Is the accuracy of blood pressure measuring devices underestimated at increasing blood pressure levels?

Richard L. Braam and Theo Thien

Background **In validation studies reporting on the accuracy of blood pressure measuring devices (ambulatory and non-ambulatory systems), it is frequently stated that the accuracy of blood pressure devices seems to decrease at increasing blood pressure levels. This has been shown for several ambulatory devices in the past. Whether more recently validated devices are less accurate at increasing blood pressure levels is unknown, however.**

Objectives **We therefore retrospectively searched the literature for studies performed between 1993 and 2003, reporting on the accuracy of blood pressure measuring devices over different blood pressure levels. When needed, additional information from the authors was requested.**

Methods **In total, 30 studies were selected. Of these, the studies reporting on the accuracy of 14 different ambulatory and nine different non-ambulatory devices were useful. For both ambulatory and non-ambulatory devices, accuracy appeared to decrease at increasing blood pressure levels. This was particularly shown for systolic blood pressure.**

Results **We speculate whether this finding is due to the oscillometric method of blood pressure measurement. Another explanation may exist, however. Blood pressure variability increases with higher blood pressure. Further, the British Hypertension Society protocol 1993 uses sequential measurements. This may be the reason that, owing to the increased blood pressure variability, the accuracy of most devices tends to decrease at higher blood pressure levels. Consequently, the accuracy of blood pressure measuring devices may be underestimated at higher blood pressure levels.**

Conclusion **Currently used automated blood pressure measurement devices seem to be less accurate at increasing blood pressure levels. It is important to be aware of this phenomenon when treating hypertensive patients. The reported decrease in accuracy, however, may well be explained by the increasing blood pressure variability at increasing blood pressure and the use of sequential measurements. If this is the case, then the accuracy of these devices is perhaps underestimated.** *Blood Press Monit* **10:283–289 © 2005 Lippincott Williams & Wilkins.**

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Department of Internal Medicine, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.

Correspondence and requests for reprints to Th. Thien, MD, Professor of Medicine, Radboud University Nijmegen Medical Centre, P.O. Box 9101, 6500 HB Nijmegen, The Netherlands.
Tel: +312 4361 3286; fax: +312 4354 1734;
e-mail: t.thien@aig.umcn.nl

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Introduction

Hypertension is one of the major risk factors for the development of cardiovascular disease. Therefore, accurate detection of patients with hypertension is very important. Increasingly, blood pressure (BP) measurements are done with devices measuring BP oscillometrically. It is frequently stated in validation studies that automated devices become less accurate at increasing BP levels [1]. This has been shown to be correct for six ambulatory devices validated in the past [2]. Whether the same is still true for more recently validated ambulatory and non-ambulatory systems remains to be seen.

We therefore analysed data obtained from validation studies performed between 1993 and 2003 regarding the accuracy of BP measuring devices at different BP levels. These devices were tested according to the British Hypertension Society (BHS) protocols or the protocol of the Association for the Advancement of Medical Instrumentation (AAMI) [3,4].

Methods

Using Pubmed (www.ncbi.nih.gov/entrez/query.fcgi) validation studies were selected on the basis of the following criteria: (1) studies had to have been performed between 1993 and 2003. (2) Validation was performed according to the BHS protocols or AAMI criteria. Use of a slightly modified BHS protocol (instead of the original) with, for example, two instead of three observers, was accepted. (3) Studies had to report the accuracy of the devices according to different BP levels. If not available, the authors were asked to give this information. (4) Devices had to measure BP auscultatorily (e.g. auscultatory mode for ambulatory BP measuring devices) or oscillometrically. (5) Studies that tested the accuracy of the BP measuring

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device during exercise, in pregnant women or in children were excluded. Devices listed in a recent review article were used as a directive for selection [5]. Studies were divided according to the BP measurement system tested: ambulatory or non-ambulatory.

Results

On the basis of the criteria mentioned, 12 studies reporting on ambulatory BP measuring devices and 18 studies reporting on the accuracy of non-ambulatory devices could be selected [1,2,6–15] [16–34]. Of these, the studies reporting on the accuracy of 13 different ambulatory and nine different non-ambulatory devices were useful (Tables 1 and 2).

We approached a number of authors for additional data. Unfortunately, there was only minimal response on the requests for information. Only Altunkan *et al.* [13] could provide us with additional data . The minimal response was probably owing to the lack of time for most authors or because of the longer time period that had evolved since their original study. As shown in Tables 1 and 2, only a limited number of studies reported the mean difference and standard deviation of differences for the different BP levels. Therefore, the percentages of differences ≤ 5 mmHg across the different BP levels were used as a measure of accuracy: the percentages are plotted for the different devices in Figs 1 and 2.

As with other biological parameters, one can expect the difference between actual and measured BP (i.e. the absolute BP difference) to increase with BP level. The relative difference, however, will be less dependent on the actual BP level. Perhaps using percentages instead of absolute values is preferable. We therefore calculated both the relative and absolute differences for the different BP levels using data from two devices we recently tested: the Welch Allyn Vital Signs Monitor, an oscillometric upper arm device and the Omron RX-M, an oscillometric device measuring BP at the wrist [34,35]. Results are shown in Figs 3 and 4, for diastolic and systolic BP. As can be seen for the Welch Allyn Vital Signs Monitor, the absolute difference increases, while the relative difference remains the same for increasing BP levels. The same results are found for the Omron RX-M, although for diastolic BP the absolute difference appears to be more constant for different BP levels.

Discussion

On the basis of the results of the studies available for this report, it could be concluded that the accuracy for most of the devices decreases at increasing BP levels. This would especially be the case for systolic BP in nonambulatory

Table 1 Accuracy of nine blood pressure measuring devices according to blood pressure level: non-ambulatory oscillometric devices for self-measurement or clinical use

Device	BP level		BHS grade		Percentage difference ≤ 5 mmHg		AAMI (mean ± SDD) (mmHg)	
	DBP	SBP	DBP	SBP	DBP	SBP	DBP	SBP
Omron HEM-705 CP [1]	<80	<130	A	C	69	49	1±7	−2±6
	80–100	130–160	A	A	88	60	−1±4	−2±6
	>100	>160	B	C	64	47	−2±7	−3±8
Welch-Allyn VSM [27]	<80	<130	A	A	81	82	n.g.	n.g.
	80–100	130–160	B	A	56	73	n.g.	n.g.
	>100	>160	A	A	78	70	n.g.	n.g.
A&D UA-767 [26]	<80	<130	B	A	78	88	0±5	1±4
	80–100	130–160	A	B	81	74	0±5	−1±5
	>100	>160	B	C	82	70	−1±6	−3±8
Microlife BP 3BTO-A [24]	<80	<130	A	A	77	80	n.g.	n.g.
	80–100	130–160	A	A	70	61	n.g.	n.g.
	>100	>160	B	C	56	50	n.g.	n.g.
Omron-MIT [25]	<80	<130	A	A	69	70	n.g.	n.g.
	80–100	130–160	A	B	73	54	n.g.	n.g.
	>100	>160	B	B	67	58	n.g.	n.g.
Welch-Allyn VSM [34]	<80	<130	B	C	52	46	−2±7	−6±6
	80–100	130–160	C	D	45	28	−7±6	−8±6
	>100	>160	D	C	31	31	−7±7	−11±14
Philips HP 5332 [1]	<80	<130	A	C	69	51	−2±5	−5±5
	80–100	130–160	A	B	72	50	−4±5	−4±6
	>100	>160	A	D	67	32	−4±5	−9±9
Nissei DS-175 [1]	<80	<130	B	B	73	59	0±9	−4±6
	80–100	130–160	A	D	69	24	−4±7	−9±6
	>100	>160	A	D	67	24	−4±6	−12±11
Dinamap 8100[a] [23]	<80	<130	D	B	42	65	n.g.	n.g.
	80–100	130–160	D	B	52	70	n.g.	n.g.
	>100	>160	D	C	39	62	n.g.	n.g.

BP, blood pressure; BHS, British Hypertension Society; SDD, standard deviation of differences; DBP, diastolic blood pressure; SBP, systolic blood pressure; n.g., not given. [a]Tested according to the BHS protocol of 1990.

Table 2 Accuracy of 14 blood pressure measuring devices according to blood pressure level: ambulatory blood pressure monitoring devices

Device	BP level		BHS grade		Percentage difference ≤ 5 mmHg		Mean ± SDD	
	DBP	SBP	DBP	SBP	DBP	SBP	DBP	SBP
Tensioday [8]	<80	<130	A	A	81	86	0 ± 5	1 ± 4
	80–100	130–160	A	A	78	67	2 ± 6	2 ± 7
	>100	>160	A	A	87	85	1 ± 4	1 ± 6
Meditech ABPM-04 [7]	<80	<130	B	B	54	54	n.g.	n.g.
	80–100	130–160	B	B	52	51	n.g.	n.g.
	>100	>160	B	B	54	51	n.g.	n.g.
SpaceLabs 90217 [6]	<80	<130	A	A	67	73	n.g.	n.g.
	80–100	130–160	A	A	71	72	n.g.	n.g.
	>100	>160	B	A	67	69	n.g.	n.g.
SpaceLabs 90207 [2]	<80	<130	B	B	79	77	n.g.	n.g.
	80–100	130–160	B	B	68	70	n.g.	n.g.
	>100	>160	B	B	52	58	n.g.	n.g.
Nissei DS-250[a] [13]	<80	<130	n.g.	n.g.	n.g.	n.g.	−3 ± 4	0 ± 7
	80–100	130–160	n.g.	n.g.	n.g.	n.g.	−1 ± 7	−5 ± 10
	>100	>160	n.g.	n.g.	n.g.	n.g.	−1 ± 9	−1 ± 9
Mobil O Graph (version 12) [12]	<80	<130	A	A	68	61	n.g.	n.g.
	80–100	130–160	A	A	71	71	n.g.	n.g.
	>100	>160	A	C	74	43	n.g.	n.g.
Schiller BR-102 (Au) [10]	<80	<130	A	C	60	47	−3 ± 4	−5 ± 5
	80–100	130–160	B	B	70	62	−3 ± 3	−2 ± 4
	>100	>160	C	A	47	66	−4 ± 6	−2 ± 4
Schiller BR-102 (Oscill) [12]	<80	<130	A	C	61	48	−3 ± 4	−3 ± 5
	80–100	130–160	B	C	54	46	−4 ± 4	−5 ± 7
	>100	>160	C	D	43	29	−5 ± 6	−9 ± 8
CH-Druck (Au) [2]	<80	<130	A	A	84	90	n.g.	n.g.
	80–100	130–160	A	B	88	75	n.g.	n.g.
	>100	>160	C	B	75	81	n.g.	n.g.
Profilomat (Au) [2]	<80	<130	A	A	83	82	n.g.	n.g.
	80–100	130–160	A	B	82	74	n.g.	n.g.
	>100	>160	D	C	74	77	n.g.	n.g.
Novacor DIASYS 200R (Au) [2]	<80	<130	C	C	68	71	n.g.	n.g.
	80–100	130–160	C	C	60	64	n.g.	n.g.
	>100	>160	B	C	73	55	n.g.	n.g.
Pressurometer IV (Au) [2]	<80	<130	D	B	60	74	n.g.	n.g.
	80–100	130–160	D	C	63	62	n.g.	n.g.
	>100	>160	D	D	39	53	n.g.	n.g.
Takeda TM-2420 (Au) [2]	<80	<130	D	B	56	71	n.g.	n.g.
	80–100	130–160	D	C	65	64	n.g.	n.g.
	>100	>160	D	D	67	42	n.g.	n.g.
Profilomat II [11]	<80	<130	B	B	57	56	−1 ± 7	−1 ± 6
	80–100	130–160	B	D	53	39	1 ± 7	2 ± 9
	>100	>160	C	D	47	31	2 ± 9	4 ± 11

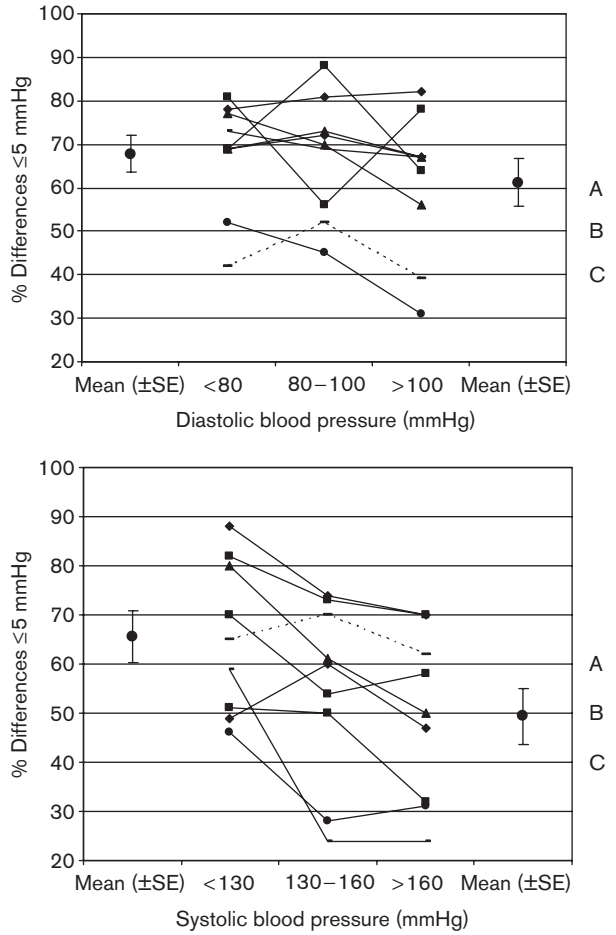
BP, blood pressure; BHS, British Hypertension Society; SDD, standard deviation of differences; DBP, diastolic blood pressure; SBP, systolic blood pressure; ABPM, ambulatory blood pressure monitoring; n.g., not given; Au, auscultatory; Oscill, oscillometrically.
[a]Validated according to the International Protocol. Additional data were provided by Altunkan *et al.* [13]. Results for this device are not shown in Fig. 2 because relevant data were missing. Devices from Ref. [2] were tested according to the BHS protocol of 1990.

devices. We believe, however, that this conclusion would be incorrect. It is our opinion that BP measuring devices seem to become less accurate at increasing BP levels because of a combination of two factors: the sequential measurements used during validation studies and the increasing BP variability at increasing BP levels.

BP has been shown to be more variable at increasing BP levels. Mancia *et al.* [36] showed that absolute short-term variability in BP was greater for hypertensive patients than for normotensive individuals. This was shown for systolic, diastolic, as well as mean arterial BP. For systolic BP, short-term variability increased from 9.5 mmHg (for normotensive individuals) to 12.2 mmHg (for severe hypertensive patients). For diastolic BP, short-term BP variability increased from 6.1 mmHg (for normotensive individuals) to 9.0 mmHg (for severe hypertensive patients). The percentual BP variabilities, however, were similar. BP variability has been linked to target organ damage in hypertension and has been shown to be an independent predictor for cardiovascular mortality in a general population [37,38].

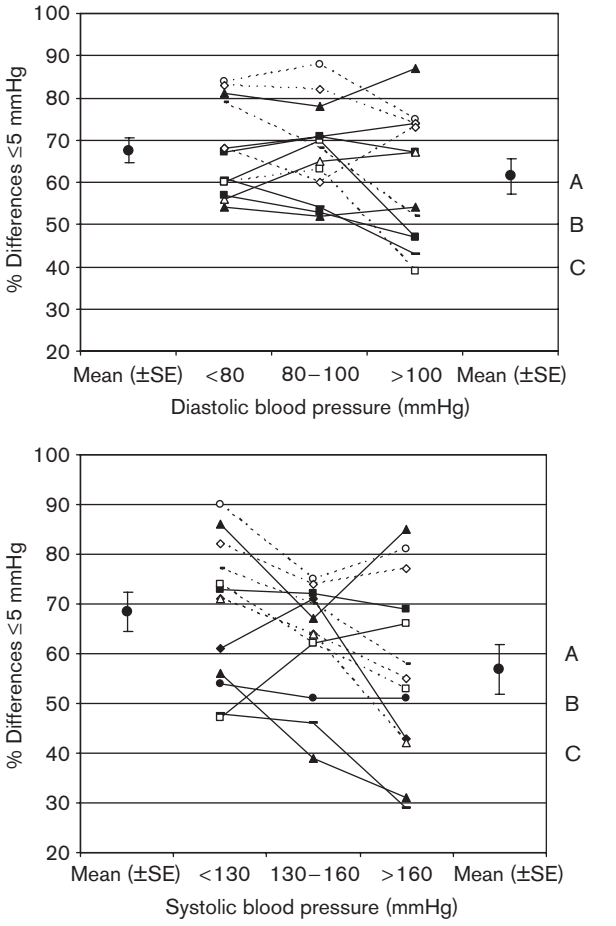
In the BHS protocol of 1993, sequential measurements are used for the validation of BP measuring devices. The absolute difference between test device and 'the gold standard' (mercury sphygmomanometer) is calculated independent of BP level [3]. The influence of the

Fig. 1



Number (percentages) of differences $\leq$ 5 mmHg for non-ambulatory blood pressure measuring devices for different diastolic and systolic blood pressure levels. The device that was tested according to the BHS protocol of 1990 is shown using a broken line. The thresholds shown on the right of the figure concern the BHS protocol of 1993. BHS, British Hypertension Society.

Fig. 2



Idem as in Fig. 1, for ambulatory blood pressure measuring devices. Open symbols designate auscultatory and closed symbols designate oscillometric blood pressure measuring devices. Devices that were tested according to the BHS protocol of 1990 are shown using broken lines. The thresholds shown on the right of the figure concern the BHS protocol of 1993. BHS, British Hypertension Society.

sequential measurements on the results of the validation of automated BP measuring devices was investigated by Atkins *et al.* [39]. They performed sequential BP measurements using the same mercury sphygmomanometer. The percentage of differences within 5 mmHg was only 69% (for systolic BP), when comparing a BP measurement using the mercury sphygmomanometer with the mean of the measurement before and after the index measurement using the same device. The only explanation could be that BP fluctuated during the sequential measurements.

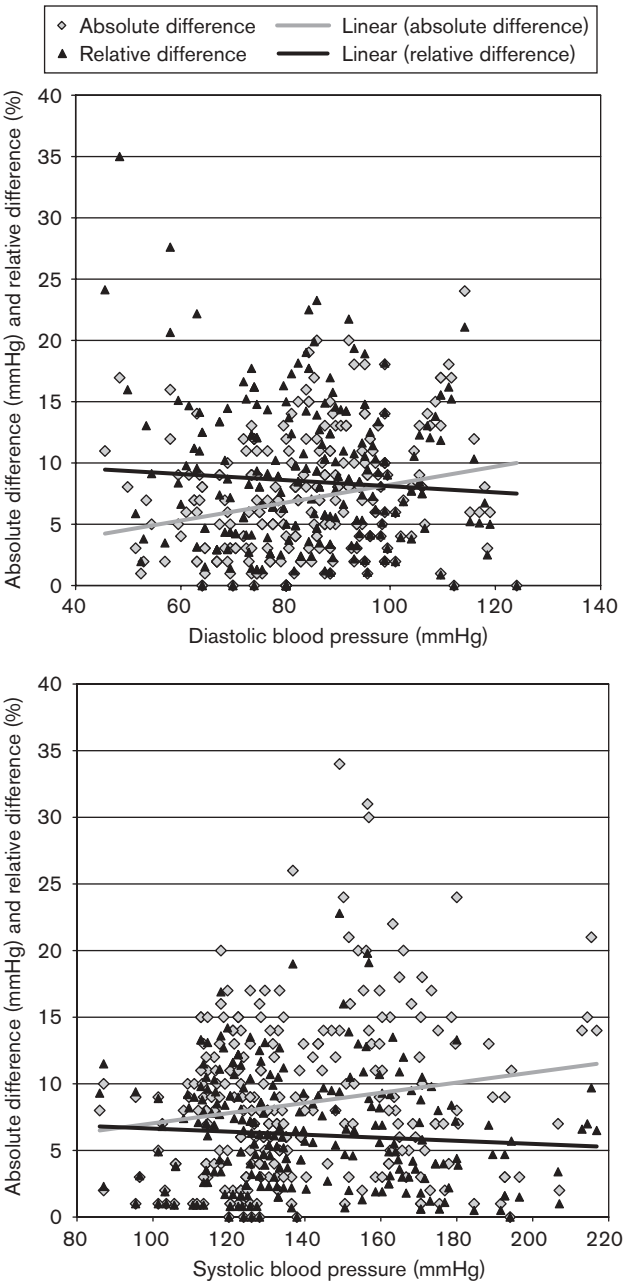
Owing to the increasing variability of BP at increasing BP levels, analysis using the absolute BP differences in sequential measurements will underestimate the accuracy of BP measuring devices at these levels.

Noticeably, all devices in the first study showing decreasing accuracy at increasing BP levels were tested using sequential measurements [2].

Analyses of the data both from the literature and from our own studies with the Welch Allyn Vital Signs Monitor and the Omron RX-M indeed shows that the absolute difference seems to be dependent on the BP level, whereas the relative difference seems to be more or less independent of the BP level.

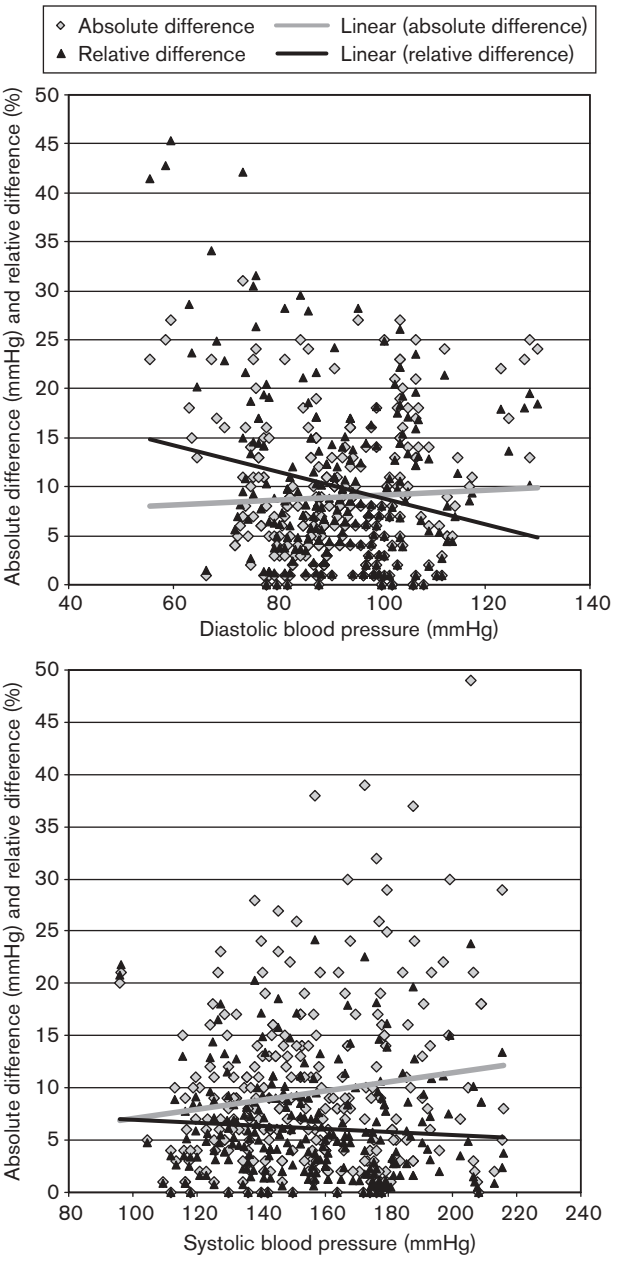
Another explanation for the current findings is that the oscillometric method itself may be responsible. The exact way in which the systolic and diastolic BPs are determined using oscillometry is held secret by the different device manufacturers. It may well be that the

Fig. 3



Absolute and relative differences between measurements by the Welch Allyn Vital Signs Monitor and standard mercury sphygmomanometer for diastolic (upper panel) and systolic (lower panel) blood pressure.

Fig. 4



Idem as in Fig. 3, for the Omron RX-M.

observed inaccuracy is due to the algorithm used to calculate the systolic and diastolic BP values.

Decreasing accuracy of BP measuring devices at increasing BP levels is a very troublesome phenomenon, as hypertension is the indication for their use. The consequence may be that patients with hypertension can erroneously be classified as non-hypertensive and treatment withheld. Furthermore, in treated hypertensive patients the necessary adaptation of treatment will not take place, while BP is judged adequately regulated. Alternatively, it is possible that a device gives readings that are too high. Non-hypertensive individuals could, therefore, erroneously be classified as hypertensive.

Owing to the limited studies available for this report, selection bias could have been introduced. The studies used, however, are well performed and the results are consistent, especially with regard to systolic BP. It is within the BP range of 80–100 mmHg for diastolic BP and 130–160 mmHg for systolic BP that the threshold for the diagnosis of hypertension is encompassed. The effect of the BP level on the accuracy of BP measuring devices within this important BP range cannot be estimated on the basis of the information currently available.

Validation studies should continue to report the accuracy of devices at different BP levels, although not explicitly stated in the new 'International Protocol' [40]. Besides the frequently shown Bland–Altman plots, we would like to report separately the accuracy at the different BP levels as shown in Tables 1 and 2. With the new 'International Protocol', however, the sample size of each BP category being 11 is quite small.

In conclusion, we would like to state that BP measuring devices seem to become less accurate at increasing BP levels. Owing to sequential measurements used during validation and to the increasing variability of BP at increasing BP levels, the decreasing accuracy of BP measuring devices, however, may have been overestimated.

Nonetheless, this is a very troublesome phenomenon as accuracy at increasing BP levels is most important for diagnosis and follow-up of hypertensive patients. Perhaps the accuracy of a device at different BP levels could become an independent criterion for recommending in favour of or against its use in clinical practice. It is our opinion that validation reports should not only address the absolute but also the relative accuracy at different BP levels.

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