

# Validation of the Omron HEM-7320-LA, upper arm blood pressure monitor with Intelli Wrap Technology Cuff HEM-FL1 for self-measurement and clinic use according to the European Society of Hypertension International Protocol revision 2010 in the Mexican population

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**Objective** The aim of this study was to determine the accuracy of the Omron HEM-7320-LA with Intelli Wrap technology cuff HEM-FL1 for self-measurement and clinic blood pressure (BP) measurement according to the European Society of Hypertension International Protocol revision 2010.

**Participants and methods** The evaluation was performed in 39 individuals. The mean age of the participants was  $47.9 \pm 14$  years; systolic BP was  $145.2 \pm 24.3$  mmHg (range: 97–190), diastolic BP was  $90.9 \pm 12.9$  mmHg (range: 68–120), and arm circumference was  $30.8 \pm 4$  cm (range: 25–38.5).

**Results** The device successfully fulfilled the established criteria of the validation protocol. The device overestimated systolic BP by  $0.6 \pm 5.7$  mmHg and diastolic BP by  $2.2 \pm 5.1$  mmHg. The specially designed cuff HEM-FL1 to

cover a broad range of arm circumferences and self-placement fulfilled the requirements of the International Protocol. *Blood Press Monit* 22:375–378 Copyright © 2017 The Author(s). Published by Wolters Kluwer Health, Inc.

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**Keywords:** diagnostic errors, home blood pressure monitoring, oscillometry, self-blood pressure monitoring

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## Introduction

In Mexico, hypertension is a public health problem because of its increased prevalence and associated cardiovascular complications [1]. Annually, eight million deaths occur because of hypertension worldwide. The inadequate control of blood pressure (BP) is the greatest cause of cerebrovascular events and heart attacks worldwide, including Mexico [2–5]; at the same time, it is responsible for an increase in public health costs in developing countries [6].

The WHO has identified the reduction of cardiovascular risk through treatment and control of the risk factors, for example, hypertension, as one of the most efficient strategies to fight the worldwide epidemic of cardiovascular illness. It has also been proven that one of the main causes of the inefficient control of subarachnoid hemorrhage is the lack of availability of reliable BP-measuring devices.

This problem will increase gradually as mercury sphygmomanometers are being removed from the market [7].

The use of oscillometric devices to measure BP has increased in the last few years, especially for self-measuring BP at home, in some health centers, and in primary care clinics. Nevertheless, there still is a certain skepticism, both in the doctors' and the patients' minds, about the reliability of this device compared with traditional mercury sphygmomanometers and aneroids.

## Materials and methods

### Device and cuff

The Omron HEM-7320-LA (Omron Healthcare Co. Ltd, Kyoto, Japan) is an automatic oscillometric device for measuring BP at the upper arm and has a pressure range of 0–299 mmHg and a heart rate range of 40–180 beats/min. The systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate are displayed on a liquid crystal digital display. The inflation function uses a fuzzy-logic system controlled by an electric pump and deflation is by means of an automatic pressure release valve. The dimensions of this device are (width × height × depth)

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**Table 1 Screening and recruitment details**

Total screened	39
Total excluded	6
Range complete	0
Range adjustment	0
Arrhythmias	4
Device failure	0
Poor-quality sounds	2
Cuff size unavailable	0
Observer disagreement	0
Distribution	0
Other reason	0
Total recruited	33

**Table 2 Participants details**

Sex	
Male : female	16 : 17
Age	
Range	26 : 71
Mean $\pm$ SD	47.9 $\pm$ 11
Arm circumference (cm)	
Range	25–38.5
Mean $\pm$ SD	30.8 $\pm$ 4.0
Cuff for the test device (standard)	33
Recruitment blood pressure (mmHg)	
SBP	
Range	97–190
Mean $\pm$ SD	145.2 $\pm$ 24.3
DBP	
Range	68–120
Mean $\pm$ SD	90.9 $\pm$ 12.9

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

124  $\times$  90  $\times$  161 mm. The cuff Intelli Wrap HEM-FL32 (Omron Healthcare Co. Ltd) included in the device provides a wide range of arm circumferences of 22–42 cm (9–17 inch), avoiding undercuffing, which has been proven to be a key source of error BP measurement [8]. The cuff is also preformed, which makes it easier to place it on in the arm by a single hand also by the patient himself/herself, making BP measurement even more simple, which can avoid incorrect BP. The integrated movement sensor detects body movements, the cuff displays whether it fits correctly, and the arrhythmia detection warns if the heartbeats are irregular.

### Familiarization

Twelve test measurements were carried out. No problems were encountered.

### Recruitment and participant selection

Hypertensive participants were recruited from the Arterial Stiffness Laboratory, Department of Physiology, University of Guadalajara, Mexico. Normotensive participants were recruited from among accompanying relatives or staff from the same laboratory and university. There was some difficulty in recruiting participants with SBP and DBP in the high range. The majority of hypertensive participants were controlled and therefore participants in the high ranges had to be drawn mainly from among new non-medicated participants, with the participation of individuals with renal disease.

**Table 3 Blood pressure distribution of comparative measurements**

	<i>n</i>
SBP (mmHg)	
Overall range (minimum : maximum)	92 : 195
Low (< 130)	30
Medium (130–160)	35
High (> 160)	34
Maximum difference	5
DBP	
Overall range	57–126
Low (< 80)	21
Medium (80–100)	50
High (> 100)	28
Maximum difference	29

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

**Table 4 Observer differences**

	SBP (mmHg)	DBP (mmHg)	Repeated measures
Observer 2 – observer 1			
Range	– 4 to 4	– 4 to 4	2
Mean $\pm$ SD	– 1.40 $\pm$ 0.4	0.32 $\pm$ 0.3	

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

### Procedure

The validation team included three individuals (two observers and a supervisor). The two observers were checked for hearing and vision and trained by an expert in BP measurement. Participants remained seated comfortably, with their legs uncrossed, and back supported for at least 10–15 min before performing the BP measurements. Each observer was blinded to the other observer's and device's measurements. A calibrated mercurial sphygmomanometer with a proper-sized cuff (at least 80% of the arm circumference and a width of at least 40% of the same) was placed over the brachial artery and at the right atrium level.

The mean first value of each observer was used to categorize the participant into low, medium, or high BP for SBP and DBP separately. Using a double-headed stethoscope, observers obtained four BP measurements (BP1, BP3, BP5, BP7) whereas three measurements (BP2, BP4, BP6) were obtained by the supervisor with the test device. Sixty seconds were given after each consecutive measurement. Each device measurement was compared with the previous and next observer mean measurement. For statistical analysis, SPSS v. 22 (SPSS Inc., Chicago, Illinois, USA) was used.

### Results

A total of 39 participants were screened and six were excluded from the analysis because of arrhythmias and poor-quality sounds, resulting in 33 (48.5% men) participants included for validation. High BP was observed in 60.6% of the participants. The mean average age was 48.9  $\pm$  11 years, with an arm circumference range of 25–38.5 cm (Table 1). Further details on the demographics and BP ranges are shown in Table 2. The study

**Table 5 Validation results**

Part 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Required						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	84	96	99	Pass	0.6	5.7
DBP	84	95	96	Pass	2.2	5.1

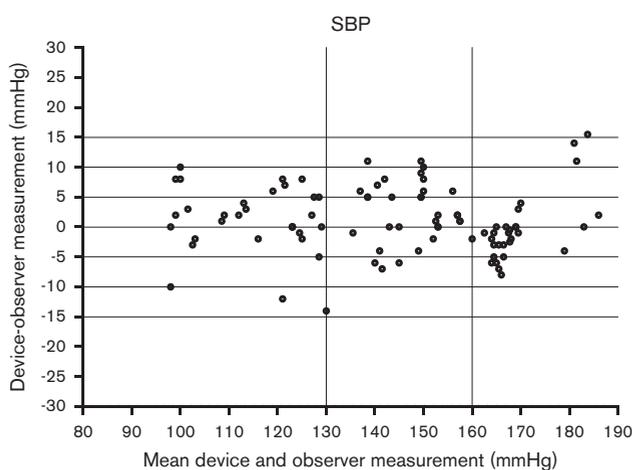
  

Part 2	2/3 ≤ 5 mmHg ≥ 24	0/3 ≤ 5 mmHg ≤ 3	Grade 2	Grade 3
Required				
Achieved				
SBP	32	1	Pass	Pass
DBP	30	1	Pass	Pass

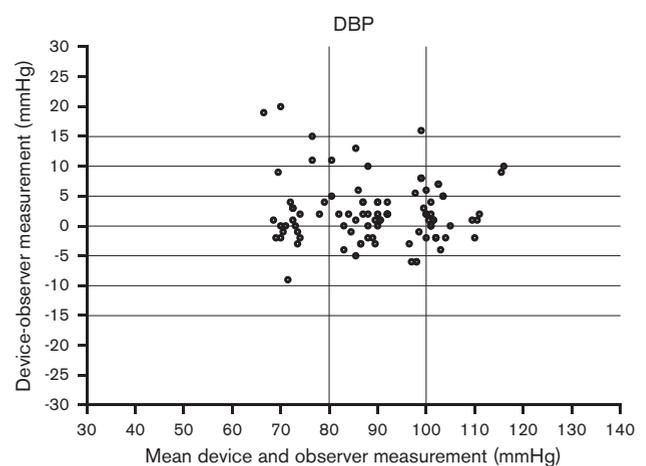
  

Part 3	Result
	Pass

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

**Fig. 1**

Plot of the systolic blood pressure device–observer difference of the 33 participants included in this study. The *y*-axis represents the difference of measurements between the device and the observer. The *x*-axis represents the mean of the device and observer measurements. SBP, systolic blood pressure.

**Fig. 2**

Plot of the diastolic blood pressure device–observer difference of the 33 participants included in this study. The *y*-axis represents the difference in measurements between the device and the observer. The *x*-axis represents the mean of the device and observer measurements. DBP, diastolic blood pressure.

results are presented in Tables 3–5. The mean observer–device difference was  $0.6 \pm 5.7$  mmHg for SBP and  $2.2 \pm 5.1$  mmHg for DBP. Measurements of both the observer and the device showed good agreement (Figs 1 and 2). From the 99 measurements, 84.4% had a difference of less than or equal to 5 mmHg against the sphygmomanometer for both SPB and DBP. The device achieved and fulfilled the criteria established by the 2010 European Society of Hypertension Revision Protocol criteria for the general population (Table 5).

## Discussion

In the present study, we validated an automatic oscillometric device with a specially designed cuff for a wide range of arm circumferences and self-placement for BP measurement intended for both self-measurement and

clinical use. This cuff eliminates two important biases of measurement: proper size and displacement of the cuff, thus enabling more accurate BP monitoring and better follow-up for hypertensive patients.

## Conclusion

The HEM-7320-LA fulfilled the criteria established by the 2010 European Society of Hypertension Revision Protocol [9] necessary to recommend and use a BP measurement device in the general population.

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### Conflicts of interest

There are no conflicts of interest.

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