type of inspection

Quantitative task	Acceptance inspection	Scheduled inspection	Both kinds of inspection
Pressure leakage	●		
Pressure accuracy			●

6. Nomenclature

The benefits of adopting a global or universal nomenclature system have been described for electronic BPMDs *(11,12)*. The classification and nomenclature of manual devices are presented in Table 10.

Table 10. Classification and nomenclature of manual BPMDs

Generic name	Sphygmomanometer
Specific type or variation (optional)	Aneroid
GMDN name ©	Sphygmomanometer, aneroid
GMDN code ©	16156
GMDN category ©	04 Electro-mechanical medical devices
UMDNS name ©	Sphygmomanometers, aneroid
UMDNS code ©	16156
Alternative names/s (optional)	BP meters (sphygmomanometers); BP manometer; aneroid sphygmomanometer
Alternative code/s (optional)	MS 30892; MS 43524; S 43839
Keywords (optional)	BP, non-invasive, BP set, non-invasive BP, auscultation
Alternative code/s (optional)	
Keywords (optional)	Automatic electronic sphygmomanometers non-invasively

7. Technical specifications for manual BPMDs

Full description of technical specifications for manual BPMD procurement:

TECHNICAL SPECIFICATIONS FOR MANUAL BLOOD PRESSURE MEASURING DEVICES (Including information on the following where relevant or appropriate)		
i	Version No.	2
ii	Date of initial version	
iii	Date of last modification	December 2019
iv	Date of publication	April 2020
v	Completed / submitted by	WHO working group
Name, category or coding		
1	WHO category or code	
2	Generic name	Sphygmomanometer
3	Specific type or variation (optional)	Aneroid
4	GMDN name ©	Sphygmomanometer, aneroid, manual
5	GMDN code ©	16156
6	GMDN category ©	04 Electromechanical medical devices
7	UMDNS name ©	Sphygmomanometers, aneroid
8	UMDNS code ©	16156
9	UNSPS code (optional) ©	
10	Alternative names/s (optional)	BP meters (sphygmomanometers); BP manometer; aneroid sphygmomanometer

TECHNICAL SPECIFICATIONS FOR MANUAL BLOOD PRESSURE MEASURING DEVICES (Including information on the following where relevant or appropriate)		
11	Alternative code/s (optional)	MS 30892; MS 43524; S 43839
12	Keywords (optional)	BP, non-invasive, BP set, non-invasive BP, auscultation
13	GMDN/UMDNS definition (optional) ©	A device designed to measure BP consisting of an inflatable cuff that fits around a limb (arm or thigh), an inflation bulb for controlling the air pressure within the cuff, an aneroid manometer and tubing. The aneroid manometer consists of a metal bellows, which expands as the pressure in the cuff increases, and a mechanical amplifier that transmits the expansion through a lever to an indicator needle, which rotates around a circular, calibrated scale. The manometer may be mounted on a wall, placed on a table, or handheld (portable); BP measurement is taken in conjunction with a stethoscope.
Purpose of use		
14	Clinical or other purpose	Diagnosis of hypertension, monitoring of BP
15	Level of use (if relevant)	Screening site, health centre, district hospital, provincial hospital, specialized hospital
16	Clinical department or ward (if relevant)	All areas
17	Overview of functional requirements	Auscultatory, oscillometric or non-invasive BP methods. Inflatable rubber cuff surrounded by durable, flexible cover that can be easily fastened around upper arm Aneroid pressure gauge displaying cuff pressure Pumping bulb and valve that allow adjustment of cuff pressure
Technical characteristics		
18	Detailed requirements	Cuff arm fixing method to allow ease of use, ease of cleaning and low attraction of dirt; washable. Neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). The sizes of the cuffs may vary by manufacturer but should not deviate by ± 5 cm from the stated sizes. Pressure gauge to allow reading of pressure to 2 mm Hg accuracy Maximum pressure, ≥ 300 mm Hg Gauge body to allow recalibration of readings but be sealed and secure in normal operation
19	Displayed parameters	mm Hg
20	User-adjustable settings	
Physical and chemical characteristics		
21	Components (if relevant)	Rubber tubes to be detachable from other parts, allowing periodic cutting of decayed ends Gauge body to include clip for mounting on cuff Tube length to be > 30 cm Cuff material to be removable and washable To be supplied in protective case
22	Mobility, portability (if relevant)	Portable
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Not applicable
Accessories, consumables, spare parts, other components		
25	Accessories (if relevant)	
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables and reagents (if relevant)	Single-use cuffs in the following sizes: Neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). Reusable cuffs in the following sizes: Neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). The sizes off the cuffs may vary by manufacturer but should not deviate by ± 5 cm from the stated sizes.
28	Spare parts (if relevant)	Rubber tube (length > 30 cm), reusable cuffs of various sizes
29	Other components (if relevant)	Protective container

TECHNICAL SPECIFICATIONS FOR MANUAL BLOOD PRESSURE MEASURING DEVICES (Including information on the following where relevant or appropriate)		
Packaging		
30	Sterility status on delivery (if relevant)	Single-use cuffs must be delivered sterile.
31	Shelf life (if relevant)	Minimum shelf life for single-use cuffs must be 1 year from the date of reception.
32	Transport and storage (if relevant)	Storage environment humidity: 10–95% relative humidity. Storage environment temperature: –20 to 60 °C
33	Labelling (if relevant)	Not applicable
Environmental requirements		
34	Context-dependent requirements	Can be stored continuously at ambient temperature of 0–50 °C and 15–90% relative humidity. Can operate continuously in ambient temperature of 10–40 °C and 15–90% relative humidity.
Installation		
35	Pre-installation requirements (if relevant)	
36	Requirements for commissioning (if relevant)	
37	Training of users (if relevant)	Training of users in operation and basic maintenance shall be provided.
38	User care (if relevant)	
Warranty and maintenance		
39	Warranty	2 years
40	Maintenance tasks	
41	Type of service contract	
42	Availability of spare parts after warranty	5 years after discontinuation by factory
43	Availability of software and hardware upgrades	
Documentation		
44	Documentation requirements	User, troubleshooting and service manuals must be available to the user and patients in the language(s) of the country in which the device is used and/or in another language authorized by national regulatory agencies. Certificate of calibration and inspection to be provided when purchased. List of equipment and procedures required for local calibration and routine maintenance to be provided. List of important spares and accessories to be provided, with their part numbers and cost Contact details of manufacturer, supplier and local service agent to be provided.
Decommissioning		
45	Estimated life span	10 years
Safety and standards		
46	Risk classification	Class A (GHTF Rule 4); Class II (USA); Class I (Australia, Canada and Japan); Class IIa (European Union)
47	Regulatory approval or certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification, by regulatory agency (e.g. by a founding member of IMDRF-EU, USA, Canada, Australia, Japan). Else, approved by local national regulatory agency.

TECHNICAL SPECIFICATIONS FOR MANUAL BLOOD PRESSURE MEASURING DEVICES (Including information on the following where relevant or appropriate)		
48	International standards	Standards applicable to the product and to the manufacturing process are listed below. Compliance to the last available version of the international standard or to its local equivalent standard is recommended and proof of compliance must be provided. Non-exhaustive list of standards applicable to general quality systems for medical devices: • EN ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purposes" • EN ISO 14971:2012, Medical devices – Application of risk management to medical devices • ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada and European Union) • ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice • ISO 14971:2007, Medical devices – Application of risk management to medical devices • ISO 16142-1:2016, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards Non-exhaustive list of standards applicable to manual BP devices: • ISO 81060-1:2007, Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type • ISO/IEEE 11073-10407:2010 (Part 10407: Device specialization – Blood pressure monitor) • BS EN 1060-2:1995 +A1:2009, Non-invasive sphygmomanometers: Supplementary requirements for mechanical sphygmomanometers
49	Regional and local standards	ANSI/AAMI SP10:2002 and ANSI/AAMI SP10:2002/A1:2003 (Manual, electronic or automated sphygmomanometers) DS/EN 1060-1, Non-invasive sphygmomanometers – Part 1: General requirements DS/EN 1060-2, Non-invasive sphygmomanometers – Part 2: Mechanical sphygmomanometers AS EN 1060.3.2004, Non-invasive sphygmomanometers – Supplementary requirements for electromechanical BP measuring systems GOST R 51959.1, Non-invasive sphygmomanometers (Measuring devices of arterial pressure). Part 1. General requirements GOST R 51959.2, Non-invasive sphygmomanometers. Supplementary requirements for mechanical sphygmomanometers GOST R 51959.3, Non-invasive sphygmomanometers (Measuring devices of arterial pressure). Part 3. Supplementary requirements for electro-mechanical blood pressure measuring systems OIML R16-2:2002, Non-invasive automated sphygmomanometers JIS T 1115:2005, Non-invasive automated sphygmomanometers
50	Regulatory framework	Compliance with (where applicable, but not limited to, and latest available version): US regulatory requirements: Code of Federal Regulations, Title 21, Part 820 Code of Federal Regulations, Title 21, Part 870, Section 1130 / Non-invasive BP measurement system Japan regulatory requirements: MHLW Ordinance No.16916156000 Aneroid sphygmomanometer European Commission regulatory requirements: Council Directive 93/42/EEC of 14 June 1993 Regulation (EU) 2017/745 of the European Parliament and the Council

8. General standardized procedure for proper manual BP measurements

The same patient preparation steps detailed in section 4.1 should be employed. However, instead of activating the device, the following steps should be followed to obtain a BP measurement by manual auscultation.

- Determine the radial pulse obliteration pressure to determine maximal cuff inflation for BP measurement. The pulse obliteration pressure is determined by palpating the radial pulse, rapidly inflating the sphygmomanometer, first to 60 mm Hg then in increments of 10 mm Hg until the pulse is no longer palpated.
- 30–60 seconds after determining the pulse obliteration pressure, rapidly inflate the cuff 20–30 mm Hg above this pressure (the peak inflation level) to ensure proper determination of systolic pressure.
- Deflate the cuff pressure by 2–3 mm Hg per second and listen for Korotkoff sounds. The onset of two sequential tapping sounds is K1 and corresponds to the systolic BP. The point at which Korotkoff sounds disappear is K5 and corresponds to the diastolic BP. Occasionally, K5 will not be heard (sounds are heard to 0 mm Hg) or will be heard at a non-physiological level (e.g. 20 mm Hg). In such instances, the point at which the Korotkoff sound is muffled (K4) should be used as the diastolic pressure.
- Record systolic and diastolic pressure to the nearest even number. Do not round the number to the nearest 5 or 10 mm Hg.

***For manual auscultatory measurement in an office or clinic*, the practitioner should have recently passed a hearing test, and the accuracy of their BP measurements should have been assessed against those of others using a double- or triple-headed stethoscope within a regular training schedule. Their hearing and accuracy should be reassessed regularly, at 6–12-month intervals. Poor vision, hearing, manual dexterity, lack of training and decay of clinical skills all contribute to inaccurate BP measurement when employing the auscultatory technique.**

References

1. Booth J. A short history of blood pressure measurement. Proc R Soc Med 1977;70:793-799.
2. Chen Y, Shi S, Liu YK, Huang SL, Ma T. (2018). Cuffless blood-pressure estimation method using a heart-rate variability-derived parameter. Physiol Meas. 5; 39(9): 095002. doi: 10.1088/1361-6579/aad902.
3. Babbs CF. The origin of Korotkoff sounds and the accuracy of auscultatory blood pressure measurements. J Am Soc Hypertens 2015;9:935-950.e3.
4. SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Mercury Sphygmomanometers in Healthcare and the Feasibility of Alternatives, 23 September 2009
5. Bruce NG, Shaper AG, Walker M, Wannamethee G. Observer bias in blood pressure studies. J Hypertens 1988;6:375-380.
6. ECRI Institute. Monitors, Vital Signs, Device Overview Specifications – Comparative Data, Published 1/1/2016.
7. Wiley Encyclopedia of Biomedical Engineering. Metin Akay, Editor. WILEY-INTERSCIENCE. httos://onlinelibrary.wiley.com
8. UN Environment MINAMATA CONVENTION ON MERCURY TEXT AND ANNEXES www.mercuryconvention.org
9. Turner MJ, Speechly C, Bignell N. Sphygmomanometer calibration--why, how and how often. Aust Fam Physician 2007;36:834-8.
10. ECRI Instructions of Preventive Maintenance, Procedure No. 454-20160810 for Sphygmomanometers (aneroid or mercury) https://www.ecri.org
11. WHO. Nomenclature of medical devices. Retrieved from: https://www.who.int/medical_devices/priority/mde_nomenclature/en/
12. WHO. Standardization of medical devices nomenclature: International classification, coding and nomenclature of medical devices. April 2019. Retrieved from: http://apps.who.int/gb/ebwha/pdf_files/EB145/B145_3-en.pdf?ua=1

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