Validation of two devices for self-measurement of brachial blood pressure according to the International Protocol of the European Society of Hypertension: the SEINEX SE-9400 and the Microlife BP 3AC1-1

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Background **Two electronic devices for self-measurement of blood pressure at the brachial artery – the Seinex SE-9400 (Seinex Electronics Ltd, Belfast, UK) and the Microlife BP 3AC1-1 (Microlife Corporation, Berneck, Switzerland) – were evaluated in two separate studies according to the International Protocol of the European Society of Hypertension.**

Design **The international validation protocol is divided into two phases: the first phase is performed on 15 selected participants (45 blood pressure measurements); if the device passes this phase, 18 supplementary participants are included (54 blood pressure measurements) making a total number of 33 participants (99 blood pressure measurements) on whom the final validation is performed.**

Methods **The same methodology recommended by the European Society of Hypertension protocol was applied for both studies. In each study and for each participant, four blood pressure measurements were taken simultaneously by two trained observers using mercury sphygmomanometers alternately with three measurements by the tested device. The difference between the blood pressure value given by the device and that obtained by the two observers (mean of the two observers) was calculated for each measure. The 99 differences were classified into three categories (≤ 5, ≤ 10, ≤ 15 mmHg). The number of differences in each category was compared with the number required by the ESH protocol. An individual analysis was then done to determine, for each participant, the number of comparisons ≤ 5 mmHg. At least 22 of the 33 participants should have two of their three comparisons ≤ 5 mmHg.**

Results **In both studies, the two tested devices passed the first phase of the validation process. For the complete analysis (phase 1 and phase 2), the average differences between the device and mercury sphygmomanometer readings were in the first study for the Seinex SE-9400 device 0.9 ± 5.2 and -1.7 ± 4.7 mmHg for systolic and diastolic blood pressure, respectively, and -0.2 ± 4.5 and -2.0 ± 4.8 mmHg for the Microlife BP 3AC1-1 device in the second study. For both devices, readings differing by less than 5, 10 and 15 mmHg for systolic and diastolic blood pressure values fulfill the recommendation criteria of the International Protocol as well as the individual analysis.**

Conclusions **The Seinex SE-9400 and the Microlife BP 3AC1-1 devices fulfilled the validation recommendations of the International Protocol.** *Blood Press Monit* **10:325–331**
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Introduction

Advantages of blood pressure (BP) self-measurement have been well documented [1–3]. Indeed, BP self-measurement not only provides valuable information for hypertension diagnosis but also on BP control of the treated patient, and it improves patient's compliance with antihypertensive therapy [4]. Therefore, it is appropriate to encourage the widespread use of self-recorded BP as an important adjunct to the clinical care of some patients with hypertension [5,6]. Clinical indications of the self-blood pressure measurement have been recently highlighted in several international scientific society recommendations [3,6] Obviously, BP self-measurement is practicable only when the devices are accurate, user-friendly and relatively inexpensive. Particular attention must be paid to ensure the accuracy of the used devices [7]. Ideally, recommended devices should have been subjected to independent clinical validation procedures. During recent years, various automated devices for self-measurement of BP have been fabricated,

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but only some of them have been validated [7–23] according to recognized protocols specifically designed for this purpose, such as the British Hypertension Society (BHS) protocol [24,25], the Association for the Advancement of Medical Instrumentation (AAMI) protocol [26,27] and the most recent international protocol [22,28] published by the European Society of Hypertension (ESH). In this regard, two devices for self-measurement of brachial BP were validated according to the ESH protocol in two separate studies [28].

Methods

Seinex SE-9400

The Seinex SE-9400 device (Seinex Electronics Ltd, Belfast, UK) records BP oscillometrically with a BP measurement range of 20 to 300 mmHg and heart rate range of 40–199 beats/min. Systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate are displayed on a liquid crystal digital (LCD) display. The inflation is performed using an automatic pumping system and the deflation by an automatic pressure release valve. A standard-sized cuff is provided, while small and large cuffs are optional.

Microlife BP 3AC1-1

For the Microlife BP 3AC1-1 device (Microlife Corporation, Berneck, Switzerland), brachial BP is measured by oscillometry, the cuff is inflated automatically by an electric pump system and deflated by an active electronic control valve system. The time, date, BP and heart rate are displayed on an LCD display. Data can be stored and printed or transferred to a personal computer via specific software. A standard-sized cuff is provided, while small and extra large cuffs are optional.

Device validation

Validation studies of each of the Seinex and Microlife devices were assessed separately in two different populations and at different times. Both studies were performed according to the ESH protocol. For each study, manufacturer was asked to loan three devices with three different-sized cuffs (small, medium and large).

Factors affecting accuracy of measurements were described by the manufacturers of both devices according to the requirements of the International Protocol, and were taken into consideration during the validation procedure.

The validation team consisted of three persons experienced in BP measurement who have, in addition, followed a training on the basis of a CD-ROM [29] specifically developed by the French Society of Hypertension for the certification of observers involved in clinical studies. Two of the three observers simultaneously measured BP using a standard mercury sphygmomanometer, the components of which were carefully checked before the study: the third observer was the supervisor who checked the values obtained by the two observers and measured the BP by the tested device.

Analysis of the BP recordings according to the ESH protocol consisted of two phases. In the first phase, 15 study participants (45 BP measurements) were recruited; devices passing this primary phase proceeded to the secondary phase, for which a further 18 participants (54 BP measurements) were recruited. Both devices were validated at the same center, by the same observers, but at different times and with different populations.

Participants' selection

For each study, selection of participants was done according to the recommendations of the ESH protocol (Table 1). Two different populations were used in the validation procedure. Arm circumferences were measured in each patient and adequate cuff sizes were used; arm circumferences were distributed by chance according to the ESH protocol. In order to fulfill the BP criteria ranges and to optimize recruitment, it is recommended that participants for the high diastolic and low systolic groups should be recruited first, and then those with high systolic and low diastolic pressures; finally the remaining gaps should be filled. Only 33 participants with both SBP and DBP measurements were selected to validate each of the two devices.

For the primary phase, five of the 15 participants should have an SBP in each of the ranges (Table 1). Similarly, five of the 15 participants should have a DBP in each of the ranges (Table 1). For the secondary phase, 11 of the 33 participants (including the first 15 participants) should have SBP and DBP in each of the ranges (Table 1). Three ranges are found for SBP and three for DBP, with 11 participants in each range to provide 99 pairs of measurements. The final analysis is performed on the 99 paired measurements.

Procedure

The participants were seated in a quiet room and BP measurements started after a 10–15 min rest period. The arm circumference was measured and brachial cuff type was adapted to the circumference. All measurements were made on the left arm at the heart level. BP was measured simultaneously (Y tube) with two calibrated mercury sphygmomanometers by the two observers alternately with the automatic device. The time interval between the two measurements was from 30 to 60 s. The observers were blinded to each other's readings. Mea-

Table 1 Blood pressure ranges for entry blood pressure

	SBP (mmHg)	DBP (mmHg)
Low	90–129	40–79
Medium	130–160	80–100
High	161–180	101–130

SBP, systolic blood pressure; DBP, diastolic blood pressure.

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surements were carried out in the following sequence:

(1) *BPA*: Entry BP, observers 1 and 2 each with the mercury standard sphygmomanometer. The mean values were used to categorize the participant into a low, medium or high range separately for SBP and DBP (Table 1).
(2) *BPB*: Device detection BP, observer 3. This BP was measured to allow the tested device to determine the BP characteristics of the participant and was not included in the analysis.
(3) *BP1*: Observers 1 and 2 with the mercury standard.
(4) *BP2*: Supervisor with the tested device.
(5) *BP3*: Observers 1 and 2 with the mercury standard.
(6) *BP4*: Supervisor with the tested device.
(7) *BP5*: Observers 1 and 2 with the mercury standard.
(8) *BP6*: Supervisor with the tested device.
(9) *BP7*: Observers 1 and 2 with the mercury standard.

Accuracy criteria

The concept of the ESH protocol is to classify the differences between device-tested and control measurements according to whether these differences lay within 5, 10 or 15 mmHg. Differences are always calculated by subtracting the tested observer measurement from the device measurement. Differences were classified separately in this way for SBP and DBP.

Participant measurements

For assessment of accuracy, only measurements BP1 to BP7 were used. The mean of each pair of observer measurements was calculated; this was denoted as observer measurement BP1, BP3, BP5 or BP7. Each device measurement was flanked by two of these observer measurements, and one of these was selected as the comparative measurement as follows:

(1) The differences BP2 – BP1, BP2 – BP3, BP4 – BP3, BP4 – BP5, BP6 – BP5 and BP6 – BP7 were calculated.
(2) The absolute values of the differences were calculated.
(3) These were paired according to the device reading.
(4) If the values in a pair were unequal, the observer measurement corresponding to the smaller difference was used.
(5) If the values in a pair were equal, the first of the two observer measurements was used.

When this was completed, there were three device readings for SBP and three for DBP for each participant. Each of these six readings had a single corresponding observer measurement, a difference between the two and a band for that difference categorized as follows: 0–5, 6–10, 11–15 and > 15 mmHg.

Assessment

After all BP ranges were filled (Table 1), there were 45 sets of measurements for both SBP and DBP for the first phase (15 participants) and 99 sets for the second phase (33 participants).

The number of differences in each zone was calculated and compared with the number required by the international protocol and a continue/fail grade for the first phase and pass/fail grade for the second phase (phase 2.1) were determined. In addition, for the second phase, the number of measurements falling within 5 mmHg was determined for each of the 33 participants and a pass/fail recommendation was determined according to the protocol (phase 2.2). For this phase, at least 22 of the 33 participants were required to have at least two of their three comparisons lying within 5 mmHg. At most, three of the 33 participants could have all three of their comparisons over 5 mmHg apart.

To pass the validation and to be recommended for clinical use, a device must pass both phase 2.1 and phase 2.2. If it does not, it fails and is not recommended for clinical use.

Results

Two different populations were used in the validation procedure. About 37 participants were screened for the Seinex study and 38 participants for the Microlife study.

Seinex SE-9400

In the Seinex study, mean age of the 33 participants included was 54 ± 14 years (18 men and 15 women), the arm circumference was 29 ± 3 cm (range: 23–36) and 30 standard cuffs and three large cuffs were used (Table 2). The difference between the two observer readings was -0.2 ± 1.4 and 0.2 ± 1.3 mmHg for SBP and DBP, respectively. The mean values of 99 measurements for SBP and DBP were $138 \pm 19/85 \pm 14$ mmHg with the Seinex SE-9400 device and $139 \pm 19/86 \pm 14$ mmHg with the standard mercury sphygmomanometer, respectively. The

Table 2 Age, arm circumference distribution and blood pressure values for both device populations

	Seinex SE-9400	Microlife BP 3AC1-1
Age (years)	54 ± 14	53 ± 14
Arm circumference distribution (cm)	29 ± 3	30 ± 3
Arm circumference range (cm)	23–36	23–38
SBP/DBP (mmHg)	138 ± 19/85 ± 14	137 ± 21/90 ± 16

SBP, systolic blood pressure; DBP, diastolic blood pressure.

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mean and standard deviation of the difference were 0.9 ± 5.2 and –1.7 ± 4.7 for SBP and DBP, respectively.

In total, 45 sets of measurements (3 measurements × 15 participants) were available for analysis in the first phase of the validation process, and 99 (3 measurements × 33 participants) in the second phase. The number of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table 3. These results are in concordance with the requested criteria of the ESH protocol for the primary and secondary phases. Thus, the Seinex SE-9400 device fulfills the validation criteria of the ESH protocol.

The difference between the mean BP of the device and those of the two observers for all 99 points for SBP and DBP are displayed in Fig. 1.

Microlife BP 3AC1-1

In the Microlife study, mean age of the 33 participants included was 53 ± 14 years (19 men and 14 women), the arm circumference was 30 ± 3 cm (range: 23–38) and 31 standard cuffs and two large cuffs were used (Table 2). The difference between the two observers was 0.7 ± 1.5 and 0.3 ± 1.4 mmHg for SBP and DBP, respectively. The mean values of 99 measurements for SBP and DBP were 137 ± 21/90 ± 16 mmHg with the Microlife BP 3AC1-1 device and 142 ± 25/90 ± 16 mmHg with the standard mercury sphygmomanometer, respectively. The mean and standard deviation of the difference were –0.2 ± 4.5 and –2.0 ± 4.8 for SBP and DBP, respectively.

In total, 45 sets of measurements (3 measurements × 15 participants) were available for analysis in the first phase of the validation process, and 99 (3 measurements × 33 participants) in the second phase. The number of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table 4. These results are in concordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus, the Microlife BP 3AC1-1 device fulfills the validation criteria of the International Protocol.

The difference between the device readings and observer readings and the mean BP of the device and those of the two observers for all 99 points for SBP and DBP are displayed in Fig. 2.

Discussion

The two tested devices, Seinex SE-9400 and Microlife BP 3AC1-1, fulfill the validation criteria of the International Protocol for SBP and for DBP. The International Protocol recommendations [28] were published in 2002 by the Working Group on Blood Pressure Monitoring of the ESH aiming to simplify the two main available guidelines, the BHS [24,25] and AAMI [26,27] protocols without sacrificing their integrity. These two validation protocols have many similarities, but experience has demonstrated that the conditions they recommend are sometimes extremely difficult to fulfill, especially because of the large number of participants who have to be recruited and the ranges of BP required. It has been demonstrated by the ESH Working Group that validation studies can be performed in such a way as to satisfy the criteria of the much more complicated earlier protocols [28]. The main advantage of the ESH protocol is that it requires fewer participants, 33 instead of 85, with the two further protocols.

Our experience with the validation of these two devices shows that the recruitment of participants having low SBP (90–129 mmHg) and especially high DBP (101–130 mmHg) is the major factor that extends the time required for the validation, although the ESH protocol recommends that recruitment of participants should commence by targeting those likely to have pressures in the low systolic and high diastolic ranges so that it will be easy to complete the recruitment with the remaining ranges.

Table 3 Results of the Seinex SE-9400 device

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation		
Required	One of	25	35	40			
	SBP	34	40	45	Continue		
	DBP	40	40	45	Continue		
Phase 2.1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation	Mean difference (mmHg)	SD (mmHg)
	Two of	65	80	95			
	All of	60	75	90			
	SBP	76	92	98	Pass	– 0.9	5.2
	DBP	79	93	97	Pass	– 1.7	4.7
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recommendation		
Required		≥ 22	≤ 3				
	SBP	28	1		Pass		
	DBP	29	1		Pass		

SBP, systolic blood pressure; DBP, diastolic blood pressure.

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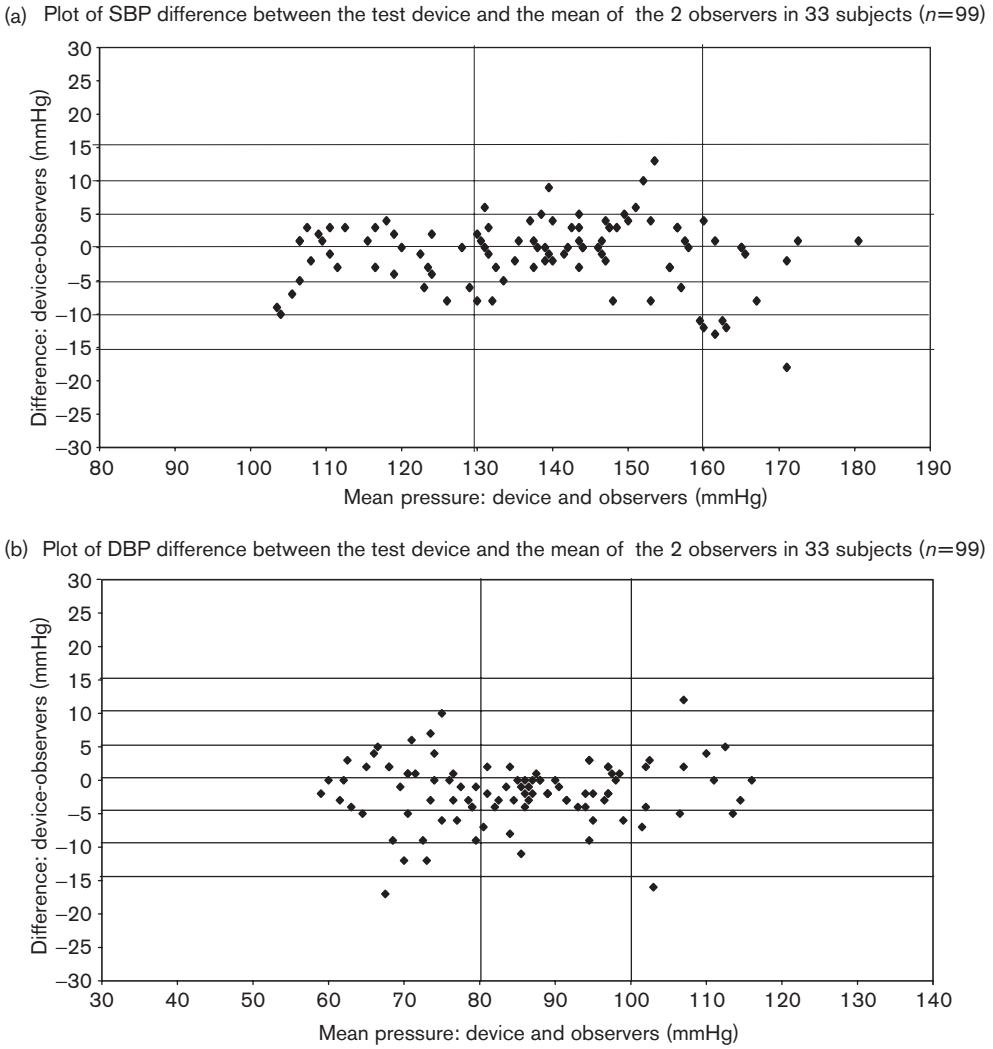
Fig. 1



Seinex SE-9400 device: plots for systolic (a) and diastolic (b) blood pressure difference between the test device readings and the mean of the two observer readings in 33 participants ($n=99$) versus the difference between the Seinex SE-9400 device and the mercury sphygmomanometer readings.

Table 4 Results of the Microlife BP 3AC1-1 device

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation		
Required	One of	25	35	40			
	SBP	36	40	44	Continue		
	DBP	32	41	43	Continue		
Phase 2.1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation	Mean difference (mmHg)	SD (mmHg)
	Two of	65	80	95			
	All of	60	75	90			
	SBP	74	87	98	Pass	−1.3	5.6
	DBP	81	93	97	Pass	−0.4	4.8
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recommendation		
Required		≥ 22	≤ 3				
	SBP	29	2		Pass		
	DBP	28	1		Pass		

SBP, systolic blood pressure; DBP, diastolic blood pressure.

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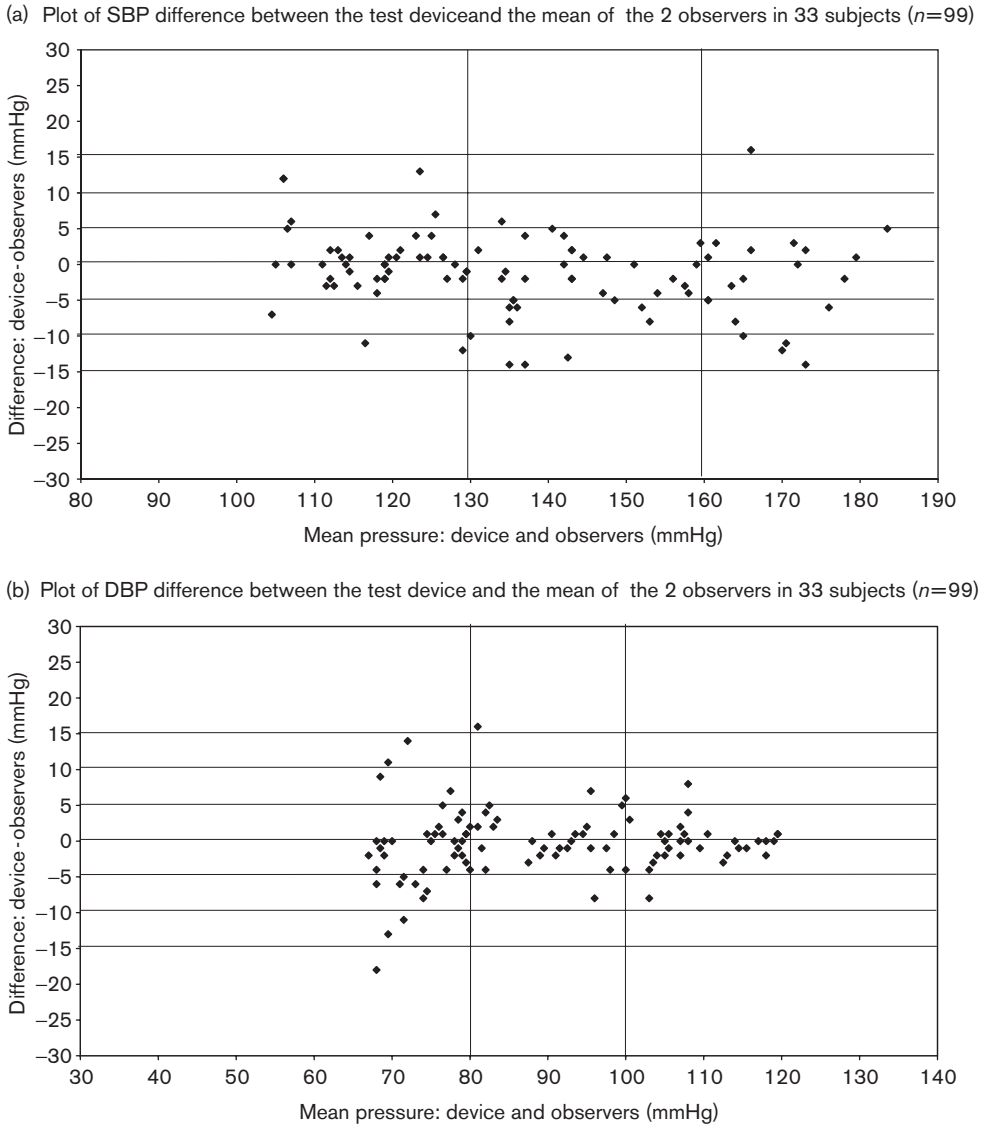
Fig. 2



Microlife 3AC1-1 device: plots for systolic (a) and diastolic (b) blood pressure difference between the test device readings and the mean of the two observer readings in 33 participants ($n=99$) versus the difference between the Microlife 3AC1-1 device and the mercury sphygmomanometer readings.

Another point that remains a limitation of the present study is that the results are based on only one device and the validation was done in only one center; however, the International Protocol [28] does not specify the number of devices to be tested or the number of study sites recommended to enhance the heterogeneity of the study population. The AAMI protocol [26,27] recommends more than one study site without specifying the number and without noting the number of devices to validate. On the other hand, the BHS protocol [24,25] does not specify performing the validation in more than one site but recommends assessing the capability of a number of devices of the model being tested to give consistent measurements, and if substantial differences between instruments of the same device occur, further device validation is not appropriate.

This analysis shows that with the Seinex SE-9400 and the Microlife BP 3AC1-1, the device–observer limits of agreement widened with SBP rather than with DBP. This difference seems to be more important at higher SBP. The difference is more obvious at lower rather than at higher DBP. The increased error at extremes of BP occurs in virtually all non-invasive devices, but the degree of error varies [15,16,30]. Moreover, a lack of individual points in the high region of the plot devices (Figs 1 and 2)

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can be observed. This may be related to either the difference between the initial BP measurement (BPA used to classify the patient in the high BP level) and the following measurements used for the validation analysis (Figs 1 and 2) or some big differences between observer measurements and device measurements can lead to a shift of some points from high BP level to medium BP level.

It is also important to recognize, however, that this usually bears little clinical relevance, as therapeutic decisions would not significantly differ [15].

In conclusion, the two tested devices, Seinex SE-9400 and Microlife BP 3AC1-1, have passed the validation criteria of the International Protocol for validation of BP measuring devices.

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