

Validation of the OMRON[®] M7 blood pressure measuring device at the upper arm according to the International Protocol of the European Society of Hypertension

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The aim of the present study was to validate the OMRON[®] M7 automatic oscillometric blood pressure (BP) device according to the International Protocol (1). This device measures BP at the upper arm. It is to be shown whether it provides accurate BP measurements. The International validation protocol was published by the European Society of Hypertension and 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[®] M7 was provided and randomly selected by the manufacturer. It is an automatic device or self-measurement of blood pressure 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 :

For all measurements, the difference between the 2 observers was -0.35 ± 1.34 mmHg and -0.08 ± 1.38 mmHg for systolic and diastolic BP respectively.

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	60
Age (years)	49,7 +/-21,3
Arm circumference (cm)	31,0 +/- 11
Gender (M/F)	33/27

Mean BP for the classification of the subjects (BPA) was $136 \pm 36,1$ mmHg and $88,8 \pm 38,8$ mmHg for the SBP and the DBP respectively.

Mean BP for all retained measures obtained by standard mercury sphygmomanometer was $137 \pm 52,9$ mmHg and $90,1 \pm 32,1$ mmHg for the SBP and the DBP respectively.

Mean BP for all measures obtained by the Omron device was $133 \pm 58,9$ mmHg and $85.6 \pm 29,4$ 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:

criteria		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.	Mean diff.	SD
Phase 2.1							
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	86	95	99	Pass	0.8	4.1
	DBP	92	99	99	Pass	-0.4	3.0

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

	2/3 ≤5mmHg	0/3 >5mmHg
Criteria	≥22	≤3
SBP	25	2
DBP	22	3

3. Discussion

The objective of the study was to assess the accuracy of the OMRON[®] M7 model HEM-780-E device according to the international validation protocol (1) that may be used to validate devices measuring blood pressure at the wrist. 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 M7. 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 wrist device by fulfilling the International Protocol acquiries. It should be emphasized, however, that each subject was in a correct sited position. For the measurements the arm was supported at the heart level.

4. Conclusion

The OMRON[®] M7 model HEM-780-E device fulfils the recommendations of the international validation protocol.

- (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.

Individual Data

Systolic values

OBS1					OBS2					Device			
BPA	BP1	BP3	BP5	BP7	BPA	BP1	BP3	BP5	BP7	BPB	BP2	BP4	BP6
140	130	136	140	130	140	130	136	140	130	133	135	127	134
190	180	170	160	175	190	180	170	165	175	161	157	147	157
130	130	130	120	130	130	126	130	120	130	125	119	113	120
130	130	130	140	130	136	130	130	140	130	129	119	126	134
126	130	132	128	130	126	130	130	128	129	125	126	121	124
130	116	140	124	140	130	116	136	120	140	134	131	131	126
178	164	170	166	166	180	160	170	164	164	162	149	141	161
130	130	132	120	120	130	130	130	120	120	134	132	129	127
140	138	160	150	145	140	140	160	150	140	144	134	139	155
160	160	158	160	152	160	160	158	158	154	158	153	144	148
142	140	124	130	136	140	140	124	130	134	139	137	115	122
100	104	100	105	90	100	104	100	100	96	115	124	108	111
130	120	120	120	130	130	120	120	118	126	127	115	115	117
100	114	110	110	106	100	110	110	110	106	102	110	107	96
144	136	140	150	150	142	134	140	150	150	131	133	132	143
120	110	116	110	110	120	110	114	110	110	113	106	108	107
110	120	118	116	112	110	120	114	114	114	118	115	114	117
130	126	128	116	128	130	128	126	118	128	122	130	123	125
120	124	116	120	116	120	124	118	120	116	117	106	112	112
140	135	140	140	140	140	135	140	145	140	134	132	139	139
135	130	135	130	132	138	130	134	130	134	133	130	130	130
120	110	120	120	116	122	110	120	120	118	113	113	112	110
118	120	116	118	110	120	120	118	116	110	116	105	112	110
104	114	100	110	104	106	112	100	108	102	107	112	101	103
136	130	130	128	132	132	130	130	128	130	127	123	120	122
136	130	136	140	138	134	130	136	138	136	141	134	136	134
116	140	130	130	130	120	138	130	130	130	118	120	122	119
130	126	128	116	128	130	128	126	118	128	122	130	123	125
140	140	138	140	136	142	140	136	136	136	135	136	138	134
130	120	126	124	130	132	124	124	126	126	122	122	121	120

124	110	116	112	110	122	110	112	112	110	113	108	112	113
172	180	190	180	178	170	180	190	180	172	178	190	170	184
116	116	110	102	106	114	116	114	104	106	103	97	97	102
156	150	138	138	140	156	154	138	136	136	140	127	126	130
100	98	82	84	100	104	98	84	82	94	85	89	70	78
150	140	130	130	130	150	140	132	130	130	143	141	138	136
104	90	106	100	94	104	94	102	100	98	93	89	91	97
120	128	128	128	128	120	128	130	126	128	128	123	131	129
130	130	122	130	128	132	132	126	128	128	123	122	123	114
150	156	154	158	156	154	152	154	156	156	132	132	129	136
134	130	130	132	132	134	130	130	132	132	130	124	135	125
160	150	150	152	150	162	152	150	150	150	145	143	135	153
136	130	130	130	124	136	128	126	130	128	117	120	118	126
158	158	160	160	150	158	158	160	156	150	165	141	147	148
164	160	150	160	160	164	160	154	162	160	163	160	160	163
138	138	140	140	140	136	140	140	140	140	138	141	138	139
160	160	158	160	152	160	160	158	158	154	158	153	144	148
170	162	150	154	140	168	160	152	154	144	134	145	154	152
170	162	162	150	160	168	162	160	148	160	164	153	152	162
132	134	132	130	128	134	134	130	128	126	132	135	135	128
118	116	116	118	116	114	116	115	112	114	114	115	116	114
170	170	174	172	176	168	168	172	172	174	171	172	174	170
110	106	108	108	106	106	108	108	110	106	105	105	109	108
178	178	176	178	176	180	178	178	176	176	177	177	179	178
178	190	186	180	170	180	190	186	178	170	178	188	187	168
180	170	168	168	166	180	170	170	168	164	178	168	166	162
188	188	189	181	180	181	181	182	186	186	190	192	191	187
166	168	166	166	164	166	166	164	168	166	166	165	169	163
116	118	118	114	115	112	114	114	112	116	110	112	113	114

Diastolic Values

OBS1					OBS2					Device				
BPA	BP1	BP3	BP5	BP7	BPA	BP1	BP3	BP5	BP7	BPB	BP2	BP4	BP6	
100	100	100	96	100	100	100	100	100	100	100	91	92	89	90
110	110	110	100	105	110	110	110	100	105	113	103	103	98	
96	90	96	90	90	96	90	100	90	90	87	91	85	86	
90	90	90	90	90	90	90	90	90	90	93	86	86	88	
90	86	88	88	86	90	86	90	88	86	83	82	84	87	
90	90	90	88	90	90	90	90	90	90	82	88	87	91	
110	100	110	110	100	110	100	110	110	100	105	96	95	100	
80	90	86	86	80	80	90	86	86	80	80	82	78	78	
98	100	100	100	110	98	100	105	100	110	88	88	88	91	
104	110	108	100	110	100	110	110	100	106	107	103	104	102	
78	76	76	76	70	80	76	76	74	70	73	71	64	64	
70	70	70	70	75	70	78	74	72	78	66	55	61	62	
80	86	80	80	82	86	86	84	80	86	85	80	79	82	
80	80	80	80	84	80	80	80	80	84	75	78	76	78	
110	108	106	110	114	110	110	106	110	112	103	103	103	107	
80	80	82	76	82	80	80	80	74	82	79	79	77	82	
86	86	86	90	88	82	82	82	88	88	81	78	75	73	
90	90	88	84	86	90	90	88	84	86	78	84	74	81	
90	80	80	80	80	90	80	80	80	80	69	69	72	67	
100	105	105	100	100	100	110	110	100	100	99	92	94	90	
92	90	90	90	90	94	90	90	90	90	92	92	91	93	
90	90	90	88	88	90	88	90	88	88	80	78	80	78	
80	80	80	74	80	80	78	80	70	78	77	73	73	65	
84	82	80	82	78	84	80	78	80	78	75	75	71	73	
98	90	98	94	96	96	90	98	96	98	92	93	89	90	
88	82	88	82	88	88	80	86	80	88	84	87	86	84	
90	100	100	100	100	90	98	100	100	100	89	87	88	89	
90	90	88	84	86	90	90	88	84	86	78	84	74	81	
86	86	84	90	84	84	84	82	84	86	74	80	74	79	
90	90	92	90	90	90	90	90	90	90	89	91	88	86	

78	70	74	72	78	78	70	70	72	74	74	69	67	68
100	104	108	104	100	100	102	104	100	100	106	109	104	109
70	70	70	70	70	70	70	70	74	70	67	71	67	72
78	78	76	78	70	76	76	74	74	74	76	70	70	69
68	62	58	64	64	70	60	58	64	62	55	61	50	51
102	100	100	98	100	104	102	100	98	98	95	93	93	91
60	60	62	58	66	64	60	62	60	68	63	59	58	60
90	90	88	90	90	88	90	90	90	90	82	78	80	87
92	90	96	94	98	92	90	94	96	98	88	86	85	81
100	90	98	98	90	98	98	98	100	90	76	80	70	76
90	80	88	84	90	90	88	90	86	88	89	85	84	87
108	110	110	112	110	108	110	110	110	112	108	99	102	106
90	94	90	90	90	88	94	90	90	90	87	84	87	88
110	110	114	110	108	110	110	110	110	110	103	95	99	98
82	78	82	84	84	80	78	80	82	80	84	87	84	88
84	88	90	88	86	90	92	90	90	86	84	87	88	88
104	110	108	100	110	100	110	110	100	106	107	103	104	102
80	80	76	78	76	78	76	74	76	76	76	79	75	75
108	102	110	110	102	106	100	110	110	102	102	99	100	99
78	76	74	78	78	76	76	78	78	78	77	76	79	79
62	66	64	64	66	64	64	66	66	62	64	63	63	65
112	114	114	116	118	110	112	114	118	116	113	113	115	115
66	68	68	70	70	70	72	72	74	72	69	67	68	72
104	102	100	102	104	100	104	104	102	100	102	101	103	99
110	110	110	110	100	110	110	110	108	100	106	107	105	97
110	112	110	110	110	110	110	110	110	110	108	109	108	107
100	102	100	98	98	102	102	100	100	98	102	102	105	103
98	102	100	98	102	100	100	100	102	100	98	99	101	101
76	78	78	74	72	74	80	78	74	72	77	75	75	77

BPAO1S: Entry systolic BP taken by Observer1.
BPAO1D: Entry diastolic BP taken by Observer1.
BPAO2S: Entry SBP taken by Observer2.
BPAO2D: Entry DBP taken by Observer2.
BPBS: Device detection SBP given by Omron M7 device.
BPBD: Device detection DBP given by Omron M7 device.
BP1O1S: SBP first measurement taken by Observer1.
BP1O1D: DBP first measurement taken by Observer1.
BP1O2S: SBP first measurement taken by Observer2.
BP1O2D: DBP first measurement taken by Observer2.
BP3O1S: SBP second measurement taken by Observer1.
BP3O1D: DBP second measurement taken by Observer1.
BP3O2S: SBP second measurement taken by Observer2.
BP3O2D: DBP second measurement taken by Observer2.
BP5O1S: SBP third measurement taken by Observer1.
BP5O1D: DBP third measurement taken by Observer1.
BP5O2S: SBP third measurement taken by Observer2.
BP5O2D: DBP third measurement taken by Observer2.
BP7O1S: SBP fourth measurement taken by Observer1.
BP7O1D: DBP fourth measurement taken by Observer1.
BP7O2S: SBP fourth measurement taken by Observer2.
BP7O2D: DBP fourth measurement taken by Observer2.
BP2S: SBP first measurement given by Omron M7device.
BP2D: DBP first measurement given by Omron M7device.
BP4S: SBP second measurement given by Omron M7device.
BP4D: DBP second measurement given by Omron M7device.
BP6S: SBP third measurement given by Omron M7device.
BP6D: DBP third measurement given by Omron M7device.