

Validation of the OMRON® HEM-6000 blood pressure monitor with
positioning sensor (sold as OMRON R6 and OMRON R5 Professional)
at the wrist according to the International Protocol of the European
Society of Hypertension

Prof. J.M. Herrmann

LVA Rehaklinik Glotterbad
Gehrenstraße 10
78684 Glottertal
Germany

The aim of the present study was to validate the OMRON[®] HEM-6000 automatic oscillometric blood pressure monitor according to the International Protocol (1). This device measures BP at the wrist and guides the patient towards an accurate usage of the monitor by its advanced positioning sensor (APS[®])

It is to be shown whether it provides accurate BP measurements. The International validation protocol that was published by the European Society of Hypertension can be applicable to the majority of BP measuring devices on the market.

It is a simplified protocol that does not sacrifice the integrity of the earlier Association for the Advancement of Medical Instrumentation (AAMI) and British Hypertension Society (BHS) protocols.

1. Methods

Device The OMRON[®] HEM-6000 was provided and randomly selected by the manufacturer. It is an automatic device or self-measurement of blood pressure at the wrist using the oscillometric method. It has a digital LCD screen that displays the measured blood pressure and pulse rate. The unit measures pressures from 0 to 299 mmHg and pulse from 40 to 180 beats/min.

Measurement Protocol The validation team consisted of three persons: two observers trained in accurate BP measurement and a supervisor. The 2 observers have completed a qualified 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. The circumference of the arm was measured to ensure that the bladder 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

Inclusions were ongoing until 15 subjects, fulfilling the criteria of the international protocol, have been included. The device was then evaluated (first phase of the international protocol). Then inclusion were carried out until 33 subjects at all, fulfilling the criteria of the international guidelines, have been included. The device was then evaluated (second phase of the international protocol).

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 the primary phase, five of the 15 subjects should have a SBP in each of the ranges. Similarly, five of the 15 subjects should have a DBP in each of the ranges. For the secondary phase, 11 of the 33 subjects (including the first 15 subjects) should have SBP and DBP in each of the ranges.

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.

2. Results :

Thirty three subjects were selected according to the international protocol recommendations. Patients with atrial fibrillation or other arrhythmia have been excluded.

Table 1: characteristics of the subjects:

Number of subjects	46
Age (years)	41 +/- 20
Wrist circumference (cm)	17,7 cm +/- 3,3
Gender (M/F)	25/21

Mean BP for the classification of the subjects (BPA) was 140 ± 40 mmHg and 86 ± 26 mmHg for the SBP and the DBP respectively.

Mean BP for all obtained measures obtained by standard mercury sphygmomanometer was 135 ± 41 mmHg and 86 ± 26 mmHg for the SBP and the DBP respectively.

Mean BP for all measures obtained by the Omron device was 137 ± 40 mmHg and 85 ± 27 mmHg for the SBP and DBP respectively.

Table 2: Number of comparisons falling within the 5, 10 and 15 mmHg error bands, Result of phase 1:

Result	SBP	DBP	criteria
within 5mmHg	31	31	25
within 10mmHg	39	43	35
within 15mmHg	44	45	40

Table 3: Number of comparisons falling within the 5, 10 and 15 mmHg error bands, mean difference (mmHg) and standard deviation (mmHg), Result of phase 2.1:

Result	SBP	DBP	criteria	
			Two of	All of
within 5mmHg	87	79	65	60
within 10mmHg	92	95	80	75
within 15mmHg	96	98	95	90

Table 4: Number of comparisons per subject falling within 5 mmHg, Result of phase 2.2:
Phase 2-2

	$2/3 \leq 5\text{mmHg}$		$0/3 > 5\text{mmHg}$
Criteria	≥ 22		≤ 3
SBP	30		1
DBP	28		0

3. Discussion

The objective of the study was to assess the accuracy of the OMRON[®] HEM-6000 blood pressure monitor according to the international validation protocol (1) that may be used to validate devices measuring blood pressure at the upper arm. 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.

In this study we directly compared blood pressure values obtained by the cuff mercury sphygmomanometer at arm level with those obtained by the Omron HEM-6000 at arm level. Mercury sphygmomanometer measurements are generally accepted as being the gold standard method of measuring blood pressure non-invasively and it is against this that the tested device measurements have been compared.

This study showed the accuracy of the oscillometric upper arm device by fulfilling the International Protocol acquiries. It should be emphasized, however, that each subject was in a correct position and used the device in the right way at heart level. We found that this was made very easy by the built in positioning sensor which guides the patient towards a proper usage of the device and reduces misuse. (2)

4. Conclusion

The OMRON[®] HEM-6000 model (OMRON R6 and OMRON R5 Professional) blood pressure monitor fulfils the criteria of the international validation protocol. The positioning sensor guides towards a correct positioning of the device. The higher accuracy of the positioning sensor has been demonstrated by a recently published study. (2)

- (1) O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, Mengden T, Imai Y, Waeber B, Palatini P. Working Group on Blood Pressure Monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; **7**:3-17.
- (2) Comparison of the Omron HEM-637 wrist monitor to the auscultation method with the wrist position sensor on or disabled. *Am J Hypertens*. 2004 Jan;17(1):54-8. Erratum in: *Am J Hypertens*. 2004 Apr;17(4):383.

Measurement data list: systolic measurements

OBS1					OBS2					Device			
BPA	BP1	BP3	BP5	BP7	BPA	BP1	BP3	BP5	BP7	BPB	BP2	BP4	BP6
110	112	106	110	108	110	112	108	108	108	110	105	106	106
110	110	110	100	110	110	108	108	98	108	112	114	110	113
138	136	138	132	130	138	136	138	130	130	128	124	131	132
114	120	118	120	120	114	120	118	118	120	122	122	118	124
122	120	120	126	124	122	120	120	122	124	124	119	120	115
100	100	102	100	110	100	100	102	100	110	120	123	121	120
150	140	148	138	148	150	140	148	138	148	146	137	140	142
120	120	118	110	118	120	120	118	110	118	122	122	116	123
158	166	166	160	150	156	166	164	160	150	156	166	160	155
138	130	128	130	132	138	130	128	130	132	134	126	132	129
150	146	138	142	142	150	146	138	140	142	141	137	146	138
110	104	104	106	104	110	104	104	110	104	106	105	100	105
134	130	134	122	124	130	130	132	120	124	131	132	125	129
128	126	128	126	126	128	124	124	124	124	138	130	121	138
120	120	120	114	120	122	120	120	114	120	118	118	115	116
140	148	140	140	136	140	148	140	140	138	139	150	141	142
122	124	124	124	126	122	122	124	124	126	121	123	122	121
152	140	150	156	146	150	138	150	156	144	129	141	138	134
168	160	170	160	166	168	158	170	160	164	165	157	168	162
162	162	160	155	156	162	162	160	152	155	161	160	158	159
120	112	120	116	120	122	116	120	112	120	118	116	115	115
108	110	100	100	100	110	110	100	100	100	110	110	106	111
120	120	120	120	120	120	120	120	120	120	109	108	104	112
140	134	130	130	122	140	136	130	130	122	130	127	127	126
154	146	140	138	130	154	148	138	140	130	163	148	144	150
140	138	140	134	144	140	138	140	130	144	129	129	132	137
108	110	110	106	108	108	110	108	106	110	102	105	104	104
140	138	136	136	134	140	138	136	138	134	124	141	127	122
160	158	156	150	150	158	158	156	150	152	147	147	147	148
166	152	160	150	150	166	152	160	150	150	144	140	146	131
164	158	160	158	168	162	156	160	160	168	159	161	162	163
120	110	110	104	108	120	110	108	102	108	113	113	110	106
108	98	100	100	98	108	98	100	98	98	103	102	97	99
100	110	108	110	112	100	110	104	110	112	105	109	106	112
174	170	168	168	162	172	172	170	170	160	175	172	170	163
160	154	166	168	160	164	156	168	168	160	157	160	165	166
164	150	150	148	150	162	150	150	148	150	159	155	152	150
104	106	104	100	100	104	104	104	98	98	107	101	104	99
162	160	148	148	150	162	160	148	148	150	158	156	151	152
102	102	100	104	102	102	102	100	102	104	104	105	104	104
100	100	94	100	98	100	100	96	98	98	100	98	98	98
120	112	110	108	108	120	112	112	108	110	118	115	108	108
146	140	142	138	144	142	140	140	138	144	143	142	137	142
180	176	170	168	162	180	174	170	168	160	177	170	169	156
168	164	162	160	168	168	164	164	160	168	163	160	162	158
162	160	166	166	162	162	160	164	166	162	159	158	162	164

Diastoli

c

OBS1					OBS2					Device			
BPA	BP1	BP3	BP5	BP7	BPA	BP1	BP3	BP5	BP7	BPB	BP2	BP4	BP6
80	78	80	80	80	80	78	80	80	80	71	73	74	77
70	70	70	70	70	70	70	70	70	70	62	70	67	68
90	90	90	82	80	90	90	88	80	80	74	77	79	77
80	82	80	82	84	80	82	80	80	80	80	77	73	77
90	88	88	78	88	90	88	88	78	88	87	87	75	78
72	78	78	72	80	70	76	80	72	80	70	84	93	79
98	92	94	90	90	96	90	94	90	90	90	87	90	92
80	80	80	80	78	80	80	80	80	78	77	77	78	71
110	108	112	110	110	110	108	112	110	110	106	105	105	105
90	90	90	88	90	90	90	90	88	90	86	86	87	85
98	90	90	90	90	98	90	90	90	90	86	84	86	84
60	64	64	60	62	60	64	64	60	60	59	61	60	58
80	80	80	72	80	78	80	80	70	80	85	78	80	76
90	82	90	90	90	90	82	90	90	90	82	78	85	93
78	80	78	76	78	78	78	78	74	78	75	75	74	75
100	104	106	102	100	100	106	110	102	100	101	101	97	103
86	84	80	80	86	86	84	80	80	82	79	84	78	76
102	100	102	106	100	100	98	100	104	98	90	91	87	93
110	106	108	104	105	100	104	108	104	102	97	103	105	102
104	98	100	102	98	104	98	100	102	98	99	95	98	97
76	76	80	80	78	76	78	80	80	78	77	76	77	78
72	72	70	70	70	70	70	70	70	70	68	72	66	67
84	74	76	72	80	84	70	76	70	76	69	72	71	68
90	92	88	90	90	90	92	90	90	90	79	77	81	80
112	110	110	110	100	112	110	110	110	100	109	104	110	111
76	70	72	70	70	76	70	74	70	70	69	68	73	71
70	70	70	74	68	70	70	70	74	68	63	66	61	66
90	80	90	84	80	90	80	90	84	80	78	80	82	75
100	100	100	96	98	100	100	100	100	98	87	89	87	82
100	90	100	100	100	100	90	100	100	100	88	84	88	81
106	110	110	110	110	104	110	110	110	110	107	100	112	108
68	68	60	60	60	68	68	60	60	60	70	68	68	63
74	72	80	72	70	74	74	78	74	70	69	71	66	72
72	76	76	76	80	72	74	74	76	80	74	70	70	78
110	108	108	104	102	110	108	108	104	102	101	99	103	94
108	100	104	102	100	108	100	102	102	100	104	104	105	108
100	100	102	100	100	100	98	100	100	100	98	102	98	99
70	70	74	70	70	70	70	72	68	70	70	65	67	65
88	88	80	80	80	88	88	80	80	80	87	85	84	76
78	76	74	76	78	78	76	74	76	78	76	63	73	62
70	70	70	70	70	70	70	70	70	70	66	66	66	67
70	72	70	72	74	70	72	70	72	74	67	67	66	67
108	108	110	110	108	110	108	110	110	110	105	104	106	105
100	92	92	92	92	100	90	90	90	90	98	95	90	95
110	108	104	100	104	100	108	104	100	104	98	106	101	98

94 94 94 96 94 92 96 94 98 94 90 92 92 95