

# Validation of the ROSSMAX blood pressure measuring monitor according to the European Society of Hypertension International Protocol for Validation of Blood Pressure Measuring Devices in Adults

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**Background** It is now accepted that blood pressure measuring devices should be subjected to an independent evaluation of their accuracy before they are marketed for clinical use. The results of validation of the ROSSMAX Blood Pressure Measuring Monitor for self-measurement according to the European Society of Hypertension International Protocol for Validation of Blood Pressure Measuring Devices in Adults are presented in this paper.

**Population** Thirty-three subjects were recruited from among staff and patients at Beaumont Hospital, Dublin, Ireland.

**Methods** The ROSSMAX monitor was connected to the Sphygmocorder, an audiovisual system for validation, which records blood pressure on tape and video for later analysis. Nine sequential same-arm measurements between the device and a standard mercury sphygmomanometer were recorded using the Sphygmocorder.

**Results** In phase 1, the ROSSMAX monitor produced 21 measurements within 5 mmHg, 31 within 10 mmHg and 38 within 15 mmHg for systolic blood pressure (SBP), and 36 within 5 mmHg, 43 within 10 mmHg and 45 within 15 mmHg for diastolic blood pressure (DBP). The mean differences were  $-5.6$  (10.2) [mean (SD)] mmHg for SBP and  $-0.5$  (4.5) mmHg for DBP. The ROSSMAX monitor failed to meet any of the criteria for SBP but comfortably passed all of the criteria for DBP. In phase 2.1, the ROSSMAX monitor had 51 measurements within 5 mmHg, 73 within 10 mmHg and 86 within 15 mmHg for SBP, and

71 measurements within 5 mmHg, 93 within 10 mmHg and 98 within 15 mmHg for DBP. The mean differences were  $-4.5$  (9.5) mmHg for SBP and  $-1.8$  (5.0) mmHg for DBP. The ROSSMAX monitor failed to meet any of the criteria for SBP but comfortably passed all of the criteria for DBP. In phase 2.2, 16 subjects had at least two of the differences lying within 5 mmHg and 10 subjects had no differences within 5 mmHg for SBP; 26 subjects had at least two of the differences falling within 5 mmHg and three subjects no differences within 5 mmHg for DBP. The ROSSMAX monitor failed to meet the criteria for SBP but passed the criteria for DBP.

**Conclusions** The ROSSMAX monitor cannot be recommended for clinical use in an adult population because it records SBP inaccurately. *Blood Press Monit* 8:261–265 © 2003 Lippincott Williams & Wilkins.

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**Keywords:** ROSSMAX, self-measurement, International Protocol, European Society of Hypertension validation, accuracy, adult

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Conflict of interest Rossmax International Ltd., 12F, No. 189, Kang Chien Rd., Taipei, 114, Taiwan, provided three devices and financial support for the study.

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## Introduction

With the increasing marketing of automated and semi-automated devices for the measurement of blood pressure, there is a need for potential purchasers to be able to satisfy themselves that such devices have been evaluated according to agreed criteria [1]. With this need in mind, the Association for the Advancement of Medical Instrumentation published a standard for electronic or aneroid sphygmomanometers in 1987 [2], which included a protocol for the evaluation of the accuracy of devices; this was followed in 1990 by the protocol of the British Hypertension Society [3]. Both protocols were revised in

1993 [4,5]. These protocols, which differed in detail, had a common objective, namely the standardization of validation procedures to establish minimum standards of accuracy and performance, and to facilitate the comparison of one device with another [6].

A number of blood pressure measuring devices have been evaluated according to one or both protocols. Experience has, however, demonstrated that the conditions demanded by the protocols are difficult to fulfil. This is especially so because of the large number of subjects that have to be recruited and the ranges of blood pressure

required. The time needed to complete a validation study is such that it is difficult to recruit trained staff for the duration of a study. These factors have made validation studies difficult to perform and very costly, with the result that fewer centres are prepared to undertake them. This is particularly unfortunate as more devices are in need of independent validation than ever before.

Aware of these problems, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension has published a simplified protocol – the International Protocol – to facilitate the evaluation process, with the expectation that manufacturers will be more likely to submit their products for validation in order to obtain the minimum approval necessary for a device to be used in clinical practice [7]. The International Protocol, which is applicable to the majority of blood pressure measuring devices on the market, is confined to adults over the age of 30 years (as these will constitute the majority of subjects with hypertension), and it does not make recommendations for special groups, such as children, pregnant women and the elderly, or for special circumstances, such as during exercise.

The ROSSMAX blood pressure monitor, manufactured by ROSSMAX International Ltd., Taiwan, is designed for measuring self-recorded blood pressure using the oscillometric technique.

## Methods

### Blood pressure measurement technique

A standard mercury sphygmomanometer, the components of which were checked carefully before the study, was used as a reference standard. All blood pressures were recorded to the nearest 2 mmHg. Blood pressure was measured with the arm supported at heart level, with the manometer at eye level and within 1 m of the observer. Device validation was performed at room temperature, and disturbing influences, such as telephones and beeps, were silenced. A Littman stethoscope was used for all manual measurements.

The circumference of the arms was measured to ensure that the bladder being used was adequate for the subject. Measurements made with the ROSSMAX monitor used

the appropriate bladder according to the manufacturer's instructions. The same cuff/bladder was used for the standard mercury manometer measurements.

The validation team were instructed in the use of the ROSSMAX monitor and used the device in practice to detect any technical peculiarities that might have influenced the validation procedure. The ROSSMAX monitor differs from most devices in that it records blood pressure during inflation. It is straightforward to use, and no operational difficulties were encountered during familiarization and throughout the study.

### Subject selection

Thirty-three subjects (15 for the phase 1 and a further 18 for phase 2) with a wide range of blood pressure were selected (Tables 1 and 2). Subjects could be taking antihypertensive medication, but subjects in atrial fibrillation or with any sustained arrhythmia were excluded. Characteristics were as follows:

- *Numbers:* Phase 1 – 15 subjects; phase 2 – 33 subjects.
- *Sex:* Phase 1 – at least five male and five female subjects were required; phase 2 – at least 10 male and 10 female subjects were required.
- *Age range:* All subjects were at least 30 years of age.
- *Arm circumference:* Distribution by chance.
- *Blood pressure range:* There were three ranges for systolic blood pressure (SBP) and three for diastolic blood pressure (DBP), with 11 subjects in each range to provide 99 pairs of measurements (Table 3). The blood pressure used to determine the range was the entry blood pressure at the time of the validation procedure (BPA), and not that measured at the time of recruitment for validation.

### Observer measurement

Measurements were recorded using the Sphygmocorder, an audiovisual system for validation [7,8]. Two observers assessed the recordings separately. Where they differed, the recording was reassessed until agreement was reached. Further references to 'observer measurement' refer to the agreed measurement using the Sphygmocorder. At least 30 s were allowed between each measurement to avoid venous congestion, but not more than 60 s,

Table 1 Demographics and entry criteria

		Sex		Age (years)		Arm circumference (cm)		Recruitment blood pressure (mmHg)	
		Male:female	Range	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	
Phase 1	SBP	10:5	30:81	56 (14)	25:37	30 (4)	108:180	143 (24)	
	DBP	10:5	30:72	56 (12)	25:37	29 (3)	54:144	87 (18)	
Phase 2	SBP	19:14	30:81	54 (11)	22:37	30 (3)	104:180	144 (24)	
	DBP	19:14	30:81	56 (11)	22:37	30 (3)	54:144	88 (17)	

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

**Table 2 Validation results**

		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean	SD
Phase 1							
Required	One of	25	35	40			
Achieved	SBP	21	31	38	Fail/stop	-5.6 mmHg	10.2 mmHg
	DBP	36	43	45	Continue	-0.5 mmHg	4.5 mmHg
Phase 2.1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	51	73	86	Fail	-4.5 mmHg	9.5 mmHg
	DBP	71	93	98	Pass	-1.8 mmHg	5.0 mmHg
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade			
Required		≥ 22	≤ 3				
Achieved	SBP	16	10	Fail			
	DBP	26	3	Pass			

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

**Table 3 Blood pressure recruitment range requirements**

	Low	Medium	High
SBP	90–129	130–160	161–180
	11	11	11
DBP	40–79	80–100	101–130
	11	11	11

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

so that variability would be minimized. In some cases, observer measurements were repeated if the supervisor had reason to believe that there might be interference with recorded sounds. Reasons included patient movement and loud external noises. To avoid bias, the repeated measurement was used in all cases regardless of the quality of the first reading.

### Procedure

First, the subject was introduced to the observer and the procedure explained. Arm circumference, sex, date of birth and current date were noted. The subject was allowed to relax for 10–15 min to minimize anxiety and any white-coat effect.

Nine sequential same-arm measurements between the test instrument and a standard mercury sphygmomanometer were then recorded as follows:

- *BPA*: Entry blood pressure recorded on the Sphygmocorder with mercury standard. This value was used to categorize the subject into the low, medium or high range separately for SBP and DBP (Table 1).
- *BPB*: Device detection blood pressure, observer 3. This blood pressure was measured to permit the ROSSMAX monitor to determine the blood pressure characteristics of the subject; this measurement was not included in the analysis.
- *BP1*: Recorded on the Sphygmocorder with the mercury standard.
- *BP2*: Supervisor with the ROSSMAX monitor.
- *BP3*: Recorded on the Sphygmocorder with the mercury standard.

- *BP4*: Supervisor with the ROSSMAX monitor.
- *BP5*: Recorded on the Sphygmocorder with the mercury standard.
- *BP6*: Supervisor with the ROSSMAX monitor.
- *BP7*: Recorded on the Sphygmocorder with the mercury standard.

Documentation is provided for data omitted for legitimate technical reasons; once a subject had been included, the data for that subject were not excluded from the study if blood pressure values were obtainable.

### Analysis

The data were analysed using a specially written software program.

### Accuracy criteria

Differences were calculated by subtracting the observer measurement from the device measurement. When comparing and categorizing differences, their absolute values were used. A difference was categorized into one of four bands according to its rounded absolute value for SBP and DBP:

- *0–5 mmHg*: These represent measurements considered to be very accurate (No error of clinical relevance).
- *6–10 mmHg*: These represent measurements considered to be slightly inaccurate.
- *11–15 mmHg*: These represent measurements considered to be moderately inaccurate.
- *> 15 mmHg*: These represent measurements considered to be very inaccurate.

The analysis was based on how values in these bands fell cumulatively into three zones:

- *Within 5 mmHg*: This zone represents all values falling in the 0–5 mmHg band.
- *Within 10 mmHg*: This zone represents all values falling in the 0–5 and 6–10 mmHg bands.
- *Within 15 mmHg*: This zone represents all values falling in the 0–5, 6–10 and 11–15 mmHg bands.

### Subject measurements

The observer measurements BP1 to BP7 were used to assess accuracy. Each ROSSMAX monitor measurement was flanked by two of these observer measurements, one of which was selected as the comparative measurement.

From these, further measurements were derived 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 these differences (i.e. without the signs) were derived.
3. The absolute values were paired according to the device reading.
4. Where the values in a pair were unequal, the observer measurement corresponding to the smaller difference was used.
5. Where the values in a pair were equal, the first of the two observer measurements was used.

For each subject there were three device readings for SBP and three for DBP. Each of these six readings now had a single corresponding observer measurement, a difference between the two and a band for that difference as described above. Owing to the requirement that subjects had to be recruited in the order they presented, subjects recruited in the later part of the study might have been suitable for SBP or DBP but not necessarily for both.

## Results

### Phase 1

#### Subject characteristics

There were 10 male and five female subjects for both SBP and DBP (11 subjects providing both SBP and DBP measurements). Mean recruitment pressures were 143 (24) [mean (SD)] mmHg for SBP and 87 (18) mmHg for DBP. Ages ranged from 30 to 81 years for SBP and 30 to 72 years for DBP. Arm circumferences ranged from 25 to 37 cm for both SBP and DBP (Table 1)

#### Validation criteria

To pass phase 1, a device had to have at least 25 of the 45 measurements within 5 mmHg, 35 within 10 mmHg or 40 within 15 mmHg of the comparative observer measurements (Table 2). The ROSSMAX monitor had 21 measurements lying within 5 mmHg, 31 within 10 mmHg and 38 within 15 mmHg for SBP, and 36 within 5 mmHg, 43 within 10 mmHg and 45 within 15 mmHg for DBP. The mean differences were  $-5.6$  (10.2) mmHg for SBP and  $-0.5$  (4.5) mmHg for DBP. The ROSSMAX monitor failed to meet any of the criteria for SBP but comfortably passed all the criteria for DBP (Table 2).

### Phase 2

#### Subject characteristics

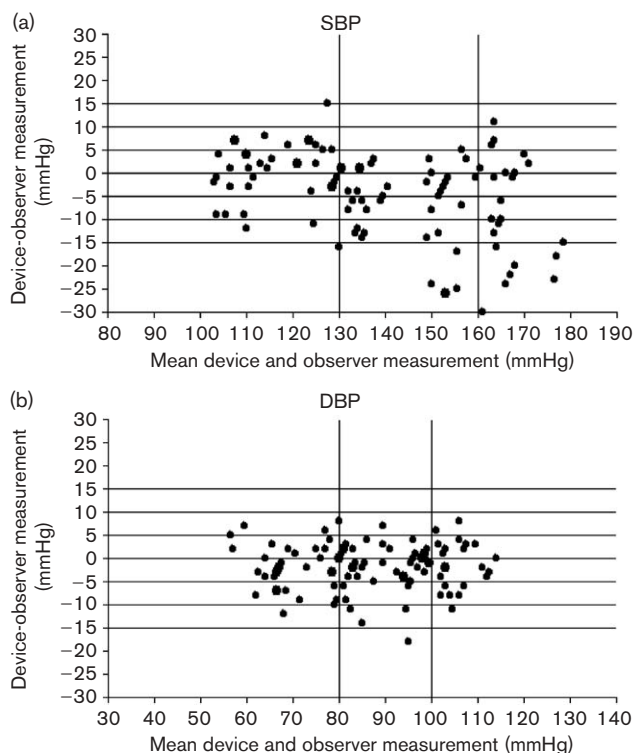
There were 19 male and 14 female subjects for both SBP and DBP (29 subjects providing both SBP and DBP

measurements). Mean recruitment pressures were 144 (24) mmHg for SBP and 88 (17) mmHg for DBP. Ages ranged from 30 to 81 years for both SBP and DBP. Arm circumferences ranged from 22 to 37 cm for both SBP and DBP (Table 1).

#### Validation criteria

*Phase 2.1:* To pass phase 2.1, a device must have at least 60 of the 99 measurements within 5 mmHg, 75 within 10 mmHg and 90 within 15 mmHg of the comparative observer measurements, and in addition must also have either 65 within 5 mmHg and 80 within 10 mmHg, or 65 within 5 mmHg and 95 within 15 mmHg, or 80 within 10 mmHg and 95 within 15 mmHg. The ROSSMAX monitor had 51 measurements within 5 mmHg, 73 within 10 mmHg and 86 within 15 mmHg for SBP, and 71 measurements within 5 mmHg, 93 within 10 mmHg and 98 within 15 mmHg for DBP. The mean differences were  $-4.5$  (9.5) mmHg for SBP and  $-1.8$  (5.0) mmHg for DBP. The ROSSMAX monitor failed to meet any of the criteria for SBP but comfortably passed all the criteria for DBP (Table 2).

Fig. 1



(a) Scatterplot showing the systolic blood pressure (SBP) differences between the ROSSMAX monitor and observer readings in 99 subjects. The slightly larger points indicate two superimposed points. The vertical lines mark the Low, Medium and High pressure ranges. (b) Scatterplot showing the diastolic blood pressure (DBP) differences between the ROSSMAX monitor and observer readings in 99 subjects. The slightly larger points indicate two superimposed points. The vertical lines mark the Low, Medium and High pressure ranges.

*Phase 2.2:* To pass phase 2.2, at least 22 of the 33 subjects had to have at least two of their three device measurements within 5 mmHg of the standard, and no more than three subjects could have none of the three measurements lying within 5 mmHg of the standard. For the ROSSMAX monitor, 16 subjects had at least two of the differences within 5 mmHg and 10 subjects with no differences within 5 mmHg for SBP, and 26 subjects had at least two of the differences within 5 mmHg and three subjects with no differences within 5 mmHg for DBP. The ROSSMAX monitor failed to meet the criteria for SBP but passed the criteria for DBP (Table 2 and Figs. 1 a and b).

### Discussion

It was evident from phase 1 that the ROSSMAX monitor was inaccurate for SBP, and if the protocol had been followed, no further testing would have been conducted. However, as the monitor was performing well for DBP, it was decided to proceed with the validation. The ROSSMAX monitor failed to meet any criteria for SBP in phases 1, 2.1 and 2.2 whereas it passed these phases for DBP.

The ROSSMAX monitor is an innovative device that assesses blood pressure during inflation rather than, as is customary, during deflation. This has the advantage of requiring less cuff inflation with consequently less subject discomfort and speedier recording of the blood pressure. As a result, the subjects participating in the validation study found the device very comfortable.

These qualities would make it a welcome addition to the devices available for the self-measurement of blood pressure [1]. However, the ROSSMAX monitor cannot be recommended for clinical use because it records SBP inaccurately. Following the validation, the manufacturers are adjusting the algorithm to provide accurate systolic measurements, and when this is complete, the device will be re-evaluated.

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