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Subject: Holter walk200b, BHS Certification

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DECLARES

The instrument Cardioline Walk 200b is equivalent to the instrument IEM MOBIL-0-Graph NG, of which I enclose the BHS certification.

Fabio Rangoni

President

Validation of the mobil-O-Graph: 24 h-blood pressure measurement device

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Objective **Twenty-four-hour blood pressure measurement is of importance not only in the detection of hypertension but also in the detection of blood pressure changes in hypertensive and nonhypertensives over the day to identify, for example, nondipper hypertensives. This study describes the validation of the mobil-O-Graph according to the criteria of the British Hypertension Society (BHS).**

Methods **For each patient three readings obtained by the mobil-O-Graph were compared with auscultatory sphygmomanometric readings obtained by two trained clinicians. The sphygmomanometric reference measurements were alternated with the readings obtained by the device. Eighty-five patients (mean age 53.4 ± 18.4 years) were recruited for the BHS protocol. Differences between blood pressure values of the test device and the mercury reading were calculated for each measurement.**

Results **In the BHS validation procedure the mean differences of the observer readings and the test device were − 2.2 ± 6.7 (systolic) and − 0.6 ± 5.6 mmHg (diastolic) for observer 1 and − 2.2 ± 7.3 mmHg (systolic) and − 0.4 ± 6.1 mmHg (diastolic) for observer 2. The device achieved grade A for systolic and diastolic blood pressure for both the observers 1 and 2 leading to a final grade A/A. According to the BHS protocol the measurements of the device have to be considered 'very accurate and with no error of clinical relevance'.**

Conclusion **The device met the accuracy requirements of the BHS standard and can be recommended for clinical use.** ***Blood Press Monit*** **00:000–000 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Keywords: ambulatory blood pressure measurement, British Hypertension Society protocol, 24 h-blood pressure, validation

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Introduction

There is an increasing number of blood pressure measurement devices to measure blood pressure over 24 h. Twenty-four-hour ambulatory blood pressure measurement (ABPM) is of importance not only in the detection of hypertension but also in the detection of blood pressure changes in hypertensives and nonhypertensives over the day to identify, for example, nondipper hypertensives. The use of these devices is recommended by hypertension guidelines [1]. Many devices have not been validated by a recognized protocol yet. This is of great importance to give doctors and patients the security that all measurements are properly performed. Owing to the large number of devices in the market, the competition of the manufacturers in the market is high. With regard to the competition in pricing of the devices might be positive for the consumer, but quality of measurements should be confirmed by validation according to British, European, or US protocols [2–4]. Validation against these protocols examines the degree of agreement between clinical readings from the automated monitor and those on a mercury sphygmomanometer, still widely accepted as the gold standard for noninvasive BP measurements.

The mobil-O-Graph (I.E.M. GmbH, Stolberg, Germany) is a new automated self-measurement 24 h-blood pressure monitoring device. The range of measurement is 70–260 mmHg for systolic blood pressure, 45–180 mmHg for diastolic blood pressure, and 40–240/min for heart rate. Data obtained by the recorder can be easily transferred to a computer-based central data base by use of a Bluetooth interface. The central data base is a hypertension management software. Data can be stored and compared with other measurements of the patient. Therefore it is possible to observe the development of blood pressure over time and also the efficiency of therapy can be controlled and presented to the patient. In addition, the device has the possibility to measure central blood pressure and augmentation index by an integrated pulse wave analysis device. It is very well documented in the recent past that central blood pressure measurement or augmentation index measurement might give additional information to patients' individual cardiovascular risk [5,6]. This feature is not validated in this protocol. To date, the device has not been tested for measurement of blood pressure accuracy. In this study, the mobil-O-Graph is validated according to the criteria of the British Hypertension Society (BHS) [2,3,7].

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Methods

The first part of the validation procedure corresponded to the BHS protocol [2,7]. Five hundred and ten measurements were performed in 85 nonpreselected patients. Informed consent was obtained from all the probands. Cardiac arrhythmia (atrial fibrillation, frequent extrasystoles) was an exclusion criterion. All the measurements were performed by physicians, registered nurses, or pharmacists. Before initiation of the study, all the members of the team were trained according to the tutorial of the BHS website. Furthermore, agreement of readings of observers and experts was shown to assure validity of measurement results. The manufacturer was asked to loan three devices with three differently sized cuffs (small, medium, large). A new mercury sphygmomanometer (Erkameter 3000, Erka Kallmeyer Medizintechnik, Bad Tölz, Germany) was used as reference device. Arm circumferences were measured and recorded to allow correct choice of cuff size. The measurements took place in a quiet room with an ambient temperature of 20–22°C. Patients had to rest seated for at least 5 min before the measurement procedure was initiated. The two observers were blinded to each other. Mercury readings were taken by a mercury column and a two-person stethoscope with a Y-connector. To avoid venous congestion and to minimize variability in blood pressure, the time between measurements was determined to be 30–60 s. All the measurements were performed at the same arm of the patient. Readings were noted and differences between device and observers were determined.

Validation procedure according to British Hypertension Society protocol

Each of the three devices underwent dynamic calibration using three observers who were blinded from each other. The test device and two sphygmomanometers were connected to one cuff, which was placed around a rigid cylinder. The first observer inflates the cuff to a pressure of 250 mmHg and called out at five random points suggested by the BHS protocol. The second observer notes the mercury reading at each of the calls and the third observer records the reading on the device. This procedure was repeated six times, leading to a final number of 30 readings. Twenty-eight of 30 readings must have a difference of ≤ 3 mmHg for the device to pass this phase. In phase 2, the devices are used in a clinical environment (in-use field assessment). As required by the BHS protocol at least 400 measurements were performed. After the validation period, all the devices were calibrated again to exclude any changes in calibration in the course of the procedure (phase 3).

Phase 4 (static device validation) measurements were started by a single mercury reading to assign the patient to one of the predefined pressure categories of the BHS protocol. Table 1 presents the number of patients in each category. Subsequently, two experienced observers conducted seven sequential blood pressure measurements alternating between mercury sphygmomanometry and the test device (four times mercury, three times device). Readings were noted and differences between device and observers were determined by calculating the differences of the test device's reading and the two mercury readings before and after the device's measurement for each observer. The lower set of values of differences (previous or subsequent mercury readings) was used for further analysis (device–observer differences). Thus, each observer produced three sets of values for each patient. The percentages of device readings within differences of 5, 10, and 15 mmHg in comparison with the mercury readings were used to grade the device according to the protocol. The BHS grading criteria are presented in Table 2. According to the protocol, devices with grades A for both systolic and diastolic blood pressure are regarded accurate.

Table 1 Number of patients required and number of patients examined in each blood pressure group of the BHS protocol

Systolic BP (mmHg)	Diastolic BP (mmHg)	Number of patients required	Number of patients examined (systolic)	Number of patients examined (diastolic)
<100	<60	8	8	8
100–129	60–79	20	23	20
130–160	80–100	20	24	29
161–180	101–110	20	20	20
>180	>110	8	10	8

BHS, British Hypertension Society; BP, blood pressure.

Table 2 Grading criteria of the BHS

	Percentage of readings with differences between standard and test device of		
Grade	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
A (%)	60	85	95
B (%)	50	75	90
C (%)	40	65	85
D	Worse than C	Worse than C	Worse than C

To obtain a grade, the device must achieve percentages ≥ those reported in the table in all the three categories.
BHS, British Hypertension Society.

BPa mercury (entry value used to categorize patients)

BPb device (to check the automated device, not included in the analysis)

BP1 mercury (observers 1 and 2)

BP2 device (supervisor with test device)

BP3 mercury (observers 1 and 2)

BP4 device (supervisor with test device)

BP5 mercury (observers 1 and 2)

BP6 device (supervisor with test device)

BP7 mercury (observers 1 and 2)

Patients were divided into three BP categories on the basis of measurement BPa. Measurement BPb was conducted to familiarize patients with the device being tested. Results were discarded. Measurements, BP1–BP7, were recorded and used for analysis of the test device's accuracy.

The BHS protocol used Bland–Altman analysis to compare the test device with the reference device. The mean of each pair of observer measurements was calculated for the reference device (BP1, BP3, BP5, BP7). Each device measurement (BP2, BP4, BP6) was flanked by two of the observer measurements, one of which was selected as the comparative measurement as described above. According to Bland–Altman the device–observer differences are plotted against the corresponding mean of observer readings.

Results

The device passed phases 1–3 of the BHS protocol. Prior to use in clinical environment (phase 2) all the devices passed calibration successfully. In phase 4, static device validation was conducted in 85 patients (39 male, 46 female; mean age 53.4 ± 18.4 years). Mean arm circumference was 31.4 ± 6.2 cm.

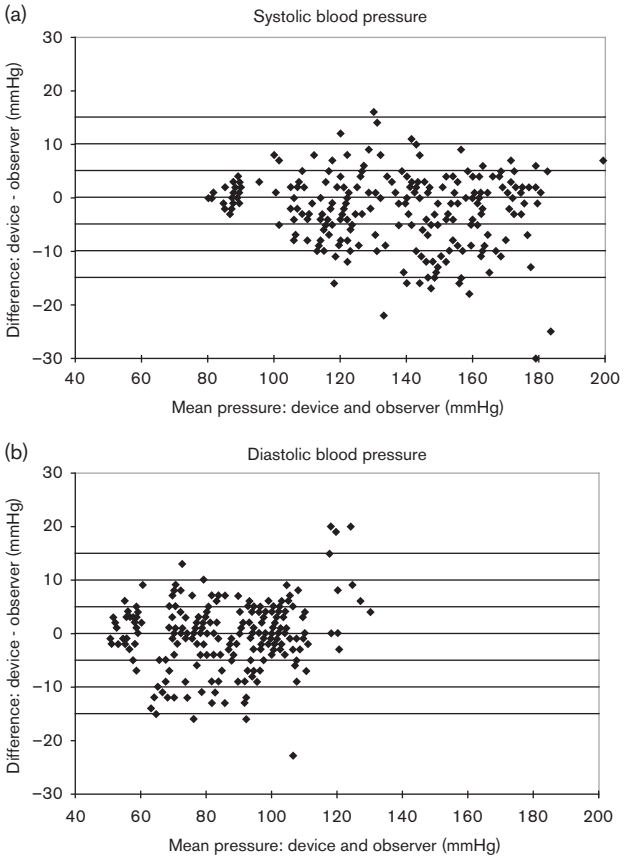
Table 3 presents the results of the validation procedure including assignment to the predefined grades of the BHS protocol. First observer's readings led to a mean systolic blood pressure of 140 ± 31 mmHg and a mean diastolic blood pressure of 87 ± 18 mmHg. Second observer's values had a systolic mean of 140 ± 31 mmHg and a diastolic mean of 87 ± 17 mmHg. The device–observer differences were −2.2 ± 6.7 (systolic) and −0.6 ± 5.6 mmHg (diastolic) for observer 1 and −2.2 ± 7.3 mmHg (systolic) and −0.4 ± 6.1 mmHg (diastolic) for observer 2. Observer 1 was the 'better observer'. Figure 1 presents Bland–Altmann plots of the differences of observer 1 and the device. The device achieved grade A for systolic and diastolic blood pressure for both observers 1 and 2 leading to a final grade A/A.

Discussion

The Mobil-O-Graph automated 24-h blood pressure monitor proved a high validity in the present BHS validation procedure. The device achieved the highest possible grade A for both systolic and diastolic blood pressure.

ABPM makes it possible to record blood pressure throughout the day while patients engage in their routine activities. Owing to the large number of measurements during day and night and the absence of digit preference and observer bias, ABPM provides several advantages

Fig. 1



Bland–Altmann plots (British Hypertension Society validation process) of systolic (a) and diastolic (b) blood pressure difference of device and observer in 85 patients (n = 255 measurements). Mean difference for systolic blood pressure is −2.2 ± 7.3 mmHg, mean difference for diastolic blood pressure is −0.4 ± 6.1 mmHg.

Table 3 Results of the BHS validation procedure, n = 85 patients

	Grade	≤ 5 (%)	≤ 10 (%)	≤ 15 (%)	≤ 30 (%)	Mean ± SD (mmHg)	Mean ± SD of differences (mmHg)
Observer 1							
SBP	A	66	88	96	100	140 ± 31	−2.2 ± 6.7
DBP	A	77	93	98	100	87 ± 18	−0.6 ± 5.6
Observer 2							
SBP	A	65	85	95	100	140 ± 31	−2.2 ± 7.3
DBP	A	72	91	97	100	87 ± 17	−0.4 ± 6.1
Final grading							
SBP	A	65	85	95	100	140 ± 31	−2.2 ± 7.3
DBP	A	72	91	97	100	87 ± 17	−0.4 ± 6.1

BHS, British Hypertension Society; DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation.

compared with office measurements: detection of white-coat hypertension, better screening for secondary hypertension, precise assessment of the individual cardiovascular risk by description of the circadian blood pressure variability, better evaluation of antihypertensive therapy. Especially the detection of masked hypertension might be relevant for future therapy.

There is a broad variety of commercially available automated blood pressure monitors in the market. The number of devices with validation according to a recognized protocol, however, is still low. The mobil-O-Graph has passed BHS with the highest degree of accuracy Thus, the Stabil-O-Graph can be recommended for clinical use.

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