

Validation of three professional devices measuring office blood pressure according to three different methods: the Omron BP10, the Omron HBP T105 and the Pic Indolor Professional

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Objective Three professional devices for office blood pressure (BP) measurement, using three different algorithms to determine BP, were evaluated according to the International Protocol of the European Society of Hypertension. The Omron BP10 uses the oscillometric method, the Omron HBP T105 (module HBP-M3600) uses the smart inflation mode and high-speed measurement and the Pic Indolor Professional check is a hybrid sphygmomanometer.

Methods The International Protocol of the European Society of Hypertension is divided into two phases and includes a total number of 33 participants on whom the validation is performed. In each study and for each participant, four BP measurements were performed simultaneously by two observers using mercury sphygmomanometers alternately with three measurements by the tested device. The difference between the observers and the device BP values was calculated for each measure. The 99 pairs BP differences were classified into three categories (≤ 5 , ≤ 10 and ≤ 15 mmHg).

Results All three tested devices passed the first and the second phase of the validation process. The mean differences between the device and mercury readings were -0.02 ± 3.7 and -2.2 ± 3.9 mmHg for SBP and DBP,

respectively, for the Omron BP10 device; 1.5 ± 5.7 and -0.6 ± 3.8 mmHg for the Omron HBP T105 device; and -0.6 ± 1.7 and -0.4 ± 1.5 mmHg for the Pic Indolor Professional device.

Conclusion Readings of the Omron BP10, the Omron HBP T105 and the Pic Professional check, fulfill the criteria of the International Protocol of the European Society of Hypertension. Therefore, these devices can be used in the clinic. *J Hypertens* 28:452–458 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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Abbreviations: BP, blood pressure; ESH, European Society of Hypertension

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Introduction

All national and international guidelines for hypertension management agree that accurate blood pressure (BP) measurement in the office is the *sine qua non* for successful management of hypertension [1,2]. Whereas most of these guidelines mention that the auscultatory method using mercury sphygmomanometer and stethoscope was the gold standard method for office BP measurement, these guidelines agree that this method is being progressively removed from clinical practice because of environmental concerns about mercury contamination and because of the number of errors and bias that may taint this method [3–5].

Because there is currently no generally accepted replacement for mercury sphygmomanometer, several nonmercury techniques have been recently developed in order to gradually supplant the mercury sphygmomanometer method [2,3]. Some of these new techniques can be considered as a substitute for the traditional mercury sphygmomanometer such as the aneroid and the hybrid sphygmomanometers [3,6], whereas others can be considered as a replacement for the whole auscultatory method such as the automatic electronic devices using algorithms based on the oscillometric technique. Some devices combine both of the above-mentioned methods, hybrid and oscillometric sphygmomanometers [7–9].

Considering these technical aspects and that mercury sphygmomanometers are progressively abandoned, recent guidelines recommend the use of the auscultatory method (mercury, aneroid and hybrid) or other noninvasive

Parts of this work have been presented at the European Society of Hypertension (abstract Pic Indolor Professional) and the French Society of Hypertension (abstract Omron BP10) meetings.

electronic devices, provided that these devices have been validated according to standardized protocols [3,4].

Different protocols are used to validate the accuracy of BP measuring devices. Currently, the most used one is the international protocol published by the working group on BP monitoring of the European Society of Hypertension (ESH) [10]. This protocol, on the basis of evidence from a large number of validation studies, is applicable to the majority of BP measuring devices on the market; it simplifies previous protocols such as the British Hypertension Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI) protocols [11,12].

This study presents the results of three validation studies of three mercury-free professional devices performed according to the ESH protocol [10]. The PIC Indolor Professional check device has the features of a hybrid sphygmomanometer, the Omron Pressmate BP10 uses the oscillometric signal analysis and the Omron HBP T105 use a specific algorithm based on oscillometric signal and smart inflation mode for a high-speed BP measurement.

Methods

Tested devices

Omron Pressmate BP 10

The Omron Pressmate BP10 monitor was provided and randomly selected by the manufacturer (Omron Healthcare, Kyoto, Japan). It is a digital automatic device for office BP measurement at the arm level using the oscillometric principle. The monitor uses a linear smart deflation method, which is automatically adapted to the pulse rate; when the BP measurement is complete, the values of SBP, DBP, mean BP and pulse rate are displayed with date and time in a large liquid crystal display (LCD) screen and the cuff air is rapidly exhausted. Two sizes of cuffs, standard (medium) and large, were used for this evaluation. The standard cuff is adapted to an arm circumference of 22–32 cm and the large cuff size is used for the arm circumference of 32–42 cm. The unit measures pressures from 40 to 300 mmHg and pulse from 40 to 240 beats/min. Four hundred measurements with time could be memorized. The unit weighs approximately 3 kg including internal battery [165 (width) × 304 (height) × 133 (depth) mm].

Omron HBP-T105

The Omron HBP T105 (module HBP-M3600) device was provided and randomly selected by the manufacturer (Omron Healthcare). This is a multiparametric monitor that measures BP, pulse oxymetry, temperature and pulse rate. It is an automatic device for professional office BP measurements using the oscillometric method; it includes an inbuilt paper roll printer. Different modes for BP measurement are available: normal mode and fast

mode; the latter uses a high-speed function to determine BP. The monitor can use a smart inflation mode, which means that the cuff pressure is automatically estimated according to the patient's BP level. The high-speed measurement mode can measure BP more quickly than the conventional mode. The monitor uses a linear deflation method; when the BP measurement is complete, the values of SBP, DBP, mean BP and pulse rate are displayed with date and time on a large LCD screen and the cuff air is rapidly exhausted. Two sizes of cuffs, standard and large, were used for this evaluation. The standard cuff is adapted to an arm circumference of 22–32 cm and the large cuff size is used for arm circumference of 32–42 cm. The unit weighs approximately 5.5 kg including internal battery and alternating current adapter [239 (width) × 150 (height) × 239 (depth) mm]; it measures BP from 40 to 250 mmHg and pulse rate from 40 to 200 beats/min. In this study, the validation covered only the high-speed mode BP measurement with the smart inflation mode.

Pic Indolor Professional check

The Pic Indolor Professional Check device was provided and randomly selected by the manufacturer (Artsana Co., Milan, Italy). This device has the characteristics of a hybrid sphygmomanometer, which combine some of the features of both electronic and auscultatory devices (original manufacturer: Nihon Seimitsu Sokki Co., Nakago, Japan; model, DM 1000). It is a 'professional', manual device for office BP measurement using the auscultatory method. The key feature is that the mercury column is replaced by an electronic pressure gauge with vertical LCD bar, which show a numerical display of the cuff pressure as it is progressively reduced during deflation. The device includes inflatable cuff and inflation bulb. BP is measured in the same way as with a mercury device by an observer using a stethoscope and listening for the Korotkoff sounds. Two sizes of cuffs, standard and large, were used, the standard cuff is adapted to an arm circumference of 22–32 cm and the large cuff size is used for arm circumference of 32–42 cm. This device allows BP measurements at a range between 0 and 300 mmHg. The unit weighs approximately 800 g without batteries [311 (width) × 86 (height) × 123 (depth) mm].

Blood pressure measurements

Before the validation study *per se*, a familiarization period of about 2 weeks took place in an outpatient clinic. During this period, the investigators involved in each study familiarized themselves with the use of the corresponding tested device.

Each device validation study was assessed in specific populations, separately from the other device validations and at another time. Therefore, each patient participated to only one study device validation. The evaluation of the devices was done according to the international protocol.

For each study, the manufacturer was asked to provide two or three devices with at least two different size cuffs (medium and large) declared by the manufacturer as standard production models. Factors affecting accuracy of measurements were described by the manufacturers according to the requirements of the international protocol and were taken into consideration during the validation procedure.

The validation team of each study consisted of three persons experienced in BP measurement. In addition, all investigators were trained on the basis of a compact disc read-only memory (CD-ROM) specifically developed by the French Society of Hypertension for the certification of observers involved in clinical studies [13]. Two of the three observers simultaneously measured BP using a Littman teaching stethoscope (3M, St. Paul, Minnesota, USA) for simultaneous measurements (Y tube) and two standard mercury sphygmomanometers (Riester, Rud. Jungingen, Germany), the components of which had been carefully checked before the study (Dupont Medical, Pantin, France). The third observer was the supervisor that checked the agreement of BP values obtained by the two observers who were blinded from each other's readings. The supervisor also measured BP using the tested automatic devices. BP measurements were performed under the supervision of R.A. for the Omron BP10 and Omron HBP T105 (team a and b) and under the supervision of G.G. for the Pic Indolor Professional check (team c). For the Pic Indolor device, the same two observers performed BP measurements alternatively using the mercury and the Pic Indolor sphygmomanometers.

Population

According to the international protocol, in phase 1, a total of 15 treated or untreated participants were included, who fulfilled the age, sex and entry BP range requirements (age ≥ 30 years, at least five men and five women, five participants with entry BP within each of the ranges 90–129, 130–160 and 161–180 mmHg for SBP and 40–79, 80–100 and 101–130 mmHg for DBP). Arm circumference was distributed by chance. If analysis of these data was successful, additional participants were recruited until a total of 33 participants fulfilled the age, sex and entry BP requirements for phase 2 (age ≥ 30 years, at least 10 men and 10 women, 11 participants with entry BP within each of the BP ranges for SBP and DBP). In order to optimize recruitment, the protocol recommends that participants for the high diastolic and low systolic groups are recruited first, then those with high systolic and low diastolic, finally those with the BP ranges.

Procedure

BP measurements by the observers

The participants were seated in a quiet room and BP measurements started after a 10-min rest period. Arm

circumference was measured and cuff type was adapted to the circumference. All measurements were made on the left arm at the heart level. Nine consecutive BP measurements were carried according to the international protocol, which was strictly followed [10].

Analysis

The international protocol classifies the differences between measurements with the device tested and control measurements, according to whether these differences lay within 5, 10 or 15 mmHg. Differences were defined as the tested device BP values subtracted from the observer's value.

The number of differences in each BP range was calculated and compared with the number required by the international protocol, and a continue/fail grade for first phase and pass/fail grade for second phase was determined as described in details elsewhere [10]. To pass the validation and to be recommended for clinical use, a device must pass both phases. Data analysis of each of the three separate studies and their respective reports were performed by a team using specific software developed by the Working Group on BP monitoring of the French Society of Hypertension.

Results

Omron Pressmate BP 10

This study included 33 participants (20 men and 13 women) with a mean age of 54 ± 13 years (range 30–80 years), their mean arm circumference was 29 ± 3 cm (range 22–35 cm). Standard size cuff was used in 27 participants and large size cuff in six participants. At entry, using standard mercury sphygmomanometer, mean values of BP measurements were, respectively, 140.8 ± 24.7 mmHg (range 90–180 mmHg) for SBP and 82.5 ± 15.9 mmHg (range 50–110 mmHg) for DBP. The difference between the two observers was 0.93 ± 1.01 and 0.58 ± 0.90 mmHg for SBP and DBP, respectively. The mean differences between the observers and the tested device were -0.02 ± 3.7 and -2.2 ± 3.9 mmHg for SBP and DBP, respectively.

The number of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table 1. The difference between the device readings and the mean BP of the two observers readings for all 99 points for SBP and DBP are displayed in Fig. 1. These results are in concordance with the requested criteria of the international Protocol for the primary and secondary phases. Thus, Omron Pressmate BP 10 device fulfills the validation criteria of the international protocol.

Omron HBP 105

This study included 33 participants (20 men and 13 women) with a mean age of 57 ± 11 years (range 40–78 years), their mean arm circumference was 29 ± 4 cm

Table 1 Results of the OMRON Pressmate BP 10 device

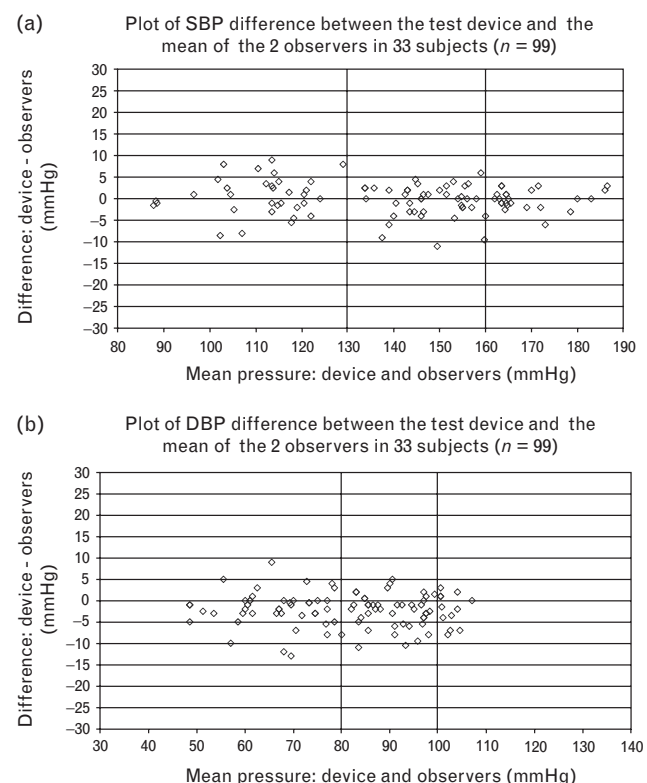
		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendations		
Phase 1							
Required	One of	25	35	40			
Achieved	SBP	40	45	45	Continue		
	DBP	38	44	45	Continue		
		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendations	Mean difference (mmHg)	SD (mmHg)
Phase 2.1							
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	85	98	99	Pass	-0.02	3.68
	DBP	78	95	99	Pass	2.24	3.95
		2/3 ≤5 mmHg	0/3 ≤5 mmHg		Recommendations		
Phase 2.2							
Required		≥22	≤3				
Achieved	SBP	31	0		Pass		
	DBP	27	3		Pass		

(range 21–39 cm). Standard size cuff was used in 26 participants and large size cuff in seven participants. At entry, using standard mercury sphygmomanometer, mean values of BP measurements were, respectively, 141.6 ± 26.8 mmHg (range 95–180 mmHg) for SBP and 85.8 ± 15.1 mmHg (range 53–107 mmHg) for DBP. The difference between the two observers was -0.5 ± 2.2 and

0.2 ± 2.2 mmHg for SBP and DBP, respectively. The mean differences between the observers and the tested device were 1.5 ± 5.7 and -0.6 ± 3.8 mmHg for SBP and DBP, respectively.

The number of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table 2. The difference between the device readings and the mean BP of device and the two observers for all 99 points for SBP and DBP are displayed in Fig. 2. These results are in concordance with the requested criteria of the international protocol for the primary and secondary phases. Thus, Omron Pressmate BP 10 device fulfills the validation criteria of the international protocol.

Fig. 1



Plots of blood pressure difference between the Omron Pressmate BP 10 readings and the mean of the two observer readings in 33 participants (*n* = 99). SBP (a) and DBP (b). Points in bold are multiple (superimposition).

Pic Indolor Professional check

This study included 33 participants (16 men and 17 women) with a mean age of 56 ± 14 years (range 31–75 years), their mean arm circumference was 29 ± 4 cm (range 21–39 cm). Standard size cuff was used in 25 participants and large size cuff in eight participants. At entry, using standard mercury sphygmomanometer, mean values of BP measurements were, respectively, 147 ± 22 mmHg (range 110–178 mmHg) for SBP and 92 ± 15 mmHg (range 72–116 mmHg) for DBP. The difference between the two observers was 0.6 ± 1.8 and 0.5 ± 1.8 mmHg for SBP and DBP, respectively. The mean differences between the observers and the tested device were -0.6 ± 1.7 and -0.4 ± 1.5 mmHg for SBP and DBP, respectively.

The number of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table 3. The difference between the device readings and the mean BP of the two observers for all 99 points for SBP and DBP are displayed in Fig. 3. These results are in concordance with the requested criteria of the international protocol for the primary and secondary phases. Thus, the Pic Indolor Professional check device fulfills the validation criteria of the international protocol.

Table 2 Results of the OMRON HBP 105 device

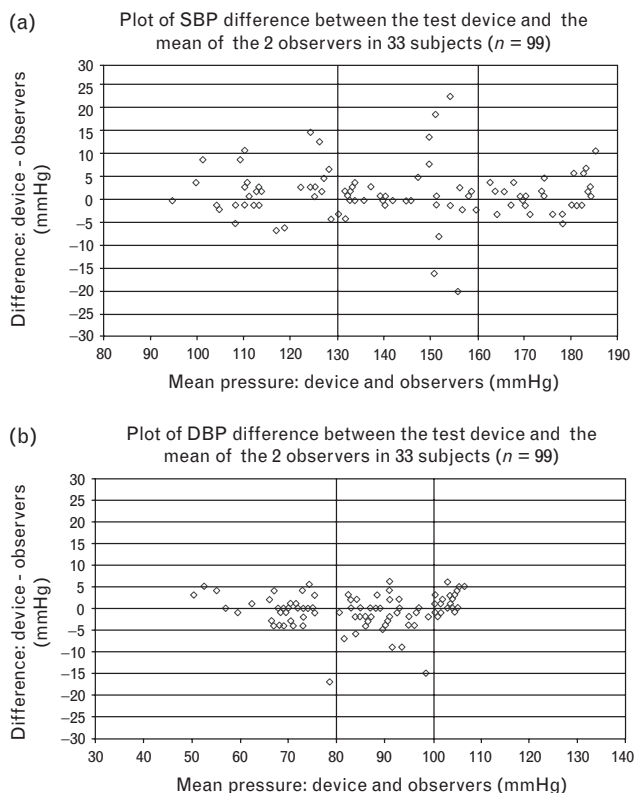
		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendations		
Phase 1							
Required	One of	25	35	40			
Achieved	SBP	39	42	43	Continue		
	DBP	41	43	44	Continue		
		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendations	Mean difference (mmHg)	SD (mmHg)
Phase 2.1							
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	80	90	95	Pass	1.5	5.7
	DBP	90	97	98	Pass	-0.6	3.8
		2/3 ≤5 mmHg	0/3 ≤5 mmHg		Recommendations		
Phase 2.2							
Required		≥22	≤3				
Achieved	SBP	27	2		Pass		
	DBP	31	0		Pass		

Discussion

This study provides information on the accuracy of three professional mercury-free devices for office BP measurements. Each of these devices measures BP according to a specific method. The Omron Pressmate BP 10 is using the oscillometric method with a linear smart deflation technique. The Omron HBP T105 is using a specific algorithm based on oscillometry with smart inflation

mode and a high-speed determination of BP. The Pic Indolor Professional check device is a hybrid sphygmomanometer using the auscultatory method. This study showed that all the three devices passed the validation requirements of the International Protocol of the ESH when used by well trained observers and respecting the factors affecting the measurements accuracy described by the manufacturers. Before the widespread application of these devices in the clinic, some important points related to both the validation protocol and to the devices need to be discussed.

Fig. 2



Plots of blood pressure difference between the Omron HBP T 105 readings and the mean of the two observer readings in 33 participants (n = 99). SBP (a) and DBP (b). Points in bold are multiple (superimposition).

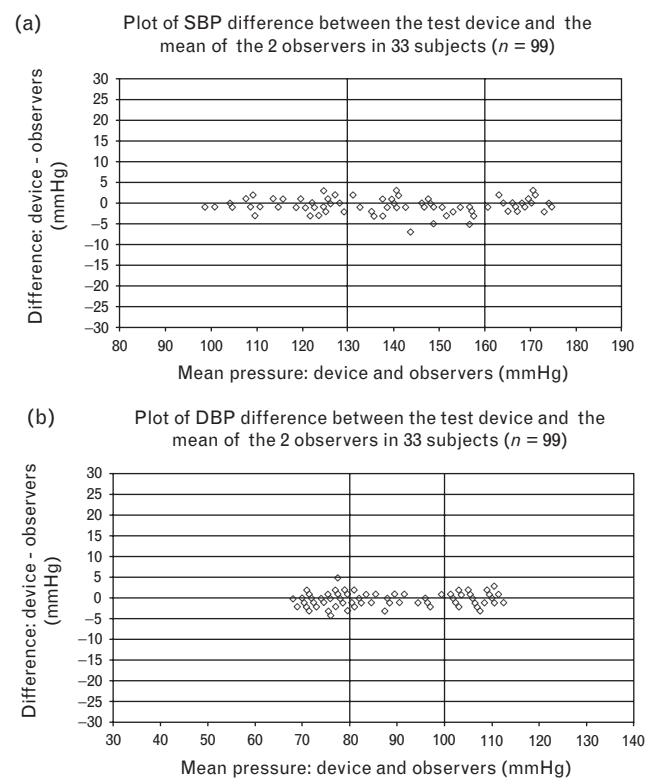
In this study, validation was performed according to the international protocol. This protocol has been published by the ESH [10] aiming at simplifying the two main available guidelines, the BHS [11] and AAMI [12] protocols without sacrificing their integrity. The main advantage of this protocol is that it requires a lower number of participants, 33 instead of 85 with the two other protocols. However, this protocol has some disadvantages and limitations. The international protocol can be applied to the majority of the BP devices but it has been drafted with a special thought to its application to home BP devices and not to professional devices for which more severe criteria may be needed [14–16]. The population requested in the international protocol is confined to adults older than 30 years with given specifications in terms of age, sex, BP level, arm circumference and so on. This very selective population is only a part of the large heterogeneous population attending a medical office; and it has been suggested that professional devices may go through at least two additional validation studies in specific populations such as children, pregnant women, elderly, obese or under specific conditions such as arrhythmia or exercise. The number of validation studies requested to approve the device accuracy is an important issue principally for professional devices. The international protocol does not specify the number of devices or study sites recommended to enhance the accuracy requirements. Experts agree that it would be important to have at least two validation

Table 3 Results of the Pic Indolor Professional check device

		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendations		
Phase 1							
Required	One of	25	35	40			
Achieved	SBP	44	45	45	Continue		
	DBP	45	45	45	Continue		
		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendations	Mean difference (mmHg)	SD (mmHg)
Phase 2.1							
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	98	99	99	Pass	-0.6	1.7
	DBP	99	99	99	Pass	-0.4	1.5
		2/3 ≤5 mmHg	0/3 ≤5 mmHg		Recommendations		
Phase 2.2							
Required		≥22	≤3				
Achieved	SBP	33	0		Pass		
	DBP	33	0		Pass		

studies conducted in different centers and various populations. In this regard, the AAMI protocol [12] recommends more than one study site but without specifying the number of studies or devices. None of the three devices tested in the present study went through prior validation and, therefore, additional validation studies should be performed by different experts in specific populations before recommending their widespread use in the clinic.

Fig. 3



Plots of blood pressure difference between the Pic Indolor readings and the mean of the two observer readings in 33 participants ($n = 99$). SBP (a) and DBP (b). Points in bold are multiple (superimposition).

Some clarifications are needed for a good use of each of the three validated devices. Results of the Omron Pressmate BP10 showed a mild underestimation and individual variability mainly for DBP; this has to be considered by the clinician and also by the manufacturer in order to improve the algorithm. The Omron HBP T105 can use three different algorithms based on oscillometry to determine BP: normal mode, quick systolic determination and the high-speed mode. In this study, only the algorithm using the high-speed mode combined to the smart inflation mode has been validated. The results of our study showed some individual variability principally for SBP. This variability occurred in a few patients with a trend for a higher prevalence in patients with large arm circumference (data not shown). Therefore, it will be important to complete the present validation by another study performed in a population with large arm circumference before drawing final conclusion. The Pic Indolor device is a hybrid sphygmomanometer in which the mercury column has been replaced by an electronic one; BP is measured in the same way as with mercury sphygmomanometer by the two observers using the auscultatory method. Therefore, the validation protocol *per se* is very simple, as the device does not measure BP automatically similar to the other two Omron devices. The equipment only needs a ‘gauge’ validation based on the agreement between the electronic and mercury values; the procedure is a more calibration rather than a true validation. These aspects may explain the very close results observed between the Pic Indolor and the mercury devices and why the scattering of the differences versus mean level (Fig. 3) is more compressed as compared with the two other Omron devices.

In conclusion, the results of the present study show that the three tested devices meet the requirements of the international protocol in a general population. Because of certain limitations of the international protocol and the professional use of these equipments, it would be desirable to strengthen the present results by other studies performed in specific populations. Devices based on

oscillometric algorithms, because of the principles of oscillometry, may have certain limits and individual variability. The hybrid devices may constitute an alternative to mercury, but continues to use the auscultatory method with all its advantages as well as its weaknesses and biases. All three tested devices passed the international protocol recommendations and can be used in clinical practice, provided that the doctor is aware of certain limitations.

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There are no conflicts of interest.

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