Validation of the QARDIO QARDIOARM upper arm blood pressure monitor, in oscillometry mode, for self measurement in persons fulfilling the population as described in this paper, according to the European Society of Hypertension International Protocol revision 2010

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Abstract

The QARDIO QARDIOARM, an upper arm blood pressure monitor, in oscillometry mode, for personal use., was validated, in persons fulfilling the population as described in this paper, according to the European Society of Hypertension International Protocol revision 2010. The protocol requirements were followed with adjustment. The device passed all of the requirements and, fulfilling the standards of the protocol, is recommended

Device Details

Brand	QARDIO
Model	QARDIOARM
Manufacturer	QARDIO
Location	Upper Arm
Method	Oscillometry
Purpose	Self/ Home Measurement
Operation	Fully Automatic
Arm Cuff	22.0 cm to 37.0 cm

Methodology

Familiarisation

The validation team consisted of three persons: two observers trained in accurate BP measurement and a supervisor. The 2 observers have completed a training session. 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 is no more than 4 mmHg for systolic and diastolic BP values. Otherwise, the measurement should be repeated.

Two standard mercury sphygmomanometers, the components of which have been carefully checked before the study, were used by the 2 observers as a reference standard. Measurements were taken to the nearest 2 mmHg simultaneously by the 2 observers. Measurements made by the mercury sphygmomanometer were made on the left arm supported at heart level. Measurements made by the QARDIO device were made on the same arm supported at the heart level as recommended by the manufacturer. The circumference of the arm was measured to ensure that the cuff being used is adequate for the subject.

At all nine sequential same-arm measurements using the test instrument and the standard mercury sphygmomanometer were recorded as follows:

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

Recruitment

Inclusion was carried out until 33 subjects at all, fulfilling the criteria of the international guidelines, have been included. The device was then evaluated according to the international protocol revised version 2010 requirements.

Recruitment of subjects was done in order to fulfill the recommended ranges of BP. There is three ranges for SBP and three for DBP:

	SBP (mmHg)	DBP (mmHg)
Low	90 – 129	40 – 79
Medium	130 – 160	80 – 100
High	161 - 180	101 - 130

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 were the means of the 2 observer measurements.

Screening and Recruitment Details

Screening and Recruitment			Recruitment Ranges				
Total Screened		36			mmHg	All	On Rx
Total Excluded		3		Low	< 90	0	1
Ranges Complete	0				90 - 129	11	
Ranges Adjustment	0		SBP	Medium	130 - 160	11	8
Arrhythmias	0			High	161 - 180	11	11
Device Failure	0				> 180	0	
Poor Quality Sounds	0						
Cuff Size Unavailable	0			Low	< 40	0	2
Observer Disagreement	0				40 - 79	11	
Distribution	0		DBP	Medium	80 - 100	11	8
Other Reasons	3			High	101 - 130	11	10
Total Recruited		33			> 130	0	

Procedure

The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely.[1] Overseen by an independent supervisor, measurements were recorded by two observers.

Results

Subject Details

Sex		
Male : Female	18 : 15	
Age (years)		
Range (Low : High)	30 : 68	
Mean (SD)	48.1 (10.5)	
Arm Circumference (cm)		
Range (Low : High)	24.0 : 37.0	
Mean (SD)	31.6 (3.0)	
Cuff for test device		
Other	33	(22.0 - 37.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	101 : 180	49 : 129
Mean (SD)	143.2 (27.4)	91.2 (20.3)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	96 : 198	Overall Range (Low : High)	50 : 139
Low (< 130)	33	Low (< 80)	36
Medium (130 – 160)	42	Medium (80 – 100)	35
High (> 160)	24	High (> 100)	28
Maximum Difference	18	Maximum Difference	8

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	-0.3 (1.7)	-0.4 (1.7)	0

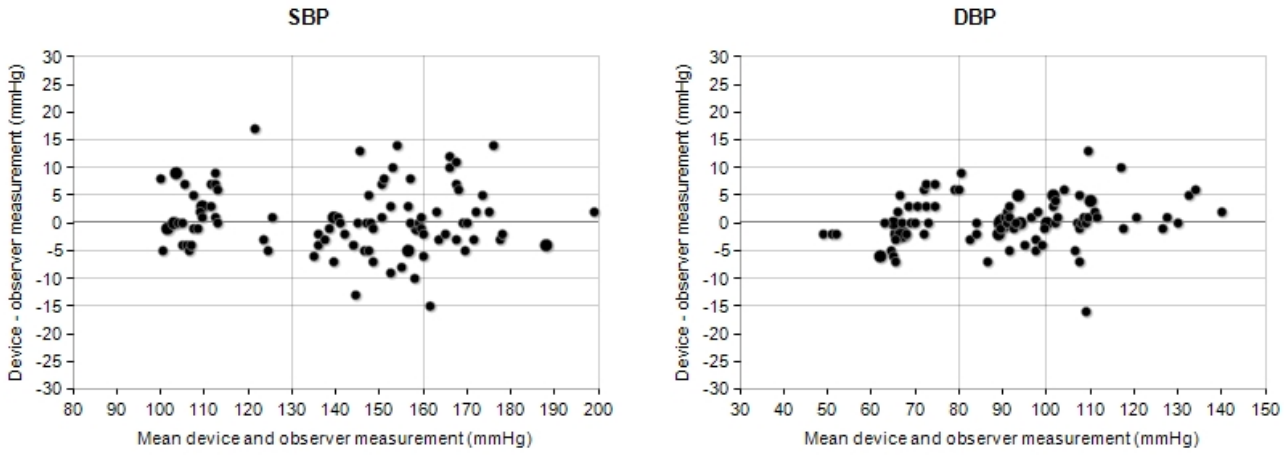
Validation Results

Part 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass Requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	69	91	98	Pass	0.7	5.9
DBP	82	97	98	Pass	0.3	4.1

Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 10 mmHg	Grade 2	Grade 3
Pass Requirements	≥ 24	≤ 3		
Achieved				
SBP	27	3	Pass	Pass
DBP	31	2	Pass	Pass

Part 3	Result
	PASS

Plots



Discussion

The objective of the study was to assess the accuracy of the QARDIO device according to the international validation protocol revised version 2010 (4). The International Protocol has been published by the Working Group on Blood Pressure Monitoring of the European Society of Hypertension aiming to simplify the 2 main available guidelines, BHS and AAMI, without losing their merits.

We compared blood pressure values obtained by the cuff mercury sphygmomanometer at arm level with those obtained by the QARDIO device. Mercury sphygmomanometer measurements are generally accepted as being the gold standard method of measuring blood pressure non-invasively.

This study showed the accuracy of the oscillometric device by fulfilling the International Protocol acquires. It should be emphasized, however, that each subject was in a correct sited position. For all measurements the arm was supported at the heart level. Recommendations given by the manufacturer are to achieve a correct posture before measuring blood pressure since an incorrect posture might give incorrect readings. The patient should relax and avoid wrist movements during measures like firm grips, large extensions or large flexions of the hand. It must, however, be emphasized that although the QARDIO device designed for measuring blood pressure is accurate when tested according to the International Protocol, it may be inaccurate for the self-measurement of blood pressure if the instructions are not strictly followed.

This validation has been performed in general population; therefore the results cannot be extrapolated to other specific populations such as the elderly, pregnancy, obese, children or other populations.

Conclusion

As the device has reached the required standards, it is recommended for personal use in persons fulfilling the population as described in this paper.

References

1. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the Validation of Blood Pressure Measuring Devices In Adults. Blood Press Monit 2010;15:23–38.