

Validation of the A&D TM-2430 device for ambulatory blood pressure monitoring and evaluation of performance according to subjects' characteristics

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Objective To determine the accuracy of the TM-2430 blood pressure monitor, recently developed by the A&D company.

Design Evaluation was performed using the 1990 and 1993 British Hypertension Society (BHS) protocols. Monitor's performance was assessed in relation to subjects' age, sex, level of blood pressure, and degree of adiposity.

Methods Three TM-2430 recorders were assessed according to the various phases of the protocols. Simultaneous, same-arm readings were taken for the main validation test. Outcome was classified according to the criteria from the 1990 BHS recommendations, which are based on the cumulative percentage of readings differing from the mercury sphygmomanometer standard by 5, 10, and 15 mmHg or less, and using the criteria of the Association for the Advancement of Medical Instrumentation protocol, which considers a device accurate when the mean device-observer difference is within 5 mmHg and the related SD < 8 mmHg.

Results During in-use assessment 2.3% of total measurements ($n = 3744$) were rejected automatically by the machine and another 5.5% were discarded after visual inspection. The main validation test was performed with 98 subjects for a total of 595 blood pressure measurements. On the basis of the percentages of measurements differing from the mercury sphygmomanometer standard by ≤ 5 , ≤ 10 , and ≤ 15 mmHg, the TM-2430 device was graded A both for systolic blood pressure and for diastolic blood pressure. Differences between mean blood pressures as measured by device and observer were 2.2 ± 3.9 mmHg for systolic blood pressure and 0.7 ± 4.4 mmHg for diastolic blood pressure. The device's performance did not vary according to subjects' age, sex, and body mass, and was slightly better for subjects with high blood pressures and lean arms.

Conclusions These data show that the A&D TM-2430 monitor satisfies the recommended BHS and Association for Advancement of Medical Instrumentation

accuracy levels for both systolic and diastolic blood pressures. *Blood Press Monit* 3:255-260 © 1998 Lippincott Williams & Wilkins.

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Introduction

Ambulatory blood pressure monitoring is being used increasingly in clinical practice [1,2]. However, a proportion of measurements outside the patient's trend values are not likely to be genuine blood pressure readings, and it is often difficult to decide whether they are artifacts [3,4]. Moreover, it was recently demonstrated that artifactual readings may be within the patient's blood pressure trend range, making it impossible to distinguish between an accurate measurement and an artifactual one [5]. Other possible drawbacks of ambulatory recorders are their bulkiness and their excessive noise when they are in operation, which can limit their application for some patients.

In recent years many manufacturers tried to improve the characteristics of the monitoring devices, by reducing their size and eliminating the noise related to the cuff's inflation, and by trying to improve the precision of measurement [6,7]. The A&D company (A&D Company Ltd, Tokyo, Japan) has recently developed a new version of the TM series, the TM-2430 model, which is based on the oscillometric principle and, compared with the previous versions, has several other technical innovations. In this article we

report on the performance of the TM-2430 device, tested according to the British Hypertension Society (BHS) recommendations [8,9].

Subjects and methods

Subjects

We recruited 98 subjects (46 men and 52 women) for the main validation study from the outpatient clinic or department wards with the ranges of blood pressure and age required by the BHS rules. All agreed to participate in the protocol after they had been informed of the purpose of the study. Their mean \pm SD lying systolic blood pressure (SBP) was 136.7 ± 22.3 mmHg (range 89–199), their diastolic blood pressure (DBP) was 78.5 ± 13.0 mmHg (range 54–112), and their age was 58.8 ± 16.6 years (range 26–88). Their body mass index was 24.8 ± 3.2 kg/m², and their mean arm circumference was 28.2 ± 2.6 cm (range 21–33).

Skinfold thickness was measured in triplicate with a Harpenden caliper (British Indicators Ltd, St Albans, Hertfordshire, UK) at the biceps and triceps according to the procedure published by Edwards *et al.* [10]. The mean of the six measurements was averaged and used in the statistical analyses.

TM-2430 device

The TM-2430 model is a portable recorder that measures blood pressure using the oscillometric method. Compared with the previous TM models [11] it has several other technical differences, including substantial changes in weight and size (see appendix), in the device software, and in the deflation sequence. During the first three measurements after initialization air is expelled such that pressure decreases at a constant rate (3 mmHg/s) down to the preset value of 20 mmHg, after which pressure in the cuff is released automatically. This allows an accurate check of DBP. From the fourth measurement onward pressure in the cuff is released 4 s after the disappearance of Korotkoff sounds.

Phases I–IV of the BHS protocol

Observers were trained by an expert and at the end of the training period were tested for accuracy against each other by measuring blood pressures in about 100 subjects for a total of 300 readings. Static accuracy was determined for three devices after the automatic deflation procedure had been disabled through a circuit card supplied by the A&D company, which allows controlled deflation by hand. After 1 month of routine use, the three devices were used to test their performance during 24 h ambulatory monitoring. Each of them was applied to 10 subjects with a wide range of blood pressure, which was measured every 10 min during daytime and every 15 min during nighttime (2300–0600 h). At the end of this phase the devices were retested to determine their static accuracy.

Main validation

One of the three devices was selected randomly for the comparisons against a Riva Rocci sphygmomanometer. Two cuffs (12 cm \times 24 cm and 15 cm \times 30 cm) were used according to patient's arm size; the bladder had to cover at least 80% of arm circumference. The large cuff was used on one patient only. The cuff was connected through a Y piece to the TM-2430 device and a mercury column. Korotkoff phase V was taken as DBP. Measurements were taken in triplicate with the subject seated by two observers blinded to the TM-2430 device's readings, which were read by a third observer. The simultaneous same-arm approach was used for comparing the measurements taken by the observers and the device. We thereby adhered to the 1990 BHS recommendations [8], which use more restrictive criteria than those in the 1993 version of the protocol [9], to calculate the grading level of the TM-2430 device (Table 1).

Bland–Altman approach was used to study the distribution of the between-reading differences [12]. Student's *t* test was used for intergroup comparisons and Pearson's test for correlations. $P < 0.05$ was considered statistically significant.

Results

Interobserver differences

Mean differences (observer 2 – observer 1) between the measurements of the two observers ($n = 294$) were 0.6 mmHg for SBP and 0.2 mmHg for DBP and the related SD were 2.6 and 2.2 mmHg, respectively (Table 2). Of measurements, 94% for SBP and 97% for DBP differed by ≤ 5 mmHg.

Static accuracy

All machines satisfied BHS requirements during phases II and IV of the protocol when we tested them over the blood pressure range 20–250 mmHg.

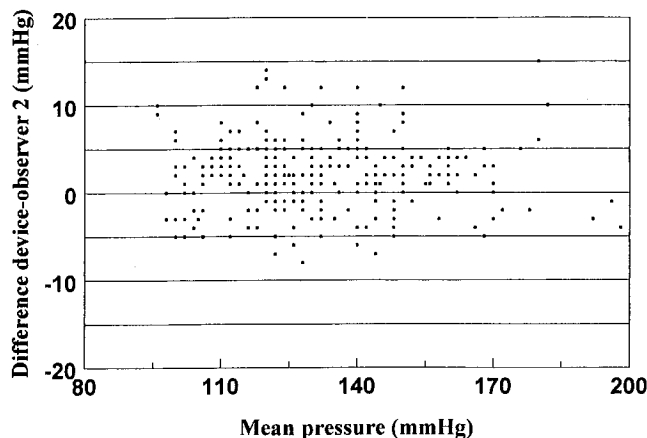
In-use assessment

During the 'field test', at least 1184 readings were taken for each device, giving a total of 3744 measurements. For all 24 h recordings <30% readings were rejected. Mean number of rejected readings was 2.3% of the total measurements (1.6% during daytime and 4.6% during sleep). After visual inspection we rejected another 5.5% of the readings according to the criteria of Kennedy *et al.* [13].

Table 1 Grading criteria according to the 1990 British Hypertension Society protocol (this grading was designed for the simultaneous same-arm measurements)

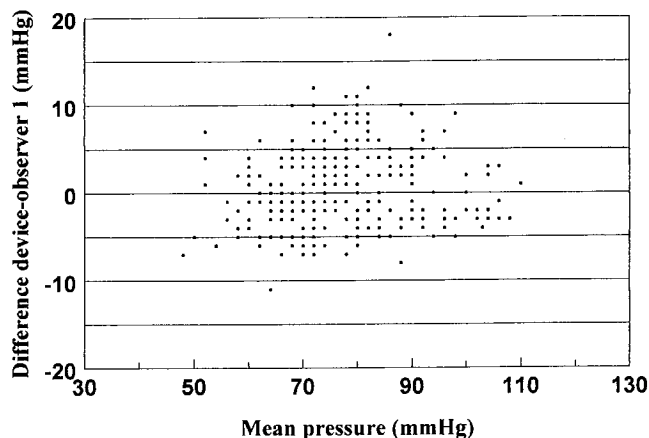
Grade	Difference between standard and test device (mmHg)		
	≤ 5	≤ 10	≤ 15
A	80	90	95
B	65	85	95
C	45	75	90
D	Worse than C	Worse than C	Worse than C

Fig. 1



Scatter plot of the differences between systolic blood pressures measured by TM-2430 device and by observer 2 versus level of mean 24 h systolic blood pressure.

Fig. 2



Scatter plot of the differences between diastolic blood pressures measured by TM-2430 device and by observer 1 versus level of mean 24 h diastolic blood pressure.

Main validation test

In total 595 blood pressure measurements were performed for the 98 subjects studied by the two observers. The device failed to provide a reading in seven instances, giving error codes E04 (low battery power), E08 (n = 4, arm motion), E21 (DBP < 40 mmHg), and E30 (measurement longer than 90 s). The analysis was therefore of the remaining 588 blood pressure readings.

The differences between blood pressures measured using the mercury sphygmomanometer standard and the TM-2430 device for the two observers with better results are shown in Figures 1 and 2. The mean differences between the TM-2430 device and each of the two observers are reported in Table 2. According to the percentage of measurements differing from the mercury sphygmomanometer standard by ≤ 5 , ≤ 10 , and

≤ 15 mmHg, the device was graded 'A' for SBP and DBP for both observers. Moreover, the TM-2430 device satisfied the Association for the Advancement of Medical Instrumentation (AAMI) recommendations (Table 2). TM-2430 device performed better for the group of subjects with high blood pressures than it did for those with intermediate and low blood pressures (Table 3), but it was satisfactory at all levels of blood pressure.

We found no relationship between the observer-device differences between blood pressures and subjects' sex, age, body mass index, and arm circumference. For the subjects divided into three groups (approximate tertiles) according to skinfold thickness (< 20 mm, 20-30 mm, and > 30 mm) we found no substantial difference in performance for SBP across the groups (Table 4). However, for DBP the TM-2430 device performed slightly better

Table 2 Results of main validation test for the A&D TM-2430 monitor (for the final grading the better results achieved with the two observers were reported)

	Grade	Difference between standard and test device (mmHg)			Value (mmHg)	Difference (mmHg)
		≤ 5	≤ 10	≤ 15		
Observer 1						
SBP	A	82	97	100	130.1 \pm 20.0	1.6 \pm 4.2
DBP	A	81	98	100	76.6 \pm 12.3	0.7 \pm 4.4
Observer 2						
SBP	A	84	97	100	130.7 \pm 19.8	2.2 \pm 3.9
DBP	A	80	97	100	76.4 \pm 12.0	0.5 \pm 4.5
Final grading						
SBP	A	84	97	100	130.7 \pm 19.8	2.2 \pm 3.9
DBP	A	81	98	100	76.6 \pm 12.3	0.7 \pm 4.4
Observer comparison						
SBP	A	94	99	100		-0.6 \pm 2.6
DBP	A	97	100	100		0.2 \pm 2.2

Values are expressed as means \pm SD. SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 3 Grading criteria according to the patients' blood pressure levels

Grade	Difference between standard and test device (mmHg)			n	Difference (mmHg)
	≤ 5	≤ 10	≤ 15		
Low blood pressure range (< 130/80 mmHg)					
SBP A	85	99	100	117	2.2 ± 3.6
DBP A	82	98	100	171	0.3 ± 4.1
Medium blood pressure range (130–160/80–100 mmHg)					
SBP A	81	95	100	129	2.2 ± 4.2
DBP B	71	97	99	87	2.6 ± 4.7
High blood pressure range (> 160/100 mmHg)					
SBP A	90	98	100	48	1.8 ± 3.8
DBP A	97	100	100	36	-1.6 ± 2.7

Values are expressed as means ± SD. SBP, systolic blood pressure; DBP, diastolic blood pressure.

for the group with low skinfold thickness, for which it achieved grade A, than it did for the other two groups, for which it achieved grade B. We encountered no technical problem during the validation tests.

Discussion

The A&D TM-2430 monitor performed with a good accuracy and precision according to the BHS protocol in the present study, insofar as it achieved grade A both for SBP and for DBP. The scores attained by the device according to the percentages of measurements differing versus those of the observers by ≤ 5, ≤ 10, and ≤ 15 mmHg were generally higher than those achieved by other devices tested with the same protocol [6,14–17], and by the older model of the TM series previously assessed in our laboratory [11]. Furthermore, the TM-2430 device also satisfied the AAMI accuracy criteria, namely the mean differences between blood pressure measured by device and by observers were well below the 5 mmHg threshold and the SD of the differences were below 8 mmHg both for SBP and for DBP [18].

In our comparisons we used simultaneous same-arm measurements, because the device is provided with a rate of deflation that allows one to use this approach [9]. In

the 1993 version of the BHS protocol the sequential same-arm measurements are suggested, for this method allows one also to evaluate recorders with fast deflation [9]. However, this comparison is less precise, and we felt that the simultaneous same-arm approach was more suitable for testing this device. The adoption of this method obviously implies the use of the 1990 grading criteria for the classification of the device.

Any monitor, even when it is fulfilling the recommendations of the official protocols, might have some advantages and disadvantages compared with others. It has been shown that the accuracy of a device for a given population need not be uniform across subgroups of subjects. The Accutracker (Suntech Medical Instruments, Inc., Raleigh, North Carolina, USA) and the SpaceLabs 90207 (SpaceLabs Inc., Redmond, Washington, USA) monitors, for instance, tended to underestimate blood pressure in elderly patients and in subjects with high blood pressures [19,20]. The SpaceLabs 90207 device was recently found to provide inaccurate measurements of DBP in children aged 6–18 years [21]. In the present study the TM-2430 device proved accurate across the whole range of age and blood pressure level, and its performance did not vary according to sex. However, a better performance was

Table 4 Grading criteria for the patients divided according to their biceps and triceps skinfold thicknesses

Grade	Difference between standard and test device (mmHg)			n	Differences (mmHg)
	≤ 5	≤ 10	≤ 15		
Low skinfold thickness range (< 20 mm)					
SBP A	84	98	100	99	2.3 ± 3.9
DBP A	88	100	100	99	0.7 ± 3.6
Medium skinfold thickness range (20–30 mm)					
SBP B	79	94	100	102	2.5 ± 4.2
DBP B	77	98	100	102	0.4 ± 4.7
High skinfold thickness range (> 30 mm)					
SBP A	88	100	100	93	1.6 ± 3.5
DBP B	77	96	99	93	1.2 ± 4.7

Values are expressed as means ± SD. SBP, systolic blood pressure; DBP, diastolic blood pressure.

observed for the patients with high blood pressure, especially for DBP. This might have been due to the low-intensity Korotkoff phase V sounds of some patients, a condition that can decrease the accuracy of the ambulatory blood pressure monitoring devices [11]. A deterioration in the performance of the TM-2420 model 7, which uses an auscultatory method, has been reported previously by our group to occur for women with large arms [11]. This was likely to have been due to the attenuation of the Korotkoff sounds by the thick layer of soft tissue present between the brachial artery and the microphone. We dealt with this issue in the present study by measuring biceps and triceps skinfold thicknesses of the study subjects and relating this measure to the differences between blood pressure measured by observers and by device. Even though the TM-2430 device satisfied the BHS recommendations across the whole range of skinfold thickness, the device achieved a better score for the subjects with lean arms irrespective of their sex. This suggests that the performance of a blood pressure monitoring device tends to be less good for obese persons, even when an oscillometric method is used.

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Appendix

In this appendix the basic information on the device is reported, according to the suggestions of the 1993 BHS protocol.

Device identification: TM-2430, A&D Company, Tokyo, Japan.

Costs: USA \$3000 for the recorder, and USA \$600 for the software program.

Compliance with standard: the device conforms to the European Directive 93/42 EEC for medical products, and the European standards for medical equipment EN60601-12-30, EN 55011, and 1060-1-3.

Validation studies: a validation study according to AAMI protocol is in progress.

Instructions for use, care and maintenance: these are reported in detail in the instruction manual.

Power supply: three 1.5 V alkaline batteries (type LR6 or type AA), or 1.2 V NiCd batteries (type AA).

Number of measurements: 200 measurements with alkaline batteries, 300 measurements with NiCd batteries.

Service facilities: for Japan, A&D Company, Limited, 3-23-14 Hgashi-Ikebukuro, Toshima-ku, Tokyo 170, Japan.

Tel: +81 53916132, Fax: +81 53916148. For USA, A&D Engineering, Inc., 1555 McCandless Drive, Milpitas, CA 95935, USA. Tel: +408 263 5333, Fax: +408 263 0119. For Italy, INTERMED Srl, Piazza C. Donegani, 1, 20133 Milano, Italy. Tel: +2 70632324, Fax: +2 70633770.

Dimensions: 72 mm × 100 mm × 28 mm (width, depth, and height). Weight, 215 g, with batteries included.

List of components: packing list, TM-2430 Recorder, adult cuff for left arm, cuff cover for adult cuff, activity record sheets, holder and belt, instruction manual. Cuffs for various arm sizes, from 15–22 cm up to 28–36 cm, are available.

Method of measurement: oscillometric.

Factors affecting accuracy: arrhythmias and noise due to arm movements can cause inaccurate measurements. The recorder should not be used on patients using a heart–lung machine, on critical patients, and in intensive care units.

Operator training requirements: the instrumentation does not require specific expertise because it is very easy to operate.

Computer analysis: data can be transferred from the device to a serial printer or to a personal computer. A software program for Windows to handle the data is available.