

# Blood Pressure Monitoring



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# Validation of the fully automated A&D TM-2656 blood pressure monitor according to the British Hypertension Society Protocol

Wei-Fang Zeng, Ming Liu, Yuan-Yuan Kang, Yan Li and Ji-Guang Wang

**Objective** The present study aimed to evaluate the accuracy of the fully automated oscillometric upper-arm blood pressure monitor TM-2656 according to the British Hypertension Society (BHS) Protocol 1993.

**Methods** We recruited individuals until there were 85 eligible participants and their blood pressure could meet the blood pressure distribution requirements specified by the BHS Protocol. For each individual, we sequentially measured the systolic and diastolic blood pressures using a mercury sphygmomanometer (two observers) and the TM-2656 device (one supervisor). Data analysis was carried out according to the BHS Protocol.

**Results** The device achieved grade A. The percentage of blood pressure differences within 5, 10, and 15 mmHg was 62, 85, and 96%, respectively, for systolic blood pressure, and 71, 93, and 99%, respectively, for diastolic blood pressure. The average ( $\pm$ SD) of the device-observer differences was  $-2.1\pm 7.8$  mmHg ( $P<0.0001$ ) and

$-1.1\pm 5.8$  mmHg ( $P<0.0001$ ) for systolic and diastolic blood pressures, respectively.

**Conclusion** The A&D upper-arm blood pressure monitor TM-2656 has passed the requirements of the BHS Protocol, and can thus be recommended for blood pressure measurement. *Blood Press Monit* 18:223–226 © 2013 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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**Keywords:** blood pressure determination, blood pressure monitor, British Hypertension Society Protocol, validation studies

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## Introduction

For blood pressure measurement in the clinical setting, securing and releasing an arm cuff can be time and manpower consuming. In addition, arm cuffing requires some standardization. For instance, the cuff has to be placed smoothly and snugly to the upper arm, and the lower edge of the cuff should be 2–3 cm proximal to the point of brachial artery pulsation [1]. Fully automated blood pressure monitors are therefore developed with an automatic arm cuffing system. Such devices are apparently convenient and easy to use. However, because of the increased technological complexity, these devices have to be validated carefully for accuracy of measurement. In the present study, we assessed the accuracy of the fully automated oscillometric upper-arm blood pressure monitor A&D TM-2656 for blood pressure measurement in adults according to the British Hypertension Society (BHS) Protocol 1993 for the evaluation of blood pressure-measuring devices [2].

## Methods

### Participants

Study participants were recruited from among the staff and hypertensive patients in Ruijin Hospital (Shanghai, China). We excluded from our study children and adolescents ( $\leq 18$  years) and individuals with cardiac arrhythmias and peripheral arterial disease. For practical

reasons, we also excluded patients with known heart disease or diagnosed with secondary hypertension. The Ethics Committee of Ruijin Hospital approved the study protocol. All participants provided informed written consent. We administered a short questionnaire to collect information on medical history, and measured body height, body weight, and arm circumference.

The selected participants were categorized on the basis of the blood pressure ranges required by the BHS Protocol rules (Table 1) [2].

### The TM-2656 device

The TM-2656 device (A&D Medical, Tokyo, Japan) is a fully automated electronic digital upper-arm blood pressure monitor with an automatic arm cuffing system. The device operates through the oscillometric technique and is designed mainly for clinical use. The device has a capacitive pressure sensor designed to measure pressure values ranging from 0 to 299 mmHg and pulse rate values from 30 to 240 beats/min. The declared specific accuracy is  $\pm 3$  mmHg for pressure and  $\pm 2$  beats/min or  $\pm 2\%$  of a reading, whichever is greater, for pulse rate. The device measures blood pressure only during deflation, and reports the last readings of measurements.

The device has a width of 424 mm, a depth of 533 mm, and a height of 304 mm (Fig. 1), and is suitable for arm



Table 1 Required and actual number of study participants according to blood pressure level

	Systolic blood pressure (mmHg)					Diastolic blood pressure (mmHg)				
	<90	90–129	130–160	161–180	>180	<60	60–79	80–100	101–110	>110
Required	8	20	20	20	8	8	20	20	20	8
Actual number	8	25	24	20	8	9	20	27	20	9

Fig. 1



The A&amp;D TM-2656 device.

circumferences ranging from 18 to 35 cm. The device has a distinct compact symmetrical design with two 'start/stop' buttons on the two sides of the arm cuffing tunnel. This design allows blood pressure measurement on either the left or the right arm.

#### Validation procedure

The validation procedure strictly followed the BHS Protocol 1993 [2], and was carried out by a team of three investigators experienced in the blood pressure measurement and trained repeatedly by an educational video program for blood pressure measurement produced by the BHS (Registered Charity Number 287635). For each participant, blood pressure was measured sequentially using a mercury sphygmomanometer (two observers) and the TM-2656 device (one supervisor). A pause of 30–60 s was allowed between two successive measurements.

Blood pressure was measured in the sitting position with the forearm at the level of the heart according to the

European recommendations [1]. The digital signals of the pressure and the oscillations were obtained during the device measurement for the real-time monitoring of the pulse rhythm.

#### Data analysis

Data analysis was carried out according to the BHS Protocol [2]. For each study participant, we calculated the differences between the device and the mercury sphygmomanometer separately for the two observers. For each of the three systolic and diastolic blood pressure readings recorded by the device, two absolute differences were calculated by subtracting, respectively, the preceding and the following measurements taken by each of the two observers with the mercury sphygmomanometer. The smaller one of the two absolute differences was used and categorized into one of the three bands according to its rounded value. The absolute values of the differences were presented in numbers in tabular format. The real numbers of the differences were plotted against the mean of the device and observers' measurements in scatter plots. To evaluate the relationship between the differences and the mean of device and observers' blood pressure values, we used the curve-fitting method for data visualization and for comparison of  $R^2$ .

## Results

#### Demographic and clinical data

Of the 103 consecutively screened participants, 15 were excluded because the blood pressure differences between two sequential readings with the mercury sphygmomanometer exceeded 12 mmHg systolic or 8 mmHg diastolic. We further excluded three participants because they did not complete the entire validation process for personal reasons ( $n=2$ ) or because cardiac arrhythmias were detected during the validation process ( $n=1$ ).

The 85 study participants included 42 men and 43 women, and had a mean ( $\pm$ SD) age of  $48\pm 15$  years (range, 22–79 years), a mean BMI of  $23.5\pm 3.4$  kg/m<sup>2</sup>, and a mean arm circumference of  $26.9\pm 2.9$  cm (range, 20.6–32.6 cm). The mean systolic/diastolic blood pressures at screening were  $141\pm 36/88\pm 19$  mmHg.

The study was carried out on the left arm in all participants. During the study, there was no measurement failure for either device.



**Table 2 Accuracy of the A&D TM-2656 blood pressure monitor according to the British Hypertension Society Protocol 1993**

Grade	Absolute value of the difference between observer and device (mmHg) (%)			Mean of observer and device ( $\pm$ SD, mmHg)	Mean difference ( $\pm$ SD, mmHg)	
	$\leq 5$	$\leq 10$	$\leq 15$			
Observer A						
SBP	A	60	85	95	139.4 $\pm$ 35.5	-1.7 $\pm$ 7.6
DBP	A	71	93	99	87.9 $\pm$ 19.1	-1.1 $\pm$ 5.8
Observer B						
SBP	A	62	85	96	139.8 $\pm$ 35.6	-2.1 $\pm$ 7.8
DBP	A	67	93	100	88.2 $\pm$ 19.0	-1.4 $\pm$ 5.8
Final grading						
SBP	A	62	85	96	139.8 $\pm$ 35.6	-2.1 $\pm$ 7.8
DBP	A	71	93	99	87.9 $\pm$ 19.1	-1.1 $\pm$ 5.8

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

### Validation of the TM-2656 device

The device achieved grade A. The percentage of the blood pressure differences within 5, 10, and 15 mmHg was 62, 85, and 96%, respectively, for systolic blood pressure, and 71, 93, and 99%, respectively, for diastolic blood pressure (Table 2 and Fig. 2).

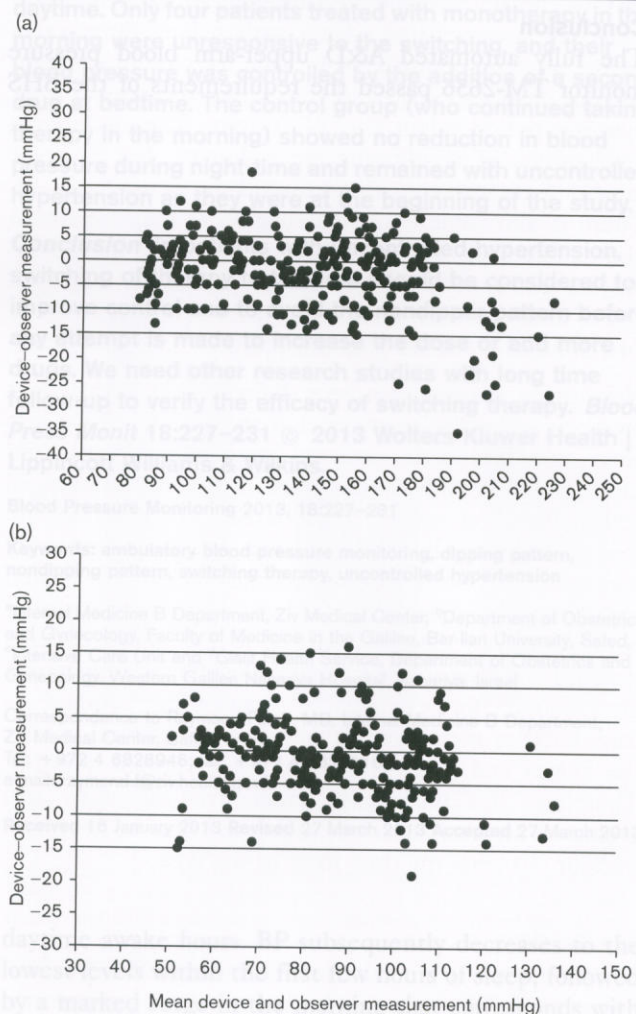
### Device-observer mean differences

The average ( $\pm$ SD) of the device-observer differences was  $-2.1\pm 7.8$  mmHg ( $P < 0.0001$ ) and  $-1.1\pm 5.8$  mmHg ( $P = 0.003$ ) for systolic and diastolic blood pressures, respectively. Figure 2 presents the scatter plots of device-observer differences against the average of device and observers' values for the 255 pairs of comparisons. The device-observer differences were significantly ( $P < 0.0001$ ) and curvilinearly associated with the mean of device and observers values for systolic ( $R^2$ , 0.25 in quadratic function vs. 0.16 in linear function;  $P < 0.0001$ ) and diastolic blood pressures ( $R^2$ , 0.13 in quadratic function vs. 0.12 in linear function;  $P = 0.05$ ).

### Discussion

The results of the present study showed that the fully automated A&D upper-arm blood pressure monitor TM-2656 achieved grade A for both systolic and diastolic blood pressures according to the BHS Protocol. On application of the Association for the Advancement of Medical Instrumentation protocol [3], the TM-2656 device also passed all requirements. Indeed, as the Association for the Advancement of Medical Instrumentation protocol required for both systolic and diastolic blood pressures [3], the mean blood pressure differences were less than 5 mmHg and the SDs were less than 8 mmHg.

In our study, the graphical presentations of the device-observer differences in systolic and diastolic blood pressures showed an acceptable agreement between the mercury sphygmomanometer and the TM-2656 device. Nonetheless, as shown by the scatter plots and confirmed by formal statistical analyses, the device-observer differences were dependent on the level of blood pressure,

**Fig. 2**

Scatter plots of the (a) systolic and (b) diastolic blood pressure differences between the A&D TM-2656 device and observers (y-axis) against the average of device and observer pressure values (x-axis).

especially systolic blood pressure. When systolic blood pressure was higher than a level of  $\sim 170$  mmHg, the device appeared to underestimate blood pressure.



This underestimation remains incompletely understood. The device applies a single-sized arm cuff to patients with a wide range of arm circumferences. Over-cuffing in patients with slim arms can be an explanation for the underestimation of blood pressure by the device [1]. We speculate that this phenomenon should be proportional to the level of blood pressure and hence become more pronounced when blood pressure is high.

Because of various advantages, such as convenience and ease of use, fully automated blood pressure monitors are being used increasingly in the evaluation of therapeutic effects in the clinical setting and in the screening for hypertension in the community setting. Our validation study therefore has clinical implications for the management of hypertension.

**Conclusion**

The fully automated A&D upper-arm blood pressure monitor TM-2656 passed the requirements of the BHS

Protocol 1993 [2], and hence can be recommended for blood pressure measurement in adults.

**Acknowledgements**

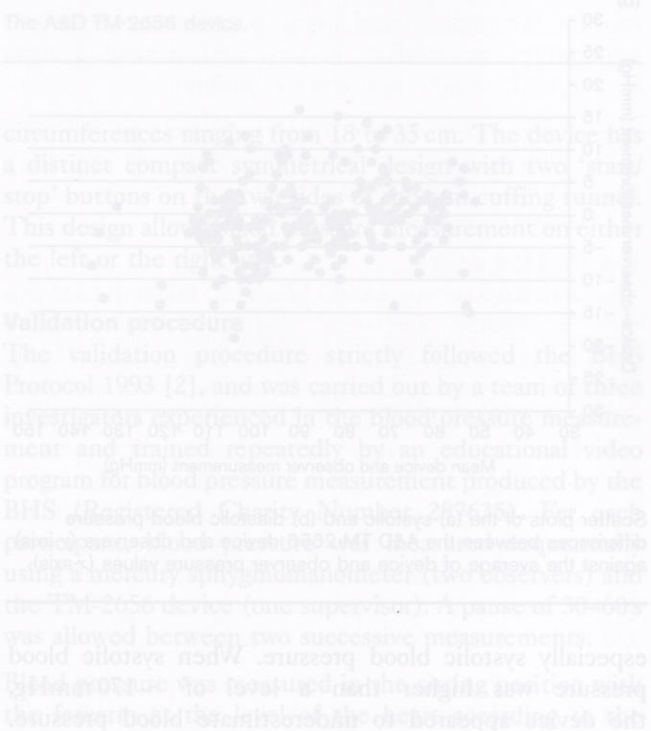
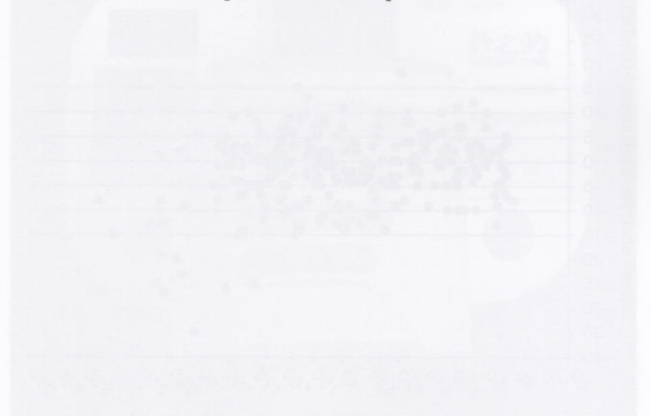
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**Conflicts of interest**

There are no conflicts of interest.

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**Discussion**

The results of the present study showed that the fully automated A&D upper-arm blood pressure monitor TM-2656 achieved grade A for both systolic and diastolic blood pressure according to the BHS Protocol. On application of the Association for the Advancement of Medical Instrumentation protocol [3], the TM-2656 device also passed all requirements, indeed as the Association for the Advancement of Medical Instrumentation protocol required for both systolic and diastolic blood pressures [3], the mean blood pressure differences were less than 5 mmHg and the BHS were less than 15 mmHg to age (15x) mean a had and narrow range, 22-79 years, mean a, easy 92-98 mmHg. In our study the temporal precision of the device-overcuffing in systolic and diastolic blood pressures showed an acceptable agreement between the mercury sphygmomanometer and the TM-2656 device. Nonetheless, tested by the sphygmomanometer and confirmed by formal statistical analysis, the device-overcuffing errors were dependent on the level of blood pressure.