Devices for Home Blood Pressure Monitoring

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1.1 Introduction

The use of home blood pressure (BP) monitoring (HBPM) for hypertension management is recommended by most of the international guidelines [1–4]. While these recommendations provide information on HBPM indications, procedures, and thresholds of BP values, they provide very few, or no, indications on device choice. In fact, the hypertension guidelines of the European Society of Hypertension (ESH) and the European society of cardiology (ESC) simply indicate: "HBPM …performed with semiautomatic validated BP monitors…; use of Apps as a cuff-independent means of measuring BP is not recommended; Telemonitoring and smartphone applications may offer additional advantages [4]." No other information on the device choice is indicated. The other guidelines [1–3] do not provide more indications (Table 1.1). Given the worldwide increasing dissemination of HBPM, more detailed indications on choice and use of HBPM devices are therefore necessary to guide physicians, patients, and users towards an adequate choice of suitable equipment.

In the absence of guidance on how to choose a reliable HBPM device and considering the great popularity of HBPM which is now widely available in most countries, the device market has evolved into an uncontrolled one with about 80% of marketed devices either not validated or with questionable accuracy [5]. This global BP monitoring market reached US$ 16.9 billion in 2015 and is expected to reach US$ 23.8 billion in 2020, thus being one of the most lucrative markets in the field of cardiovascular health [5, 6].

Table 1.1 Indications on HBPM devices from current hypertension guidelines

ESH/ESC	AHA/ACC	CHEP
• Semiautomatic validated BP monitor. • Memory to store and review BP data • Use of Apps as cuff-independent means of measuring BP is not recommended • Tele monitoring and smartphone Apps may offer advantages	• Use of automated validated device • BP device validated with an internationally accepted protocol • Use of auscultatory devices is not generally useful for HBPM • Monitors with data storage in memory are preferred • Use of appropriate cuff size to fit the arm	• Use only BPM devices that are appropriate for the individual and have met the standards (AAMI, ISO, BHS, ESH-IP) • Encourage devices with data recording capabilities or automatic data transmission

ESH/ESC European Guidelines [4], *AHA/ACC* American Guidelines [1], *CHEP* Canadian guidelines [3]

The widespread use of HBPM, the scientific recommendations of its use, and the large financial potential of the device market emphasize the need of device accuracy and certification and the necessity of providing clear guidance to this market by giving strict indications for the choice of HBPM devices. Publication of lists of validated home BP devices has been successfully conducted. Updated lists of the validated devices are available at several non-profit (www.bihsoc.org, https://hypertension.ca) or for-profit organizations: www.medaval.ie, www.dableducational.org [3, 7–9]. Despite the establishment of such lists, they are currently accessed only by small groups of scientists and experts and thus do not reach most of the concerned public, including physicians, pharmacists, and patients [5]. The purpose of this chapter is to describe the main characteristics of the most widely used HBPM devices and to help prescribers, consumers, and users in choosing the most reliable and suitable device.

1.2 Blood Pressure Measurement Techniques Used For HBPM

Several techniques for measuring BP are used by HBPM devices. These devices are either manual, semiautomated, or automated. Semiautomated are characterized by automatic inflation and manual cuff deflation; automated devices are characterized by automatic cuff inflation and deflation. The most widely used techniques are described below.

1.2.1 Manual Auscultatory Method

The manual auscultatory method to detect the Korotkoff sounds using either aneroid or mercury devices—where mercury manometers remain available —are not recommended for HBPM as they require substantial patient training and regular calibration [1–4].

1.2.2 Automatic Auscultatory Method

Very few devices incorporate microphones or specific sensors to perform automatic auscultatory (microphonic) measurement of BP with less user interference. Some of these devices offer automatic BP measurement using dual methods (auscultatory and/or oscillometry). Their use remains limited to exceptional cases where automatic BP measurement is problematic. Overall, the auscultatory method is not currently recommended for HBPM by clinical guidelines.

1.2.3 Oscillometric Method

Most automatic or semiautomatic electronic devices for BP measurements are using the oscillometric method [10]. Each device has its specific algorithm to calculate BP

and pulse rate from the collected oscillometric signal. Most of these devices acquire data for measurements during cuff deflation whereas others do this during cuff inflation. Since each device has its own specific proprietary algorithm and technical characteristics, the measurement accuracy of one device cannot be extrapolated to another even if produced by the same manufacturer. Moreover, since the cuff in the oscillometric method is used not only to obtain arterial occlusion but also as a sensor to collect the oscillometric signal, experts agree that each oscillometric device must be used only with its own specific cuff(s) as provided by the manufacturer. Therefore, HBPM devices must be considered as the combination of a device and its accompanying cuff(s), whereas the cuff size and type used in the auscultatory method may not be applicable.

Electronic oscillometric devices require little to no training and are user-friendly, relatively inexpensive, and generally not affected by observer bias if used correctly. These devices, as well as all the other BP measurements devices, must meet the requirements of national and international regulatory bodies for medical devices such as the Food and Drug Administration (FDA) in the United States (US), and the CE (Conformité Européene) labeling according to the medical device Directives and Regulations in Europe. Since these regulations are mainly focused on safety rather than accuracy, it is recommended to use only devices that have undergone independent validation and passed the criteria of established validation protocols (CF. Accuracy).

Automatic oscillometric devices have been designed to measure BP at different arterial sites. The most popular (and recommended) ones are those measuring BP at the upper-arm (brachial artery) level and to a lesser extent those measuring BP at the wrist (radial artery) level. Even though several automated wrist devices have successfully passed recommended validation protocols, they are considered less accurate than the upper-arm devices. Oscillometric wrist device accuracy can be affected by wrist anatomy and position (with reference to the heart level), as well as by the wrist cuff characteristics (soft or pre-shaped). The pre-shaped cuffs are easier for patients to use but they conform less well than the soft one to the wrist.

Many of the electronic oscillometric devices include additional features such as memory, connectivity (PC, smartphone, or telemonitoring), and position sensor (CF Features), which may facilitate the HBPM procedures and improve its impact for hypertension management.

Taking into consideration all these aspects, current guidelines recommend the use of automated electronic oscillometric upper-arm cuff devices which meet regulatory authority requirements and have been validated according to established protocols. Moreover, some of these guidelines also do support wrist devices if used correctly in certain clinical circumstances. Indeed, wrist measurements can be helpful when the upper-arm cuff cannot be correctly fitted or is structurally impossible, such as in obese subjects with a very large upper-arm circumference.

1.2.4 Hybrid Devices

Hybrid devices have two BP measuring methods—the manual auscultatory method and the oscillometric method (CF). Even though these devices, originally developed

for office BP measurement, are accurate and require less maintenance than the aneroid device, their use for HBPM is not recommended. Additionally, the use of the auscultatory method remains affected by observer bias and other disadvantages of this method; moreover, they are more expensive than most of the other digital oscillometric HBPM devices. If a hybrid device is used for HBPM, then the automatic oscillometric method would be preferable.

1.2.5 Plethysmography: Cuffless Method

For many years, many device manufacturers have been attempting to develop cuffless BP measurement devices as these would avoid many of the inconveniences associated with cuff measurements. Among these techniques such as tonometry, pulse wave velocity, pulse transit time, and plethysmography, the plethysmographic approach appears to be the most likely method to succeed [11]. Briefly, plethysmography measures volume changes. When applied to an arterial segment, the measured changes of volume are transformed into changes of pressure with calculation of systolic and diastolic BP and pulse rate values according to specific algorithms. To date, most of the cuffless devices used at the finger or at the wrist level (watches, bracelets), or even those applied at the earlobe level, are based on the plethysmographic method. These use an infrared (or other) photoelectric sensor to record changes in pulsatile blood flow by calculating the light absorption changes, which are then translated into BP values. Cuffless BP values are derived through various methods including calculation of pulse transit time, analysis of the signal using the Fast Fourier Transform (FFT) and Generalized Transfer Function (GTF), or relationships between BP and the arterial radial volume changes.

Accuracy of most plethysmography-based cuffless devices for BP measurements which may be used for HBPM remains controversial. In fact, to our knowledge, none of these very popular devices (watches, bracelets, smartphone Apps) satisfy regulatory requirements or has been validated according to currently established protocols. Therefore, despite their large distribution, mainly as multiple parameters monitoring bracelets or watches, the use of these devices is not presently recommended for HBPM as their accuracy and reliability remains highly questionable. It should be mentioned, however, that established validation standards have not been developed to assess cuffless devices and a new ISO standard for such devices is currently under development.

1.2.6 Tonometry

Principles of tonometry for measuring radial BP and performing pulse wave analysis using the transfer function has been reported and described in detail previously elsewhere [12]. Briefly, tonometry means “measuring of pressure” whereas applanation means “to flatten” the arterial wall. Applanation tonometry is performed by placing one or several tonometers (strain gauge pressure sensor) over the radial artery and applying soft pressure to obtain an assumed flattened arterial wall. This method was

designed particularly for clinical use by researchers to measure the radial BP and calculate aortic (central) BP by performing the pulse wave analysis and using algorithms such as the Transfer Function. Considering the importance of aortic BP, manufacturers have tried to extrapolate the use of this technique for HBPM, but this approach is still under development and at this time remains reserved for research.

1.2.7 Other Techniques

Several other techniques to measure BP have been proposed for HBPM. The most current methods include:

- Pulse transit time: this technique is based on the assessment of pulse wave velocity and on use of its reciprocal variable, the pulse transit time, to calculate beat-by-beat BP values through a dedicated algorithm [13].
- Smartphone Apps turning the smartphone into a cuffless device. Most of these Apps use the light absorption changes from a finger to estimate changes in blood volume and to calculate finger BP values by considering the relationships between changes of blood volume and the corresponding changes in BP.

None of these techniques can be currently recommended as reliable methods for performing HBPM.

1.3 Arterial Sites: Which Are Most Suitable for HBPM?

HBPM devices measuring or calculating BP at different arterial sites are now available: upper-arm, wrist, finger, or even aortic. The choice of the arterial site is important, not only because most, if not all, of the hypertension studies have been performed using brachial BP measurements but also because BP values are not identical at the different arterial sites due to an "amplification" phenomenon.

1.3.1 Brachial Artery

Most HBPM devices measure BP at the upper-arm level (brachial artery). This measurement is currently recommended by all guidelines.

1.3.2 Radial Artery

- Oscillometric devices: several HBPM devices measuring BP at the wrist level (radial artery) are available. These devices are very popular because they are user-friendly for patients. To limit observer bias and the BP variations between brachial and radial arteries or those due to the wrist position in relation to the heart level, several wrist devices incorporate interesting features such as a position

sensors or movement detectors. Some of the recently marketed wrist devices are of good quality and have passed one or more validation protocols. However, even though oscillometric wrist devices are regarded as less accurate than the upper-arm devices in daily practice, they remain useful for those conditions (e.g., severe obesity) where the upper-arm measurements may be problematic [1–4]. These recommendations are reflected in HBPM guidelines (references).

– Bracelets and Watches: several devices designed as watches or bracelets provide BP values using the photo-plethysmography method. To our knowledge, none of these devices has been validated; therefore, they cannot be recommended for HBPM.

1.3.3 Finger

Several devices or smartphone Apps provide BP values at the finger level using mainly the photo-plethysmographic method. When used to measure BP, this method can be affected by many factors which may constitute causes of error. Apart from some professional devices used in the research lab (Finapres®, Finometer® Pro), none of the other devices intended for public use has been validated. Therefore, these devices cannot be recommended for HBPM.

1.3.4 Aortic: Central BP

Considering the importance of aortic central BP and pulse wave analysis, a few HBPM devices provide central BP values and other arterial hemodynamic parameters. These values are obtained using algorithms such as a transfer function from peripheral arterial pulse waves to central pulse waves and/or other algorithms applied on the oscillometric signal recorded at the brachial artery level. Despite the importance of these parameters, their use remains reserved for research; thus, they are not recommended for routine HBPM.

1.4 Accuracy of HBPM Devices

1.4.1 Validation Protocols

Accuracy of HBPM devices is a prerequisite for correct diagnosis and management of hypertension. Thus, our task as experts and physicians should be to ensure that patients are using accurate devices and that inaccurate devices should not be made available to consumers. The quest for accuracy of BP measuring devices has been ongoing for several decades. Since the 1980s, several validation protocols have been developed. Among those most commonly used, we should mention: [1] the Association for the Advancement of Medical Instrumentation (AAMI) standard (US-based) [2, 14] the British Hypertension Society (BHS) protocol [3, 15] the European Society of Hypertension International Protocol (ESH-IP) which has been

the most commonly used validation protocol during the last decade [16]; and [4] the International Organization for Standardization (ISO) standard for clinical validation of noninvasive sphygmomanometers [17]. Despite their differences, all these validation protocols have the common objective of establishing standards of accuracy for BP devices. The availability of a multitude of protocols causes confusion among physicians, users, and manufacturers but also adds difficulties in making validation a mandatory requirement. Considering these concerns, experts from ESH, AAMI, and ISO have now established a "Universal" Standard which will be applicable worldwide [18]. Therefore, experts agree that BP device validation studies must follow this single protocol, and that in the future only devices that have passed validation based on this "Universal" protocol will be used for HBPM.

1.4.2 General and Special Populations

Validation protocols include several procedures related to subject selection. Usually, subjects recruited for a validation study must represent the so-called "general population" defined as adults with no specific condition (other than hypertension) or major associated disease, and covering well-defined BP ranges, arm circumferences, and gender distribution. Since there is evidence that in several special populations automatic BP devices may have different levels of precision than in the general population, it makes sense to ask that validation of HBPM devices must be performed in both general and special populations if that is the intended future use for that device [19–21].

Special populations are defined as those with theoretical and clinical evidence that may affect accuracy of BP monitors. Experts agree that young children, pregnant women (including preeclampsia), subjects with a large arm circumference (>42 cm), and patients with arrhythmias must be considered as special populations [18]. Patients with chronic arrhythmias have been usually excluded from validation studies. Recent evidence is available that, when specifically tested in patients with arrhythmias, automated BP measurement is considered as uncertain or with reasonable accuracy [22, 23]. Other conditions which could be considered as "special populations" include adolescents, individuals aged >80 years, and those with diabetes or end-stage renal disease who have modified arterial hemodynamics. However, it is still unclear to what extent this may affect accuracy of HBPM devices. It is important to highlight that all these special populations constitute a very large part of patients attending hypertension centers. Therefore, the choice of validated HBPM devices must consider also individual phenotypes.

1.5 Cuff Issues and HBPM

Blood pressure cuff issues in HBPM are of high importance for accurate measurements; a specific chapter in this book has been dedicated to this subject. Considering that the majority of HBPM is performed using semiautomatic upper-arm devices, it is of high importance that devices be used with their specifically designed cuff(s) according to the manufacturer recommendations. Interchangeability of cuffs is strongly discouraged.

1.6 Device Features

Most HBPM devices include several features to either facilitate successful HBPM readings or to increase accuracy of BP values.

1.6.1 Blood Pressure Parameters

All automatic HBPM devices provide systolic and diastolic BP as well as the pulse rate. Some devices provide additional BP values such as mean arterial pressure or pulse pressure.

1.6.2 Other Parameters

Additional parameters can be acquired such as single lead electrocardiogram (ECG), blood glucose, oximetry, central BP, or arterial hemodynamic parameters derived from pulse wave analysis. Some devices now will calculate the shock index (heart rate/systolic blood pressure) that may be used to monitor vital signs in conditions such as hemorrhage and sepsis [24].

1.6.3 Built-in Memory

Most of the HBPM monitors include a built-in memory which allows storage and review of BP measurements for one or more users. These devices are preferred to those without such features.

1.6.4 Communication: Data Transmission

Different techniques are used to download data from the monitor: (1) wired (USB cable) or wireless connection to a computer and (2) Wi-Fi or Bluetooth connections to smartphones or tablets via specific Apps or other servers. These features are very important to enable the incorporation of HBPM data in telemedicine. Currently, these devices are preferable and used frequently in hypertension specialty centers. A chapter in this book is dedicated to these specific issues.

1.6.5 Averaging Function

Some HBPM devices can be used in mode “Average” or “Repeat” which allow repetition of 2 or 3 BP measurements at about 1-min interval and display their average with or without the first measurement. This averaging function may facilitate achieving a standardization of HBPM.

1.6.6 Position Sensor

In order to avoid positioning errors, some wrist devices have a built-in position sensor that allows BP measurement only when the wrist is in a suitable position (e.g., at the level of the heart). This function is important for limiting arm position-related errors with wrist BP devices [25].

1.6.7 Arrhythmia/Atrial Fibrillation

Most recent upper-arm or wrist HBPM devices also have a cardiac arrhythmia detection function. Some of these oscillometric devices include a specific algorithm for atrial fibrillation (AF) detection; this specific algorithm can be used also for opportunistic AF screening in the elderly according to the NICE guideline [26].

1.7 HBPM Devices: State of the Market

The market for BP measuring devices is very large and active; its financial attraction created a substantial market often driven principally by the lure of profitability. This phenomenon has resulted in a market in which about 80% of devices are either without validation or with questionable accuracy. To help providing assistance to physicians and users of HBPM lists of all validated devices have been made available by either scientific, not-for-profit or private institutions. Updated lists of validated devices are published on the internet and are available at several websites. Therefore, it would be important to check the listings of the validated HBPM devices before purchasing or prescribing them.

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