Accuracy of the Takeda TM-2420/TM-2020 determined by the British Hypertension Society Protocol

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Objective: To evaluate the Takeda TM-2420/TM-2020 Ambulatory Blood Pressure System according to the protocol of the British Hypertension Society (BHS).

Methods: Three Takeda TM-2420 recorders were evaluated according to the BHS protocol which consists of six phases: (1) observer training and assessment; (2) before-use interdevice variability assessment; (3) in-use (field) assessment; (4) after-use interdevice variability assessment; (5) device validation; and (6) report of evaluation.

Results: The three recorders passed the before-use interdevice variability assessment, after which 85% of inflations recorded with these devices during the in-use phase gave valid readings, and the three devices subsequently passed the after-use interdevice variability assessment. The main validation test was carried out in 86 subjects with a wide range of pressures, the results being analysed according to a grading system from A to D. The first Takeda TM-2420 achieved D rating for both systolic and diastolic pressures. The first Takeda used in the main validation test failed to function after testing in 36 subjects and had to be replaced. The Takeda TM-2420 failed to satisfy the criteria for accuracy of the Association for the Advancement of Medical Instrumentation (AAMI), with an average difference (± s.d.) of -4 ± 11 and -2 ± 11 mmHg for systolic and diastolic pressure, respectively. Subject acceptability was good. The manufacturer's manual was clear and reasonably comprehensive.

Conclusions: The Takeda TM-2420 ambulatory monitor achieved D rating for systolic and diastolic pressures according to the criteria of the BHS protocol and failed to satisfy the AAMI criteria for both systolic and diastolic pressure. It also performed badly during the validation test and on the basis of these results cannot be recommended for ambulatory measurement in clinical practice.

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Introduction

Ambulatory blood pressure measurement is rapidly gaining acceptance as a useful procedure in the clinical management of hypertension [1,2], in the assessment of antihypertensive drugs [3] and as a means of predicting outcome in hypertension [4]. The procedure also gives data on the physiology of blood pressure behaviour [5]. Ambulatory blood pressure provides an assessment of blood pressure behaviour over time in the patient's environment and is likely to result in reappraisal of the clinical management of hypertension which is presently based upon conventional measurement techniques [6]. It is not surprising, therefore, that many devices are being marketed for the measurement of 24-h blood pressure. Most are technically complex and expensive. In an effort to ensure that such devices are manufactured to meet the requirements of clinical practice, the British Hypertension Society (BHS) recently published a comprehensive protocol for the evaluation of blood pressure measuring de-

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vices, with special reference to ambulatory systems [7]. This protocol incorporates many of the previously established validation criteria of the Association for the Advancement of Medical Instrumentation (AAMI) [8], but includes additional aspects of validation such as evaluation after ambulatory use and the accuracy requirements are graded rather than absolute, as in the AAMI Standard. The BHS protocol is used in this study to evaluate the Takeda TM-2420/TM-2020 ambulatory blood pressure system.

Methods

Takeda TM-2420/TM-2020 system

The Takeda TM-2420/2020 system consists of the TM-2420 Recorder and the TM-2020 Processor. The TM-2420 Monitor is a small (6.5× 14.2× 4.2 cm) unit weighing 390 g (including built-in rechargeable battery) with pouch and strap, designed to take up to 614 blood pressure measurements (range, systolic 60–280 mmHg; diastolic, 40–160 mmHg) and heart rate measurements (range, 40–200 beats/min). These measurements are recorded and stored in the monitor from which they may be printed directly using the TM-2020. The recorder is carried in a pouch which may be worn on a waist-belt, a shoulder strap or a vest. Blood pressure and heart rate measurements are taken by Korotkoff sound detection, with a cuff containing an occluding bladder and a microphone placed over the brachial artery. For accurate reading, it is recommended that a second microphone is taken out of the cuff and placed over the brachial artery. The Takeda TM-2420 can measure pressure at a number of preselected time intervals in the recording period, from 1 to 60 min, to a total of 614 recordings. The recorder may be programmed as to the duration of the monitoring period, subject information to be incorporated in the analysis, the time format, the measurement interval, the presence or absence of the audible monitor tone during specified periods of the recording period (e.g. sleep), event code display and whether or not to display readings on the digital display for reading by the subject. The Takeda system can be interfaced with other computer systems.

Evaluation programme

The evaluation programme [7] consisted of six phases: (1) observer training and assessment; (2) before-use interdevice variability assessment; (3) in-use (field) assessment; (4) after-use interdevice variability asesssment; (5) device validation; and (6) report of evaluation.

Observer training and assessment

Three nurses were trained and assessed according to the criteria of the BHS protocol [7] using the British Hypertension Society video film 'Blood Pressure Measurement' [9]. After training, the observers were tested for accuracy against each other and the expert observer on five subjects in each of whom 10 blood pressure measurements were made. Criteria for this assessment are that 90% of systolic and diastolic differences between the trainees and expert must not differ by more than 5 mmHg and 98% by not more than 10 mmHg, and that 85% of systolic and diastolic differences between each trainee should not differ by more than 5 mmHg and 95% by not more than 10 mmHg. After successfully passing the training assessment, the observers were instructed in the use of the devices to be tested and practice measurements were made on a number of subjects.

Calibration accuracy was checked according to the manufacturer's instructions before any testing began by connecting the Takeda TM-2420 to a mercury column and checking that pressures throughout the pressure range were within ± 4 mmHg.

Before-use interdevice variability assessment

This test differed from that recommended in the published BHS protocol [7] which had not been finalized at the time of the study. It was originally planned that the interdevice variability test used in this study would be incorporated in the protocol, but experience in performing the test demonstrated its impracticality for general use and the final protocol included a simpler calibration test. Three Takeda TM-2420 monitors were assessed in six subjects, with blood pressure in the range 76–168/44–124 mmHg, by one observer who measured blood pressure simultaneously in the same arm with the test device and a mercury sphygmomanometer connected by a special connector provided with the system. Six pairs of blood pressure measurements were made in each of the six subjects in a randomized sequence to give 12 pairs of measurements per device and 36 pairs overall. During this phase, it became apparent that simultaneous measurement between a mercury sphygmomanometer and the Takeda TM-2020 was not an appropriate test because when the monitor sensed that it was close to the blood pressure, cuff deflation slowed, thereby alerting an observer using a simultaneous mercury sphygmomanometer that a pressure reading was about to be recorded with the attendant potential for bias. Furthermore, after recording diastolic pressure, the Takeda TM-2020 deflated rapidly without affording an auscultatory observer the opportunity of accurately recording the diastolic pressure.

Therefore, sequential same-arm testing was used in all further evaluation phases [7,10].

In-use assessment

The three Takeda TM-2420 monitors used for the interdevice assessment were next used to test performance during and after 24-h ambulatory monitoring in 24 subjects over a 4-week period to provide at least 600 recordings per device. The protocol requires that at least 85% of the possible 75 measurements for the 24-h period should be valid on 18 of the 24 recording days, and that on 4 of the remaining 6 recording days, at least 70% of readings should be valid, thus allowing for 2 failed recording days.

After-use interdevice variability assessment

At the end of the month of ambulatory assessment, the three monitors were retested for interdevice variability to determine whether there had been any change in interdevice agreement during ambulatory use. The test was similar to the before-use test except that sequential same-arm comparisons were used. The range of blood pressure in the 10 subjects was 80–180/40–120 mmHg.

Device validation

As there was no alteration of interdevice variability after the month of use, one device was randomly selected for the main validation test. Eighty six subjects aged from 15 to 80 years were selected, with blood pressures in the range recommended by the BHS protocol [7]. Simultaneous measurement of blood pressure by a mercury sphygmomanometer and the device being evaluated is recommended as the validation test of choice in the BHS protocol. However, this was not practicable with the Takeda TM-2420 as explained above and sequential same-arm measurements with the Takeda TM-2420 and a standard mercury sphygmomanometer were, therefore, performed as recommended in the protocol [7]. The test measurement is bracketed by two readings with the standard mercury sphygmomanometers, the difference being calculated as follows: if the test device pressure lies between the first and third pressure the difference is taken as 0, otherwise the nearer of the two readings is subtracted to give the difference [10]. The procedure was performed in 43 subjects by observer one and in the other 43 subjects by observer two. The Takeda TM-2420 failed to function after testing in 36 subjects and had to be replaced by one of the other devices for the remainder of the validation test. A total of 258 (3 × 86) sets of measurements were available for analysis.

Results

Evaluation programme

Observer training and assessment

All three trainee observers passed the accuracy criteria.

Before-use and after-use interdevice variability assessment

Analysis of variance did not demonstrate any change in interdevice variability between the three devices before and after the in-use phase.

In-use assessment

Eight-five per cent of 24-h measurements recorded with the three devices were valid on 23 of the 24 recording days, and on the remaining day more than 70% of measurements were valid, thus fulfilling the protocol requirement. The Takeda TM-2420 provided an average of 78 measurements on each of the 24 recording days. Excess measurements were mostly due to the device being operative for a little longer than 24 h and to the occasional patient-activated additional measurement. The average ratio of day : night measurements was 3.1 : 1. An analysis of performance during the in-use phase is shown in Table 1.

Patient/subject acceptability

Each subject was asked to comment on the performance of the device and these comments are summarized in Table 2.

Device validation

The percentage of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are

Table 1. In-use assessment.

	24 h							Day		Night	
	Inflations	Valid	Rejected	Aborted	Second attempt	Valid second attempt	Day : night ratio	Inflations	Valid	Inflations	Valid
Goal:											
n	1800	1800	0	0	0	–	3:1	1350	1350	450	450
%	100	100	0	0	0	100	–	100	100	100	100
TM-2420:											
n	2204	1880	107	217	259	187	3.1:1	1670	1450	534	430
%	122	85	5	10	12	72	–	124	87	119	81

Figures are for 24 recording days in 24 subjects.

shown in Table 3 and plotted in Figs 1 and 2; the Takeda TM-2420 was graded as A, B, C or D according to the criteria in Table 3. To obtain a particular grade, all three cumulative percentages had to exceed the tabulated values. The Takeda TM-2420 achieved a D grading for both systolic and diastolic pressure according to the BHS criteria [7]. It failed to satisfy the AAMI criteria of a mean difference of 5 mmHg with a standard deviation of 8 mmHg [8] (mean differences, -4 ± 11 mmHg systolic and -2 ± 11 mmHg diastolic pressure).

Table 2. Summary of comments from 24 patients.

Specific problems:	**Cuff uncomfortable**/tubing too short
General impression:	Fifteen commented favourable/easy to wear
Comfort/discomfort:	Seven commented on cuff discomfort
Interference of sleep:	Three commented on disturbed sleep
Noise:	No complaints about noise disturbance
Anxiety:	No comments
Difficulty in use:	No comments
Clarify of instructions:	**No unfavourable** comments
Suggestions:	Two subjects found measurements every 15 min too frequent

Table 3. British Hypertension Society grading criteria.

		Difference between standard and test device (mmHg)		
	Grade	≤5	≤10	≤15
Grading criteria:	A	80	90	95
Cumulative %	B	65	85	95
of readings	C	45	75	90
	D		Worse than C	
Takeda TM-2420:				
SBP	D	59	78	88
DBP	D	62	78	85

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

Calibration accuracy of the Takeda TM-2420 after undergoing the above programme of testing remained within ± 4 mmHg.

Graphic presentation

The data is displayed as plots of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the Takeda TM-2420 and the nearer of these observer measurements in 86 subjects (n = 258) for systolic and diastolic pressure (Figs 1 and 2). Reference lines indicate − 15 to + mmHg in 5 mmHg steps.

Basic information

In accordance with Appendix B of the BHS Protocol [7], the following aspects of the Takeda system were assessed:

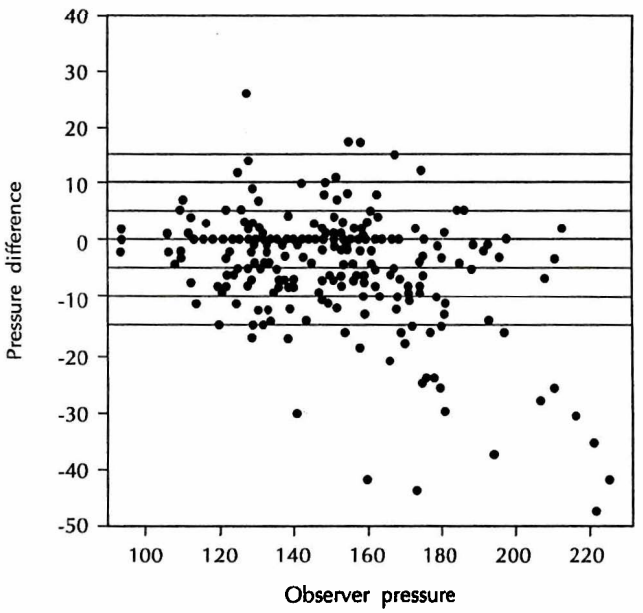

Fig. 1. Plot of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the Takeda TM-2420 and the nearer of observer measurements in 86 subjects (n = 258) for systolic pressure. References lines: − 15 to +15 mmHg in 5 mmHg steps.

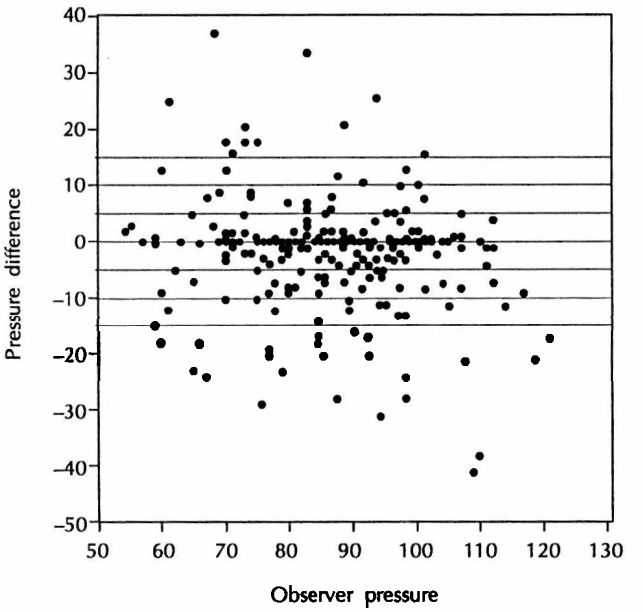

Fig. 2. Plot of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the Takeda TM-2420 and the nearer of observer measurements in 86 subjects (n = 258) for diastolic pressure. Reference lines: − 15 to + 15 mmHg steps.

Model identification

The model was clearly identified as the TM-2420 although no indication was given as to how this differed from the earlier series.

Costs

The cost of the recorder, the decoder, computer analysis facilities, components and the consumables needed for device operation have been provided by

Takeda (prices are in £ sterling, exclusive of VAT, in 1991):

Takeda TM-2420 ABP Recorder	1643
Takeda TM-2020 Decoder/Printer	890

(Prices of accessories not provided.)

Compliance with standard(s)
The system complies with the limits of a Class A computing device pursuant to Subpart J of Part 15 of Federal Communications Commission (FCC) in the USA. Compliance with other safety and accuracy standards are not provided.

Validation studies and results:
Three validation studies [11–13] and one abstract [14] have been published on the Takeda TM-2420.

Instruction for use
The instruction manual provided with the Takeda TM-2420 is clear, concise and easy to follow. Step by step instruction is given. Instruction for using the software was inadequate.

Patient instruction card
A diary/instruction card is provided for distribution to patients giving somewhat complicated operational instructions. Precautions to be taken in the event of the device malfunctioning are not provided.

Precautions for use
The BHS protocol requires that the operator must be alerted as to any weaknesses in the system which might affect performance or patient safety and that the safety precautions incorporated in the system to prevent the cuff remaining inflated be clearly stated. The manual lists a number of general safety precautions such as ensuring that there are no inflammable substances in the area, but does not state the rationale behind these precautions.

Power supply
The manual supplies adequate detail on the power requirements. The recorder is powered by rechargeable batteries which take, at most, 90 min to recharge. Error codes alert the operator to inadequate power and the recorder ceases functioning until it is recharged.

Instructions for care and maintenance
The manual gives the operator clear instructions on the day-to-day care of the equipment and the need for regular maintenance. Product warranty information is provided in the manual and states that a warranty applies for 1 year from the date of purchase.

Service facilities
The BHS protocol recommends that the location of national and international service facilities should be listed and that an estimate of the cost of routine servicing out of warranty, together with an estimate of the costs of transporting the equipment for such servicing, should be given. The Takeda manual lists the telephone numbers for service and maintenance facilities in the United States and Japan, but not elsewhere. Details of service costs and maintenance contracts are not given.

Dimensions
The dimensions and weight of all components and the means of attachment etc., are provided (see Methods).

List of components
The major components of the system are listed in the manual. The dimensions of the bladders available are: large, 14.3× 30 cm; adult, 12× 22 cm; each available with 85 and 120 cm air/mike cords. One adult cuff is supplied with each recorder. Neither of these bladder sizes comply with the British Hypertension Society recommendation that a bladder with the dimensions 35× 12 cm be used for most adult arms [15].

Method(s) of blood pressure measurement
The Takeda TM-2420 measures blood pressure with a microphone, using the Korotkoff sound detection method. There is no electrocardiographic gating or synchronization. However, a second microphone is used to obtain more accurate readings than with one microphone. The mechanism of action of this system is not given.

Artefact editing
The Takeda TM-2420 has in-built editing criteria which cannot be altered manually; these are: diastolic pressure > 160 mmHg; systolic pressure < 60 mmHg; difference between systolic and diastolic pressure < 10 mmHg or > 150 mmHg.

Facility for checking device accuracy and recalibration
No instructions are provided for checking the accuracy of the recorder. The manual does not make recommendations as to how the operator should proceed in the event of the calibration test showing inaccuracy.

Factors affecting accuracy
The BHS protocol recommends that circumstances which might affect accurate performance should be listed — this is not done in the manual.

Operator training requirements
The Takeda system is easy to operate and the instruction manual takes the operator through the operative procedure step by step.

Computer analysis
The TM-2020 processor may be used on its own to process and print data collected using the TM-2420 Recorder. An optional RS-232C interface can be used to output measurement to 'select computers', but the requirements of these computers are not provided. Instructions for using the software facilities were considered inadequate. Obtaining a printed re-

port was slow because all the graphics had to be printed.

Problem list and solutions

A list of common operational problems and their solutions was not provided in the manual.

Supplier names and addresses

The following are names, addresses and telephone numbers of Japan, USA and EC suppliers: Mr Toru Saitoh, Manager, International Division, Mr T. Yamaguchi, Assistant Manager, Mr Manabu Terao, International Division, A & D Company Ltd, Shintaiso Building, No. 5-1052, 10-7 Dogenzaka 2-Chome, Shibuya-ku, Tokyo 150, Japan. Tel: 81-3-4764741; Fax: 81-3-4621903.

A & D Engineering Inc., 1555 McCandless Drive, Milpitas, California 95035, USA. Tel: 1-408-2635333; Fax: 1-408-2630119.

Electramed Ireland Ltd, 9 Mornington Park, Malahide Road, Artane, Dublin 5, Ireland. Tel: 353-1-318222; Fax: 353-1-318579.

Discussion

In this study, the Takeda TM-2420/TM-2020 ambulatory blood pressure measuring system was evaluated according to the BHS protocol [7]. This protocol contains many of the recommendations of the earlier AAMI Standard, [8] but has a number of additional features. These include strict criteria for observer training and assessment before the evaluation procedure begins, an assessment of interdevice variability before and after a period in use and an assessment of the product information and the instructions for operation provided by the manufacturer.

In addition, the BHS protocol takes a new approach to the methods of assessing device accuracy. Whereas the AAMI criteria for acceptable inaccuracy allows a mean difference of 5 mmHg with a standard deviation of 8 mmHg, the BHS protocol regards this as too liberal and recommends instead a system of grading that ranges from Grade A, representing the accuracy achieved with trained observers using a mercury sphygmomanometer, to Grade D.

The Takeda failed to fulfil the AAMI criteria [8] and achieved a Grade D rating for both systolic and diastolic pressures, with just 60% of systolic and diastolic pressures being within 5 mmHg of the mercury sphygmomanometer and 78% within 10 mmHg.

In a validation of the Takeda TM-2420 by the manufacturers [11], the device gave better results than in this study but comparison between the Takeda and a mercury sphygmomanometer was performed simultaneously. We were unable to perform simultaneous measurement for two reasons. First, the deflation mechanism of the Takeda tends to slow down as it senses pressure, thus leading to the potential for bias in the observer recording with the mercury sphygmomanometer and second, the device deflates promptly after recording diastolic pressure, leaving the mercury observer no time to complete auscultation. We overcame this problem by using sequential measurement, as recommended in the BHS protocol [7,10]. In another validation study, in a small number of subjects the Takeda TM-2420 was shown to underestimate systolic pressure [12]. As has been pointed out by De Gaudemaris [13], an apparently closely corresponding agreement may be obtained, especially for diastolic measurement, when simultaneous comparison is used, simply because the observer on a mercury sphygmomanometer cannot complete auscultation and must accept the device reading. In a recent evaluation of the Takeda TM-2420, two of four devices tested developed faults that precluded further testing and only one of the remaining devices met the criteria for accuracy of the AAMI standard [14].

To overcome the problem of devices losing accuracy under the stress of everyday use, the BHS protocol stipulates that validation should take place only after the device has had a reasonable period of use and this validation was performed after the Takeda TM-2420 had been subjected to a month of ambulatory use. The first Takeda used in the main validation test failed to function after testing in 36 subjects and had to be replaced. This must be seen as a serious occurrence which would normally result in the validation procedure being abandoned.

The period of ambulatory use also permits some expression by the user as to device acceptability. For example, as a result of the comments made in this study we can ask the manufacturers to improve the quality of cloth in the cuff to minimize discomfort during inflation. Furthermore, as operators, we can recommend to the manufacturers that an extra cuff should be provided with each bladder to facilitate washing of the cuff and that the Takeda TM-2420 should be provided with all the available bladder sizes.

The data from the in-use assessment was helpful in arriving at an estimate of the unnecessary disturbance to the subject by repeated inflations. For example, on each recording day, an average of 13.5 attempted measurements were rejected or aborted by the Takeda recorder and a repeat measurement was attempted in 11, resulting in eight valid readings. The perfect device should provide a valid measurement for each inflation. The Takeda had to perform approximately 17 excess inflations in order to achieve the required 75 readings over the 24-h period. Manufacturers should attempt to reduce the number of repeat inflations so as to keep distur-

bance to the patient at a minimum and thus minimize interference with daily activities.

A critical analysis of the manual accompanying ambulatory systems is one of the BHS stipulations. The Takeda manual was generally found to be comprehensive, clearly written and well presented. However, there were some omissions. No addresses for suppliers and service centres in the UK are given, costings are not provided and the rate of deflation of the system is not stated.

Similarly, the BHS protocol requires a statement on the computer aspects of the system. The manual does not provide any details as to the compatability of the Takeda system with other computers. This information is essential so that a would-be purchaser can determine, in advance of purchasing, whether it will be possible to utilize, for example, the graphics facility of the system.

Although this protocol provides an assessment of performance during ambulatory use, it needs to be emphasized that blood pressure measurements are usually made with the subject at rest and an ambulatory device that meets the criteria of this protocol cannot be assumed to be accurate during physiological manoeuvres such as exercise, isometric handgrip, Valsalva manoeuvre, etc. Moreover, the protocol does not test the device in the variety of positions in which ambulatory measurement may be made.

In conclusion, the Takeda TM-2420/TM-2020 ambulatory monitor achieved D rating for both systolic and diastolic pressure according to the criteria of the BHS protocol and did not fulfil the AAMI criteria for both systolic and diastolic pressures. Moreover, it failed to satisfy the in-use criteria of the protocol. It cannot, therefore, be recommended for ambulatory measurement.

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