

Requirements for professional office blood pressure monitors

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For more than half a century measurement of blood pressure in the doctor's office using a mercury sphygmomanometer and the auscultatory method has been the cornerstone for hypertension management. However, due to the environmental and service issues mercury devices will not be available in the near future. As the mercury sphygmomanometer is being progressively eliminated from clinical use, it is being replaced by a variety of devices, which may not have been validated. This change in the practice of measurement may have an unpredictable impact on the threshold levels used for the diagnosis of hypertension and may also influence the management of hypertension. This expert document provides (i) information on the current availability of technologies and devices with potential for professional use (oscillometric, hybrid, aneroid and mercury devices) and the advantages and limitations of each one of them, and (ii) guidance on the requirements and selection of mercury-free blood pressure monitors for professional use. With the increasing use of automated oscillometric devices it is likely that the auscultatory technique will soon become redundant. However, consideration will be given to some of the technical aspects of the oscillometric technique and to the educational aspects of auscultation that may make it premature to abandon the technique altogether.

Keywords: blood pressure measurement, clinic, hypertension, office, professional, validation

Abbreviations: AAMI/ISO, Association for the Advancement of Medical Instrumentation/International Organization for Standardization; BHS, British Hypertension Society; ESH-IP, European Society of Hypertension International Protocol

BACKGROUND

The measurement of blood pressure in the office or clinic, by the doctor, or nurse, or medical assistant remains the basis for the assessment of hypertension [1–3]. The history of clinical epidemiology and research in hypertension, which demonstrated the risk associated with elevated blood pressure and the benefits of treatment-induced blood pressure decline has been almost exclusively based on measurements taken using conventional mercury sphygmomanometers. This device has been widely used for more than a century to detect hypertension

and guide long-term treatment in millions of people around the world. However, environmental considerations have influenced several countries to ban mercury devices from clinical use [4] and it seems that mercury sphygmomanometers will soon only be available for designated institutions such as validation laboratories. Consequently, there has been considerable discussion and debate on an optimal alternative to the mercury device for professional use which is urgently needed [5–11]. As the mercury sphygmomanometer is being progressively eliminated from clinical use, it is being replaced by a variety of devices, which may not have been validated. This change in the practice of measurement may have an unpredictable impact on the threshold levels used for the diagnosis of hypertension and may also influence the management of hypertension [12,13]. Therefore, guidance is needed on the requirements of any alternative mercury-free blood pressure monitor to replace the mercury device for professional use. The issue is complicated by the fact that replacement of the mercury sphygmomanometer might also herald the demise of the auscultatory technique.

OBJECTIVE

This expert document is addressed to all doctors dealing with blood pressure measurements and aims to provide (i) information on the current availability of technologies and devices with potential for professional use and the advantages and limitations of each one of them, and (ii) guidance on the selection of devices to replace mercury sphygmomanometers for professional use and their clinical validation.

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DEFINITION OF THE PROFESSIONAL BLOOD PRESSURE MONITORS

The document is confined to dealing with blood pressure monitors for use by medical staff in the office, clinic, or hospital wards. It does not deal with devices for out-of-office measurement, such as ambulatory blood pressure monitors that also are professional devices, or with devices designed for blood pressure measurements by patients at home. It deals with available techniques and does not consider future techniques under development.

TECHNOLOGY OF PROFESSIONAL BLOOD PRESSURE MONITORS

The main characteristics of the different types of blood pressure monitors designed for professional use are presented in Table 1.

Oscillometric devices

- These devices have dominated the ambulatory and self-home blood pressure monitoring market, yet their use in the office, clinic or hospital is still debatable [7,10,12–16]. They are becoming very popular and used in many medical centers at least in developed countries. Several oscillometric devices for professional use are available on the market [17].
- They use the oscillometric principle to measure mean blood pressure and apply a manufacturer and device-specific algorithm to estimate systolic and diastolic blood pressure.
- The oscillometric devices have the advantage of requiring little training (compared to auscultatory devices) and of being devoid of the observer bias if correctly used.
- In patients with arrhythmia the oscillometric devices may not be able to give accurate blood pressure measurements [14–16]. This issue is still under investigation. Also, in some cases the oscillometric devices are in disagreement with the auscultatory method without clear reason. This does not imply that the auscultatory reading always gives the correct blood pressure. Such disagreement may be related to arterial stiffness and pulse pressure [18] or other hemodynamic parameters (e.g. increased cardiac output in children and pregnancy, tissue composition, obesity, etc.).
- The role of automated oscillometric devices in measuring hemodynamic changes, such as postural changes in blood pressure, has not been adequately investigated. Fast blood pressure changes occurring when shifting from seated to standing would need continuous beat-by-beat blood pressure monitoring to be reliably assessed, which is now available through noninvasive plethysmographic finger-cuff blood pressure monitors. In most patients, however, the information provided by automated arm cuff devices is sufficient to identify clinically relevant cases of both orthostatic hypotension and orthostatic hypertension. Some new professional oscillometric cuff devices offer a ‘fast’ mode to measure blood pressure

TABLE 1. Main characteristics of the different types of professional blood pressure monitors

	Oscillometric	Hybrid	Aneroid	Mercury
Availability	Wide	Limited	Wide	Decreasing and will not be available in the near future due to the environmental and service issues
Measurement method	Automated oscillometric	Auscultatory	Auscultatory	Auscultatory
Method advantages	Avoids observer prejudice and bias Can take multiple automated measurements even in the absence of a physician Automatic calculation of average Cable or bluetooth transfer of results	Probably same accuracy in all individuals	Same accuracy in all individuals	Same accuracy in all individuals
Method limitations	Questionable accuracy in arrhythmia Inaccurate in some individuals for unclear reason	Observer prejudice and bias, terminal digit preference, etc.	Observer prejudice and bias, terminal digit preference, etc. May lose accuracy in long-term use	Observer prejudice and bias, terminal digit preference, etc.
Validation	Clinical validation required. Separate in subgroups of individuals (elderly, diabetic patients, pregnancy, obese, children, etc.)	Clinical validation required. Separate validation in subgroups of individuals not deemed necessary	Clinical validation required. Separate validation in subgroups of individuals not deemed necessary	Gold standard method. Maintenance required only
Training	Little training required	Observer training required	Observer training required	Observer training required
Cuffs	Device-specific cuffs required	Device-specific cuffs required in most cases	Can operate with different, not manufacturer-specific cuffs	Can operate with different, not manufacturer-specific cuffs
Maintenance – calibration	Little required	Requirements largely unknown but expected to be minimal	Regular maintenance and calibration required	Regular maintenance required which is becoming difficult to perform
Cost	€ 150–650*	€ 150	€ 70–150	€ 60–150. High cost of mercury leakage management.

*Lower price is for oscillometric devices and higher price for devices having both oscillometric and auscultatory measurement mode.

in less than 30 s and others may offer the possibility to determine only systolic blood pressure in a 'very fast' mode [19]. Such specific modes might be used in the clinic to detect rapid blood pressure changes as observed in orthostatic hypotension and other critical situation. However, although such fast and very fast modes are based on the oscillometric method, their clinical validation is necessary [19].

- Some professional oscillometric devices have been programmed to take multiple blood pressure readings in the office or clinic (by manual activation or blue-tooth), which allows measurements to be obtained in the absence of an observer, while patients are alone in the examination room (automated office blood pressure measurement). It has been argued that these measurements might be devoid of the office reaction (white-coat effect) and give blood pressure values similar to those obtained by daytime ambulatory blood pressure monitoring [20].
- The oscillometric devices require formal clinical validation against a mercury sphygmomanometer using a recognized protocol, the most commonly used being the European Society of Hypertension. International Protocol (ESH-IP) [21]. Separate validation is required in subgroups of patients, for example elderly, diabetic patients, pregnancy, obese, children, etc. Some oscillometric devices designed for professional use in the office or clinic have been successfully validated using established protocols [17].
- Oscillometric devices require far less maintenance and calibration than mercury or aneroid devices and are usually discarded if they cease to function.
- Some professional oscillometric devices obtain blood pressure measurements using different modes (algorithms), for example, normal, fast blood pressure determination, smart inflation, etc. therefore, the same device may use different algorithms to measure blood pressure. Each method (algorithm) requires independent and specific validation.

Hybrid devices

- These are mercury-free devices which have a mercury-like column with LCD (A&D UM 101 [22] and Pic Indolor Professional [19]) or LED technology (Nissei DM3000) [23], or an aneroid device-like screen with LED technology (Accosson Greenlight) [24], or a digital LCD screen (Omron HEM907 [25,26], Microlife WatchBP Office [27]) to display the cuff pressure.
- An observer using the auscultatory method to detect the Korotkov sounds is required to estimate systolic and diastolic blood pressure. Thus, these devices also have the limitations of the auscultatory method, such as need for trained observers, observer inattention, prejudice and bias, terminal digit preference, and so on [1]. In patients with atrial fibrillation, frequent ectopic beats or other arrhythmias, the auscultatory estimation of blood pressure is difficult and uncertain and several readings should be obtained and averaged.

- These devices require clinical validation against a mercury sphygmomanometer. Several such devices have been successfully validated. The option to substitute a full clinical validation in patients with a range of blood pressure with metrological calibration in which only the pressure measurement is checked for accuracy is not recommended for these devices because unexpected issues may arise in their clinical use by observers, which might affect the measurement accuracy (e.g. in reading LCD, LED or digital display). These issues can only be identified by formal clinical validation and will be missed if only metrological calibration is performed. One example is a 'mark button' function available in one of the hybrid devices (A&D UM101), which was intended to prevent the observers' rounding of recorded blood pressure values (terminal digit preference, usually 0 or 5) by pressing the 'mark' button when detecting the systolic and diastolic blood pressure and thereby marking on the LCD mercury-like column the detected blood pressure values. However, the use of the 'mark button' was shown to reduce the accuracy of the device due to the observers' reaction time required to press the button [22]. These data suggest that clinical validation is usually required to demonstrate the effect of novel features of devices on the measurement accuracy. Separate validation of the hybrid auscultatory devices in specific populations (e.g. elderly, diabetic patients, children, etc.) generally is not deemed necessary.

Aneroid devices

- Require the use of the auscultatory method with its limitation and bias, which often is not properly applied.
- Require validation against mercury. Few such devices have been validated. Whether formal clinical validation [e.g. using the ESH-IP [21,28], the British Society of Hypertension (BHS) protocol [29], or the Association for the Advancement of Medical Instrumentation/International Organization for Standardization (AAMI/ISO) protocol] [30], or only metrological calibration (without involving patients) is required might be debatable, yet the safest approach would be to obtain both. In general, separate validation in specific populations (e.g. elderly, diabetic patients, children) is not deemed necessary.
- Require regular maintenance and calibration, otherwise they may lose accuracy in long-term use. This is why they are not preferred for professional use [31,32].

Mercury sphygmomanometer

- Considered as the gold standard when properly used and maintained.
- Requires the use of the auscultatory method with its limitation and bias, which often is not properly applied.
- The weaknesses include a defective control valve, which causes leakage of air with underestimation of systolic and overestimation of diastolic blood

pressure; leaks in cracked or perished tubing and loose connections, which make it difficult to control the fall of mercury leading to inaccurate measurement [33].

- Will not be available in the near future due to the abovementioned environmental and service issues.

VALIDATION REQUIREMENTS FOR PROFESSIONAL BLOOD PRESSURE MONITORS FOR USE IN THE OFFICE OR CLINIC

- At least two clinical validation studies are required. These should be conducted using one of the established protocols (ESH-IP [21,28], BHS [29], AAMI/ISO [30]) in two different research centers. At least one of the two validation studies should involve adults of general population with blood pressure range as requested by the used protocol, whereas the second might investigate a special population (e.g. elderly, diabetics, pregnancy, obese, children, end-stage renal disease). To be considered as validated, the device has to pass both studies. If there is disagreement in the conclusion of the two studies, the device will not be recommended for professional use. If similar studies performed in similar populations but in different centers provide contradictory results, a third validation study in the same population will be necessary.
- In the past decade the ESH-IP has been the preferred validation protocol worldwide, with two-fold more studies reported using this protocol than the BHS and AAMI taken together [34]. Moreover, there is evidence suggesting improved performance of the oscillometric devices in terms of the ESH-IP criteria and 85% of the published ESH-IP studies have passed the protocol [34,35]. This issue has been addressed in the revised ESH-IP 2010 in which the pass levels have been

tightened [28]. Because of the wide acceptance of the ESH-IP and its recent revision to meet the improvement in technology, this protocol is recommended for the validation of new blood pressure monitors.

- Some devices may use more than one technology for blood pressure measurement, for example oscillometric and auscultatory, the operation of which might be manual (decided each time by the observer) or automated (the device automatically activates the auscultatory mode when the oscillometric curve is inadequate). In these cases each measurement function requires separate clinical validation.
- The application of an arm cuff at the forearm might be considered in case of severe obesity with conical shaped arm in which the conventional large cuff may not be easily applicable, yet its actual clinical value has not been assessed by ad hoc validation studies.
- It should be mentioned that a change in the measurement algorithm, the deflation system, or the cuff can affect the blood pressure measurement accuracy. Thus, specific models rather than brands are validated and any change in the model features should be considered for separate validation, unless it is clear that the modification does not affect the measurement accuracy [17]. Aiming to ensure that all new device models with changes that might affect the blood pressure measurement accuracy will be subjected to separate validation and also to prevent unnecessary validation of new models with minor changes, the Dabl Educational Trust has initiated the 'Declaration of Blood Pressure Measuring Device Equivalence' procedure [17,36]. The declaration requires manufacturers to provide detailed information and assurances that a new nonvalidated device is identical to a validated device in all blood pressure measuring aspects and that all the differences between the devices do not affect the accuracy of blood pressure measurement.

TABLE 2. Features of professional blood pressure monitors for office, clinic or hospital use

<p>Required (essential)</p> <ul style="list-style-type: none"> • Measurement method: (i) aneroid or hybrid devices (LCD, LED or digital screen) with auscultatory measurement mode; (ii) devices with oscillometric and also auscultatory measurement mode (LED or LCD or digital screen) to allow the physician to select the measurement method in each individual (e.g. auscultation in arrhythmia). Whether devices that allow only oscillometric blood pressure measurement should be used in the office, clinic or hospital is still debatable. • Power: mains electricity operation but also by a rechargeable battery which should allow more than 500 measurements. • Cuffs: at least three of different size to cover arm circumference range from less than 17 to greater than 42 cm. For pediatric application, cuff size for arm circumference at 14 cm or smaller is required. Cuff size for very large arms (up to 50 cm) is desirable. • Housing: appropriate device design for different healthcare facilities (office, clinic, hospital wards), for example wall mounted, to be placed on a table, hand-held, on wheels, etc. • Deflation rate: for auscultatory devices (aneroid or hybrid) either manual deflation (bulb) or by an automatic pressure release valve with deflation rate at 2–3 mm/s. Deflation triggered by heart rate at 2–3 mmHg per heart beat would be more appropriate in the presence of bradycardia. <p>Recommended (important but not necessary)</p> <ul style="list-style-type: none"> • Monitoring blood pressure at variable intervals. • Memory capacity to recall previous measurements. • Automated triplicate blood pressure measurement and calculation of the average. • More thorough assessment of devices in terms of overall quality (e.g. PA.NET certification [37]). <p>Optional (desirable but in most cases not important)</p> <ul style="list-style-type: none"> • In-build printer. • Bluetooth or USB connection for automated transmission to patients' electronic records. • Simultaneous both-arm blood pressure measurement. • Simultaneous arm-leg blood pressure measurement for ABI calculation.

FEATURES OF PROFESSIONAL BLOOD PRESSURE MONITORS FOR OFFICE OR CLINIC USE

- There are several features that are essential for a professional blood pressure monitor (classified as 'required') (Table 2). Other features are important but not necessary (classified as 'recommended') and other are desirable but in most cases not important (classified as 'optional').
- Caution is needed when any additional feature is added to a professional blood pressure monitor. Although in theory a novel feature might appear to be useful, its true impact when applied in clinical practice is not always apparent and predictable and special testing is required before being accepted and applied. A typical example is the 'mark button' of the hybrid device, which aimed to eliminate the observer bias and terminal digit preference, yet it was proved to reduce the accuracy of blood pressure measurement when it was subjected in clinical testing [22].

CONCLUSION

As the mercury sphygmomanometer is progressively eliminated from clinical use, it is being replaced by several alternative devices. Unless this trend is carefully monitored and managed the impact on the management of hypertensive patients in clinical practice will be unpredictable. As a first step in the process this review provides information on the current availability and features of technologies and devices with potential for professional use together with guidance on the requirements and selection of mercury-free blood pressure monitors for use in clinical practice.

Although the present trend favors replacing the mercury sphygmomanometer with oscillometric devices which remove the need for auscultation, there is continuing debate on some of the technical aspects of oscillometry. Although the use of the auscultatory technique is being reduced in clinical practice, at present there are merits in retaining the technique with the mercury component replaced by other validated technologies, such as good-quality aneroid, digital electronic and hybrid devices.

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Conflicts of interest

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