

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

Paolo Palatini<sup>a</sup>, Gianfranco Frigo<sup>a</sup>, Olivo Bertolo<sup>a</sup>, Elisabetta Roman<sup>a</sup>, Rita Da Cortà<sup>a</sup> and Mikolaj Winnicki<sup>b</sup>

**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  $\leq 5$ ,  $\leq 10$ , and  $\leq 15$  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  $2.2 \pm 3.9$  mmHg for systolic blood pressure and  $0.7 \pm 4.4$  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.

Blood Pressure Monitoring 1998, 3:255-260

**Keywords:** ambulatory monitoring, blood pressure, device, validation, BHS protocol

<sup>a</sup>Department of Clinical and Experimental Medicine, University of Padova, Italy and <sup>b</sup>Department of Hypertension and Diabetology, Medical University of Gdańsk, Poland.

Correspondence and requests for reprints to Professor Paolo Palatini, Dipartimento di Medicina Clinica e Sperimentale, Università di Padova, via Giustiniani, 2, 35126 Padova, Italy.  
Tel: +39 49 821 2278; fax: +39 49 875 4179;  
e-mail: palatini@ipdunidx.unipd.it

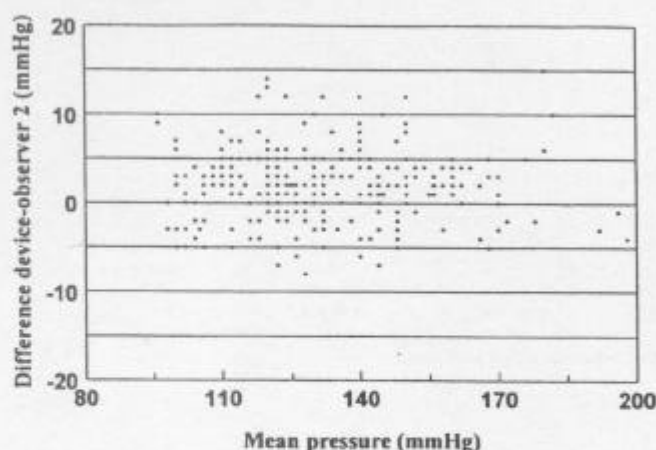
Received 20 March 1998 Revised 1 June 1998  
Accepted 2 June 1998

### 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.

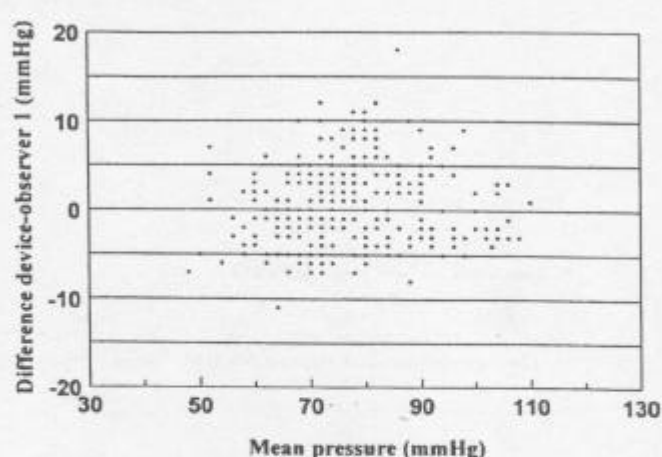
In recent years many manufacturers tried to improve the characteristics of the monitoring devices, by reducing their size and eliminating the noise related to the cuff's inflation, and by trying to improve the precision of measurement [6,7]. The A&D company (A&D Company Ltd, Tokyo, Japan) has recently 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

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  $\leq 5$ ,  $\leq 10$ , and

$\leq 15$  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)
		$\leq 5$	$\leq 10$	$\leq 15$		
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.

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.

### Acknowledgements

The devices used in this study were donated by INTERMED Srl, Milan, Italy, and were chosen at random from the production line.

### References

- American College of Physicians. Automated ambulatory blood pressure and self-measured blood pressure monitoring devices: their role in the diagnosis and management of hypertension. *Ann Intern Med* 1993; 118:889-892.
- Krakoff LR. Ambulatory blood pressure monitoring can improve cost-effective management of hypertension. *Am J Hypertens* 1993; 6 (suppl 6):220S-224S.
- Berardi L, Chau NP, Chanudet X, Vilar J, Larroque P. Ambulatory blood pressure monitoring: a critical review of the current methods to handle outliers. *J Hypertens* 1992; 10:1243-1248.
- Winnicki M, Canali C, Mornino P, Palatini P. Ambulatory blood pressure monitoring editing criteria: is a standardization needed? *Am J Hypertens* 1997; 10:419-427.
- Lee DR, Farmer AJ, Swift CG, Jackson SHD. Investigation of ambulatory blood pressure monitoring data editing criteria. *J Hum Hypertens* 1995; 9:195-198.
- O'Brien E, Atkins N, Staessen J. State of the market. A review of ambulatory blood pressure monitoring devices. *Hypertension* 1995; 26:835-842.
- White WB, Berson AS, Robbins C, Jamieson MJ, Prisant LM, Roccella E, et al. National standard for measurement of resting and ambulatory blood pressures with automated sphygmomanometers. *Hypertension* 1993; 21:504-509.
- O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, O'Malley K, et al. The British Hypertension Society protocol for the evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *J Hypertens* 1990; 8:607-619.
- O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, Altman DG, et al. The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; 11 (suppl 2):S43-S63.
- Edwards DA, Hammond DH, Healy MJ, Tanner JM, Whitehouse RH. Design and accuracy of calipers for measuring subcutaneous tissue thickness. *Br J Nutr* 1955; 9:133-143.
- Palatini P, Perzo M, Canali C, Pessina AC. Validation of the accuracy of the A&D TM-2420 model 7 for ambulatory blood pressure monitoring and effect of microphone replacement on its performance. *J Ambul Monitor* 1991; 4:281-288.
- Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinic measurement. *Lancet* 1986; i:307-310.
- Kennedy HL, Padgett NE, Horan MJ. Performance reliability of the Del Mar Avionics non-invasive ambulatory blood pressure instrument in clinical use. *Ambul Electrocardiol* 1979; 4:13-17.
- White WB. Assessment of ambulatory blood pressure recorders: accuracy and clinical performance. *Clin Invest Med* 1991; 14:202-211.
- O'Brien E, Mee F, Atkins N, O'Malley K. Accuracy of the Space Labs 90207 determined by the British Hypertension Society protocol. *J Hypertens* 1991; 9 (suppl 5):S25-S31.
- O'Brien E, Mee F, Atkins N, O'Malley K. Accuracy of the Novacor DIASYS 200 determined by the British Hypertension Society protocol. *J Hypertens* 1991; 9 (suppl 5):S9-S15.
- O'Brien E, Mee F, Atkins N, O'Malley K. Accuracy of the Del Mar Avionics Pressurometer IV determined by the British Hypertension Society protocol. *J Hypertens* 1991; 9 (suppl 5):S1-S7.
- Association for the Advancement of Medical Instrumentation. *American national standard for electronic or automated sphygmomanometers*. Arlington: AAMI; 1987.
- Appel LJ, Whelton PK, Seidler AJ, Patel AR, Klag MJ. The accuracy and precision of the Accutracker ambulatory blood pressure monitor. *Am J Epidemiol* 1990; 132:343-354.
- Iqbal P, Foltherby MD, Potter JF. Validation of the SpaceLabs 90207 automatic non-invasive blood pressure monitor in elderly subjects. *Blood Press Monit* 1996; 1:367-373.
- Belsha CW, Wells TG, Rice HB, Neaville WA, Berry PL. Accuracy of the SpaceLabs 90207 ambulatory blood pressure monitor in children and adolescents. *Blood Press Monit* 1996; 1:127-133.

### 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.