REPORT

Validation of the OMRON RS7® (HEM-6232T-E) in Patients with arm circumference ≥ 32 cm according to the European Society of Hypertension International Protocol (ESH-IP).

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Short title: Validation of the Omron RS7 in Obese Population

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1. INTRODUCTION

For many years, the gold standard instrument for blood pressure (BP) measurement was a mercury sphygmomanometer and a stethoscope, but this century-old technique of Riva-Rocci / Korotkov is being progressively removed from clinical practice because of environmental concerns about mercury contamination and because number of errors and bias that may taint this method[1,2]. Several non-mercury techniques have been developed during the last ten years in order to gradually supplant the mercury-auscultatory method[3,4], such as the aneroid, the hybrid sphygmomanometers, the automatic electronic devices using algorithms based on the oscillometric technique[5,6]. It is evident that these devices need to go through a validation by experts in independent centers as recommended and requested by guidelines and societies. Different protocols are used to validate the accuracy of BP measuring devices such as the International protocol published by the working group on BP monitoring of the European Society of Hypertension (ESH)[7], the British Hypertension Society (BHS) protocol and the Association for the Advancement of Medical Instrumentation (AAMI) protocol[8,9]. Over the last ten years, several automated devices have been successfully validated using established protocols[10], mostly on the general population. However, few studies have tested the accuracy of automated BP monitors in specific populations such as diabetic patients[11], pregnant women[12], obese[13,14], elderly[51], and in arrhythmic patients[16-18].

Large arm circumference of 32 cm and over, with or without obesity, is associated to specific vascular hemodynamic conditions where blood pressure measurement may become problematic. In fact, this specific condition of the arterial characteristics influences the arterial signals and therefore the blood pressure determination. In this regard, all the validations protocols recommend, for blood pressure devices designed to be used in patient with large arm circumference ≥ 32 cm or obesity, to go through specific validation of their accuracy in this specific population. Only few devices have been shown accurate in the obese population or in patients with arm circumference ≥ 32 cm [19-24]. Furthermore, in obese patients with large arm circumference, wrist BP measurement has been suggested as one of the possible solutions. The purpose of this study is to assess the accuracy of the OMRON RS7® (HEM-6232T-E) device, which allows automatic oscillometric BP determination at the wrist level according to the criteria of the modified ESH-IP validation protocol in patents with large arm circumference ≥ 32 cm or obesity.

2. STUDY OBJECTIVES

The objective of the study is to assess the accuracy of the automatic oscillometric BP device measurements at the wrist level, the OMRON RS7® (HEM-6232T-E) in patents with large arm circumference ≥ 32 cm or obesity according to the modified ESH-IP validation protocol.

3. STUDY DESIGN, PROCEDURES, AND ANALYSIS

Ethical Information

The study was submitted to the local ethical committee. Prior to any BP measurements, a written informed consent form was signed by all eligible subjects included in this study.

General study design

This is a prospective non –interventional, non-randomized, study using a medical device.

Study population

Number of patients

Thirty-three subjects selected according to the modified ESH-IP protocol requirements were included. The main inclusion and exclusion criteria are:

	Inclusion criteria	**Non-Inclusion Criteria**
MEN or WOMEN	- Age = > 25 years - In-patient or out-patient - Informed consent - Arm circumference ≥ 32 cm - Wrist circumference:13.5-21.5 cm - Treated or untreated - Normotensive, hypertensive.	- Heart rhythm: Arrhythmia - Poor quality Korotkov sounds - Absence of K 5 sounds - Arm circumference < 32cm - Wrist circumference <13.5 or > 21.5 cm.

Validation Team

The study was organized by Prof Roland Asmar (Principal Investigator), coordinated by Dr Jirar Topouchian and realized with the contribution of Pr Nebojsa Tasic and 3 other collaborators: Dr Dalibor Dragisic, Dr Daniela Tasic and Dr Marko Filipovic, who are familiar and trained in blood pressure measurement and validation procedures.

Procedures & Measurements

The study consists of a BP device validation in patents with large arm circumference ≥ 32 cm or obesity, as it is testing the accuracy of the wrist automatic oscillometric BP device: OMRON RS7® (HEM-6232T-E).

Tested device

The OMRON RS7® (HEM-6232T-E) device was randomly selected among three devices provided by Omron Healthcare company. This is a new generation of digital automatic device for home BP measurement at the wrist level. The monitor uses electric inflation pump and rapid automatic deflation system. The device measures BP using the oscillometric method with a pressure range of 0-299 mmHg and pulse rate range of 40-180 beats/min. Systolic BP (SBP), diastolic BP (DBP) and pulse rate are displayed on a liquid crystal digital (LCD) screen. Technical details of the device are described in its User-Manual.

Cuff sizes and corresponding arm circumferences

Only the large cuff size was used for the brachial mercury sphygmomanometer BP measurements since only patients with arm circumference ≥ 32 cm were included in this study.

Blood pressure Measurements protocol

The validation was performed according to the European Society of Hypertension International Protocol revision 2010 described in detail elsewhere (7). The validation team consisted of three persons: two observers trained in accurate BP measurement and a supervisor. Thirty-three patients had their BP measured by the two observers using parallel connected mercury sphygmomanometers and a teaching stethoscope, blinded from each other's result, and then by the supervisor using the tested devices. The agreement between the 2 observers was checked all over the evaluation period by the supervisor to make sure that the difference between the two observers is no more than 4 mmHg for systolic and diastolic BP values. Otherwise, the measurement was repeated.

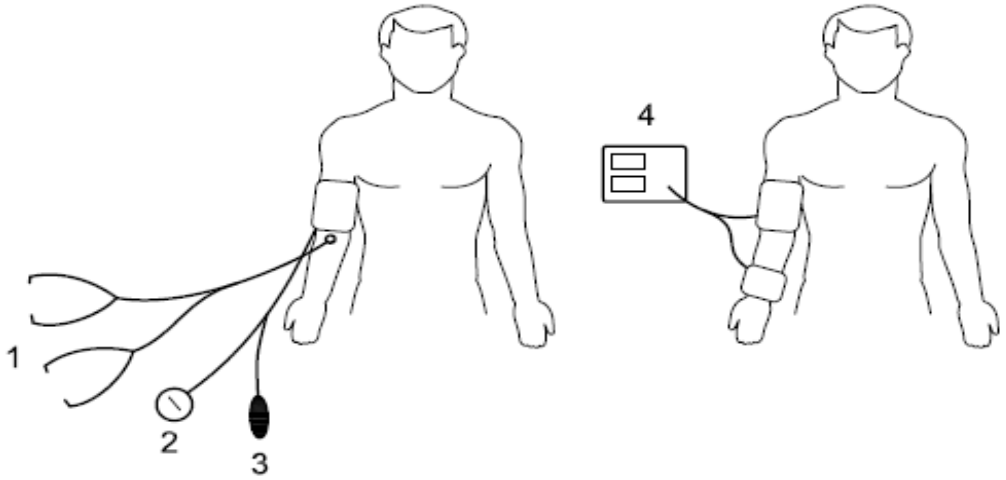
Two standard mercury sphygmomanometers were used by the 2 observers as a reference standard. The circumference of the arm was measured to ensure the inclusion criteria (≥32 cm) and that the cuff-size (Large cuff) being used is adequate for the subject. Measurements made by the mercury sphygmomanometer, was performed according to the "same *arm, consecutive measurements*" (Figure 1), a variant of the ESH-IP on the left arm supported at heart level.

Measurements by the OMRON RS7® (HEM-6232T-E) device were performed at the wrist level of the same arm supported at the heart level, as recommended by the manufacturer with the following procedure:

a) Ask the subject to relax for 5-10 min.

b) make sure that the subject is seated with legs uncrossed and back supported.

Figure 1: Illustration of the same arm sequential method



Key

ouble stethoscope

2 **reference sphygmomanometer** display

3 **reference sphygmomanometer** hand pump

4 **sphygmomanometer-under-test**

In total, nine consecutive BP measurements were performed in each patient using the mercury sphygmomanometers (5 times) and the tested devices (4 times).

All nine-sequential same-arm measurements were recorded as shown in Table 1, starting with the standard mercury sphygmomanometer, followed by the device.

Table 1: Sequential measurements of BP recorded by the standard mercury sphygmomanometer and the tested device:

BPA	Entry BP, observers 1 and 2 each with the mercury standard
BPB	Device detection BP, supervisor
BP1	Observers 1 and 2 with mercury standard
BP2	Supervisor with the test instrument
BP3	Observers 1 and 2 with mercury standard
BP4	Supervisor with the test instrument
BP5	Observers 1 and 2 with mercury standard
BP6	Supervisor with the test instrument
BP7	Observers 1 and 2 with mercury standard

The first auscultatory and the first device measurement represent the recruitment pressures (BPA and BPB). For each subject, the device measurements BP2, BP4 and BP6 were first compared to observer measurements BP1, BP3 and BP5 respectively and then to observer measurements BP3, BP5 and BP7, respectively. Comparisons more favourable to the device were used. BP1, BP3, BP5 and BP7 are the means of the 2 observer measurements.

Recruitment of subjects was done to fulfill the recommended criteria as shown in Table 2. The number of subjects in each sub-group must be 11 subjects.

Table 2: Recommended criteria of included subjects according to the BP ranges.

N= 33. (at least 10 M and 10 F)	
11 – Low. SBP / DBP	90-129 / 40 – 79 mmHg
11 – Medium	130-160 / 80-100 mmHg
11 - High	161-180 / 101-130 mmHg
Overall SBP ≤ 100 to ≥170 and DBP ≤ 50 to ≥120 mmHg	

3.4.3 Data Analysis

Results were analysed and expressed according the protocol requirements to conclude if the device passes or fails to pass the validation protocol. The statistical analysis was realized by using specific analysis software.

The numbers of 'A's, 'B's, 'C's, and 'D's are used in the analysis to calculate the number of device-observer differences within 5 mmHg, 10 mmHg, 15 mmHg and > 15 mmHg as shown in Table 3.

Table 3: Numbers corresponding to the differences between device and observers BP values:

Numbers	**Difference**	**Protocol requirement**			
A ***B*** ***C*** ***D***	0-5 mmHg 6-10 mmHg 11-15 mmHg >15 mmHg		≤ 5 (%)	≤ 10 (%)	≤ 15 (%)
		A	60	85	95
		B	50	75	90
		C	40	65	85

Accuracy is determined by the number of differences in these ranges as shown in Table 4. To be recommended for clinical use, a device must achieve a grade A or B for both systolic and diastolic blood pressure. An additional evaluation was also performed based on the AAMI criteria, requiring a mean difference (standard deviation) of ≤ 5 ± (8) mmHg.

Plots

The Bland–Altman graphs were performed to show the device–observer differences versus average device and observer values for all pairs of comparisons (n=99).

4. RESULTS

Screening and Recruitment Details

Screening and Recruitment		
Total Screened		53
Total Excluded		20
Ranges Complete	9	
Range Adjustment	2	
Arrhythmias	0	
Device Failure	0	
Poor Quality Sounds	0	
Cuff Size Unavailable	0	
Observer Disagreement	0	
Distribution	9	
Other Reasons	0	
Total Recruited		33

Recruitment Ranges			
		mmHg	All
SBP	Low	< 90	0
		90-129	11
	Medium	130-160	10
	High	161-180	11
		> 180	1
DBP	Low	< 40	0
		40-79	11
	Medium	80-100	11
	High	101-130	11
		> 130	0

Subject Details

Sex	Male:Female	16:17	
Age (years)	Range (Low:High)	28:74	
	Mean (SD)	55.2 (12.0)	
Arm Circumference (cm)	Range (Low:High)	32:41	
	Mean (SD)	35.1 (3.0)	
Wrist Circumference (cm)	Range (Low:High)	14:21	
	Mean (SD)	18.0 (2.0)	
Cuff for Test Device	Wrist		
Mercury Cuff	Small	0	
	Standard	0	
	Large	33	
		SBP	DBP
Recruitment BP (mmHg)	Range (Low:High)	97:195	50:121
	Mean (SD)	142.2 (24.0)	88.7 (18.0)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low:High)	90:191	Overall Range (Low:High)	50:123
Low (< 130)	33	Low (< 80)	35
Medium (130 – 160)	38	Medium (80 – 100)	41
High (> 160)	28	High (> 100)	23
Maximum Difference	10	Maximum Difference	18

Observer Differences

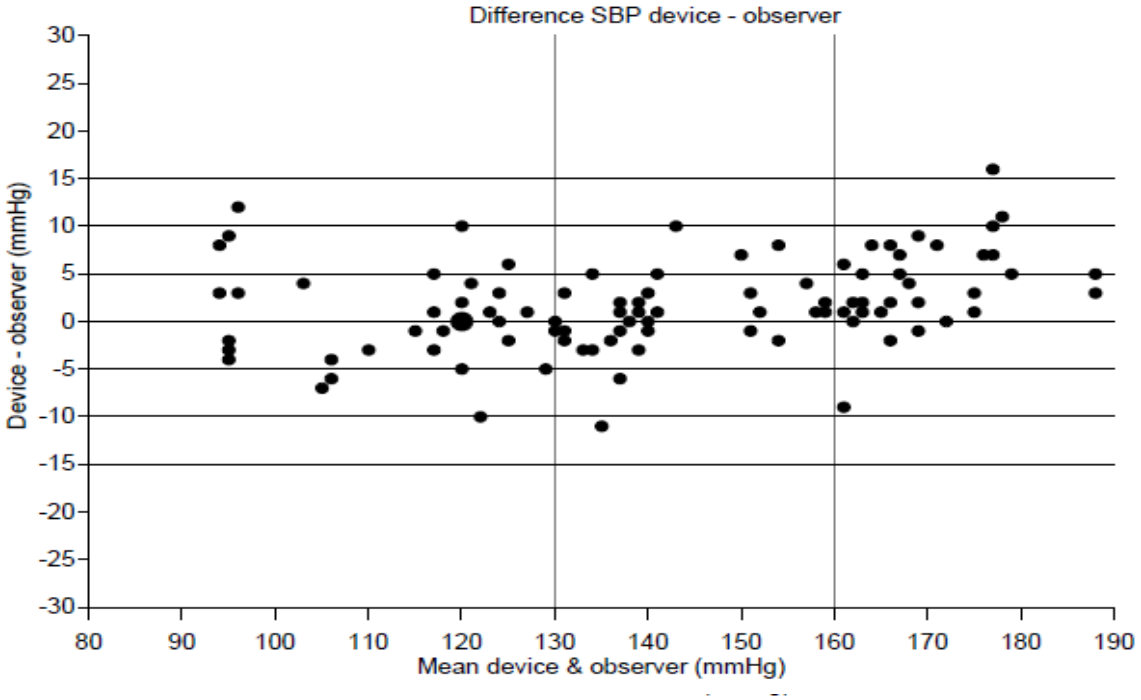
		SBP (mmHg)	DBP (mmHg)
Observer 2 – Observer 1	Range (Low:High)	-4:+4	-4:+4
	Mean (SD)	+0.2 (2.1)	+0.0 (1.8)

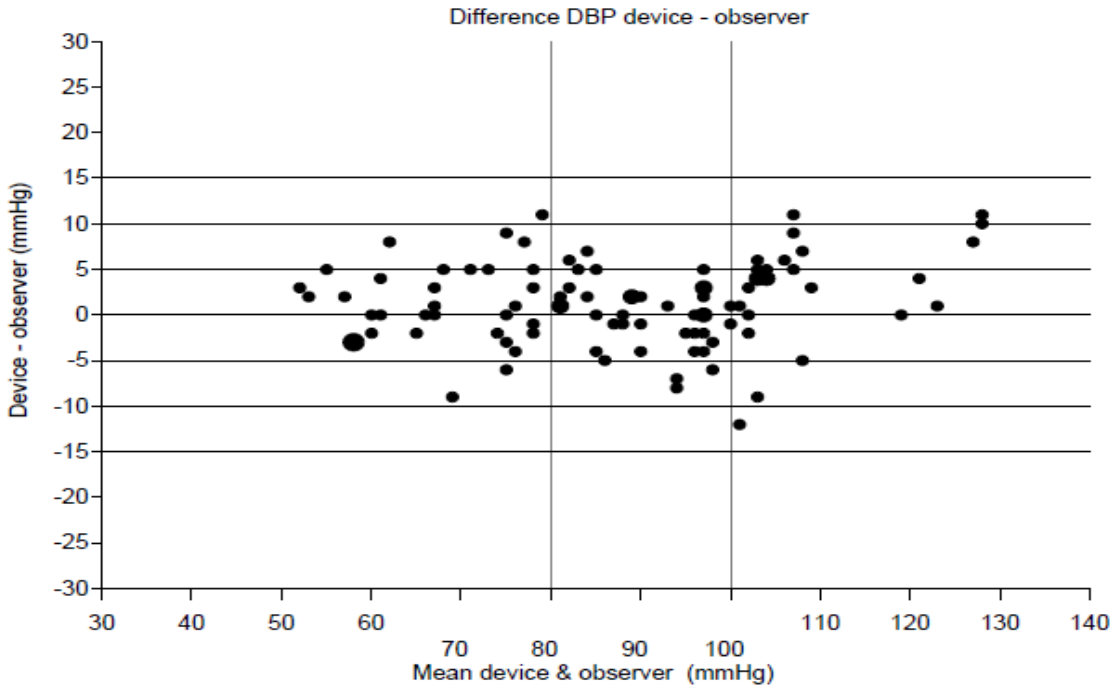
Validation Results

Part 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean mmHg	SD mmHg
Pass Req.	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	74	95	98	Pass	1.7	4.8
	DBP	78	95	99	Pass	1.2	4.6

Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade 2	Grade 3
Pass Req.		≥ 24	≤ 3		
Achieved	SBP	25	2	Pass	Pass
	DBP	28	2	Pass	Pass

Part 3	Result
	Pass





5. DISCUSSION

This study is the first to provide information on the accuracy of the OMRON RS7® (HEM-6232T-E) device for BP measurement at the wrist level in patients with arm circumference ≥ 32 cm. The results of the study showed that the OMRON RS7® (HEM-6232T-E) device successfully passed the validation requirements in this special population according to the ESH International Protocol.

There are important points related to OMRON RS7® (HEM-6232T-E) and the validation protocol (ESH-IP) that need to be discussed: The OMRON RS7® (HEM-6232T-E) has been validated in this study in special population (arm circumference ≥ 32 cm); Therefore, the results of our study cannot be extrapolated to the other specific populations such as arrythmia, elderly and pregnant women. The OMRON RS7® (HEM-6232T-E) has been used in this study according to the manufacturer recommendations with full respect of the user-manual. This must be respected when the device is used by the patient for home blood pressure monitoring.

The ESH-IP was used in this study. It has been published in 2002 then revised in 2010. The aim of this protocol was to simplify the earlier protocols without violating their integrity. However, the number of validation studies needed to approve the device accuracy is not specified by the ESH- IP although there is an agreement among experts that a device should be validated in at least two different centers separately.

6. CONCLUSION

This study showed that OMRON RS7® (HEM-6232T-E) device successfully passed the validation requirements in patients with arm circumference ≥ 32 cm according to the ESH International Protocol and therefore, can be recommended for patients use for home blood pressure monitoring.

7. REFERENCES

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