

Validation of the OMRON[®] M6 (HEM -7001-E) blood pressure
measuring device 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[®] M6 automatic oscillometric blood pressure (BP) device according to the International Protocol (1). This device measures BP at the arm level. 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 (2,3).

1. Methods

Device: The OMRON[®] M6 device was provided and randomly selected by the manufacturer (4). It is an automatic device for self-measurement of blood pressure at the arm level using the oscillometric method. Inflation is fuzzy-logic control by electric pump. Deflation is automatic by pressure release valve. The unit weighs approximately 355 g (without batteries). The included cuff is applicable to arm circumferences ranging from 220 to 320 mm. Optional small cuffs (170 – 220 mm) and large cuffs (320 – 420 mm) can be applied. The device has a digital LCD screen that displays the measured blood pressure and pulse rate in addition to date and time. The unit measures pressures from 0 to 299 mmHg and pulse from 40 to 180 beats/min. 90 Measurements with date and time could be memorized.

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 training session according to the training program of the French Society of Hypertension. 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 OMRON[®] M6 device were made on the left arm supported at the heart level as recommended by the manufacturer. 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 -0.1 ± 2.0 mmHg and 0.4 ± 1.5 mmHg for systolic and diastolic BP respectively.

Thirty three subjects were selected according to the international protocol recommendations. No patient had atrial fibrillation or other arrhythmia.

Table 1: characteristics of the subjects:

Number of subjects	33
Age (years)	57 ± 13
Arm circumference (cm)	30 ± 7
Gender (M/F)	18/15

Arm circumference range for the 33 subjects was 23 – 42 cm so the standard cuff was used in 26 of them and the large cuff in the other seven.

Mean BP for all retained measures obtained by standard mercury sphygmomanometer was 139.9 ± 22.8 mmHg and 85.9 ± 16.1 mmHg for the SBP and the DBP respectively.

Mean BP for all measures obtained by the OMRON[®] M6 device was 140.7 ± 22.2 mmHg and 84.0 ± 16.2 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:

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation
Required	One of	25	35	40	
Achieved	SBP	35	43	45	Continue
	DBP	36	41	44	Continue

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:

Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.	Mean diff.	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	83	97	99	Pass	-0.8	4.2
	DBP	84	95	98	Pass	-1.9	3.8

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

Phase 2.2		2/3 ≤5 mmHg	0/3 ≤5 mmHg	Recommendation
Required		≥ 22	≤ 3	
Achieved	SBP	30	0	Pass
	DBP	29	2	Pass

3. Discussion

The objective of the study was to assess the accuracy of the OMRON[®] M6 device according to the international validation protocol (1). 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 OMRON[®] M6 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 acquiries. 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 OMRON M6 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.

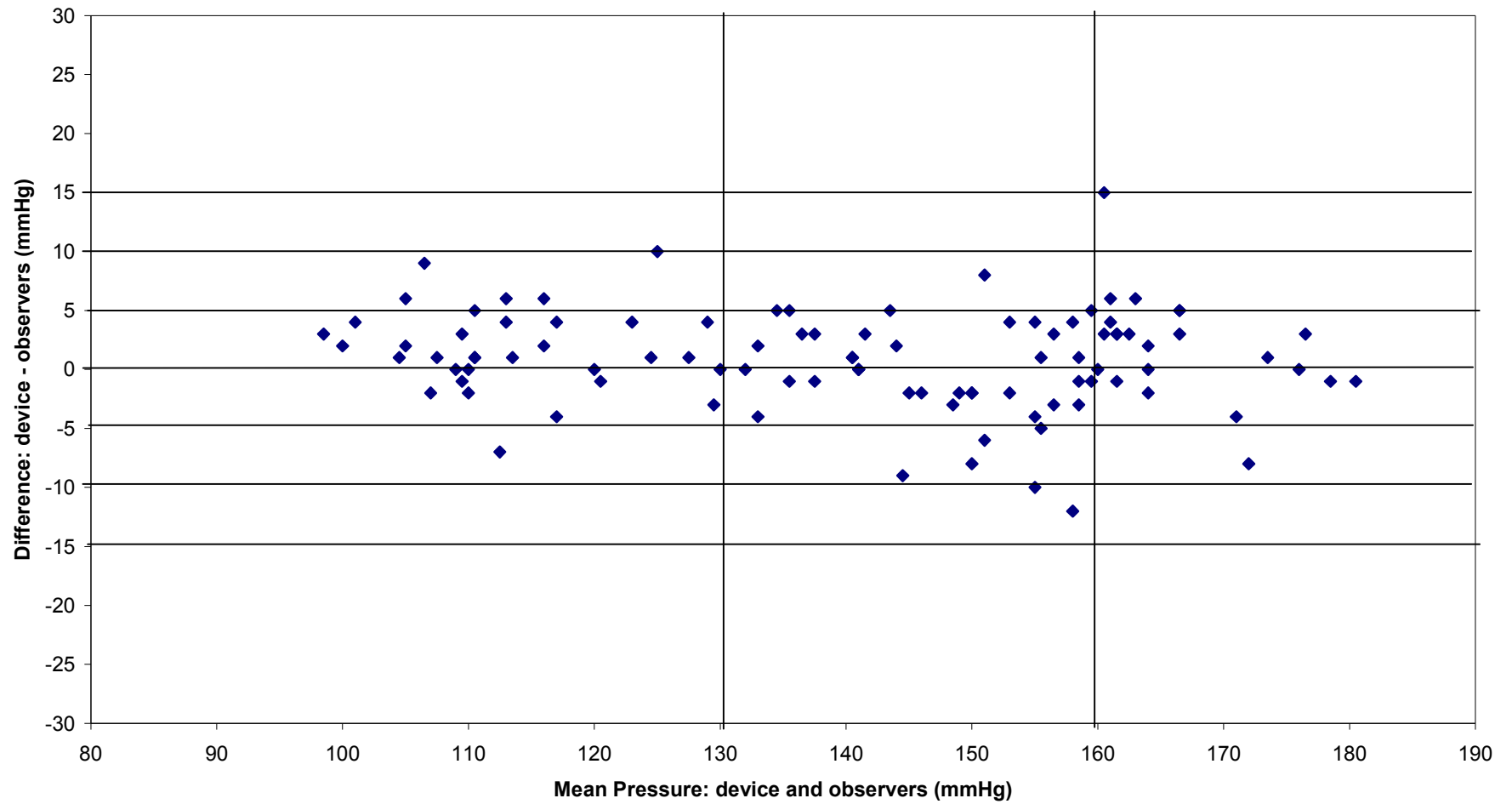
4. Conclusion

The OMRON[®] M6 (HEM-7001-E) device fulfils the recommendations of the international validation protocol.

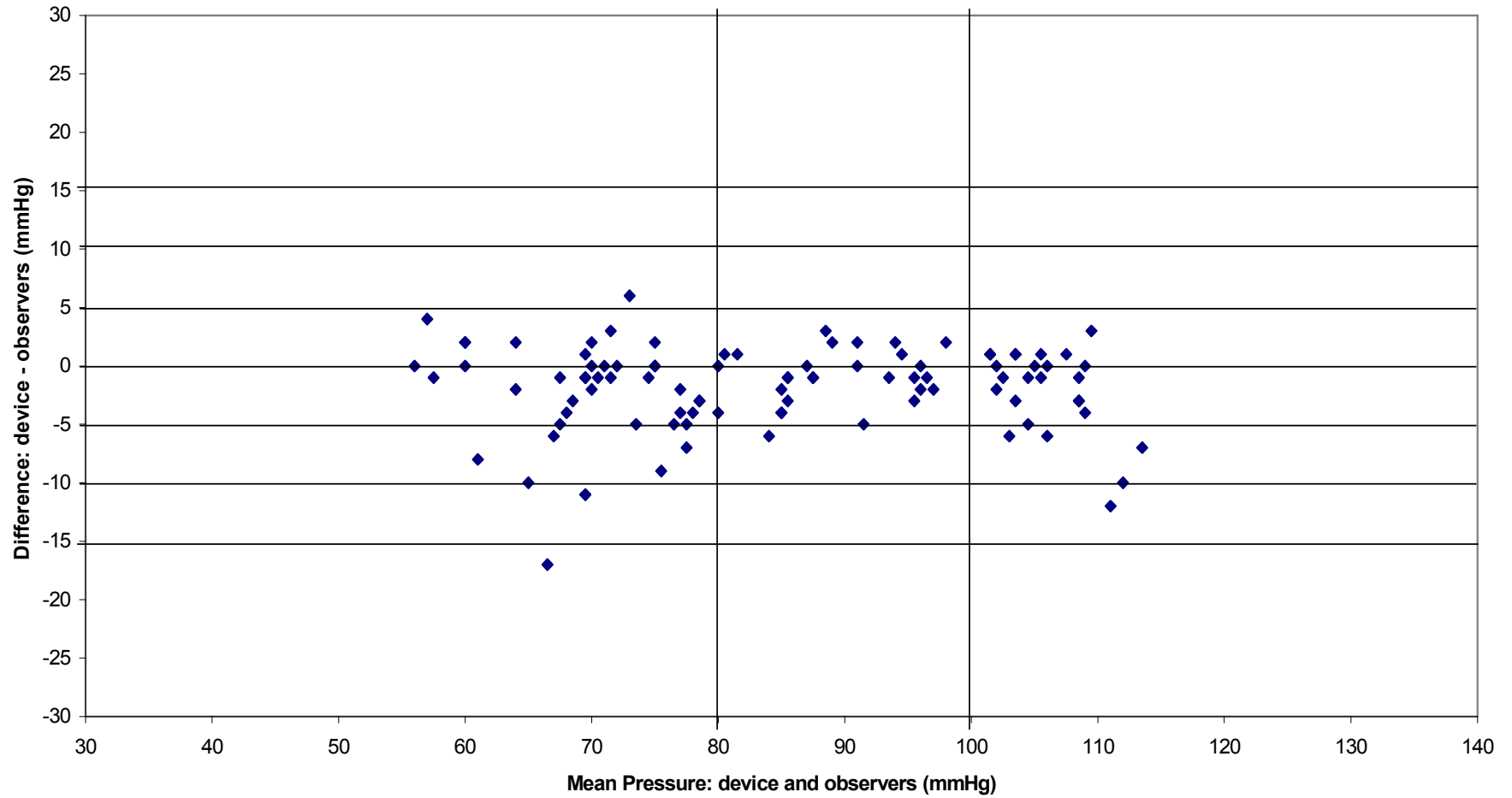
References

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- (3) O'Brien E, Petrie J, Littler WA, de Swiet M, Padfield PL, Altman D, Bland M, Coats A, Atkins N. The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; 11(suppl 2): S43-S62.

Plot of SBP difference between the test device and the mean of the 2 observers in 33 subjects (n=99)



Plot of DBP difference between the test device and the mean of the 2 observers in 33 subjects (n=99)



Individual Data

Number	ID	Age (year)	Sex (1=F, 2= M)	Arm circ. (cm)	BPA-S obs1	BPA-D obs1	BPA-S obs2	BPA-D obs2	BPB-S dev	BPB-D dev
1	1	49	1	23	110	78	110	78	109	64
2	3	60	2	31	172	88	170	86	171	93
3	4	55	2	33	100	64	100	62	98	55
4	5	77	1	27	110	68	110	68	113	70
5	6	76	2	27	164	84	162	86	172	83
6	9	60	1	28	156	100	154	98	157	102
7	10	54	1	28	176	78	176	80	173	88
8	18	50	2	27	126	88	124	86	121	76
9	25	55	2	33	158	110	156	108	169	94
10	26	84	2	26	180	68	178	70	187	68
11	27	58	1	23	164	104	162	102	170	101
12	33	60	2	26	154	120	154	118	148	109
13	39	57	1	30	148	106	148	106	153	104
14	40	48	2	36	150	110	152	108	142	106
15	42	60	2	29	124	82	122	80	128	75
16	8	46	1	27	126	74	124	74	116	76
17	11	70	2	28	146	84	144	84	141	80
18	12	77	1	28	112	74	112	72	121	73
19	14	68	1	28	154	84	154	86	150	79
20	15	38	2	31	132	92	132	90	141	91
21	16	43	2	28	110	64	110	62	107	61
22	17	34	1	31	112	72	110	72	113	69
23	20	41	1	31	144	86	146	86	142	82
24	24	73	2	29	116	70	114	70	120	63
25	28	54	2	28	162	90	164	90	166	92
26	31	74	1	23	164	96	164	96	163	92
27	36	38	2	38	122	64	122	64	125	70
28	41	56	1	29	162	112	162	110	164	111
29	43	66	1	31	174	102	174	100	172	105
30	46	42	1	38	166	102	166	102	168	108
31	47	42	2	42	180	110	178	112	186	108
32	48	56	2	31	158	106	158	104	160	101
33	49	60	2	34	140	108	142	108	141	100

BP1-S obs1	BP1-D obs1	BP1-S obs2	BP1-D obs2	BP3-S obs1	BP3-D obs1	BP3-S obs2	BP3-D obs2	BP5-S obs1	BP5-D obs1	BP5-S obs2	BP5-D obs2
108	78	110	78	110	76	110	74	108	76	110	74
174	92	172	90	176	88	174	84	166	84	162	82
96	60	94	58	100	66	98	64	104	66	100	64
114	70	112	68	116	76	114	76	114	76	116	78
158	88	160	86	154	86	158	88	158	88	158	86
150	94	150	92	154	98	152	96	156	102	154	100
162	88	166	86	164	88	164	86	164	88	164	86
124	78	124	80	126	80	126	80	120	80	122	80
162	108	160	108	152	102	156	104	140	96	144	98
180	72	178	70	172	70	174	70	188	66	184	70
166	96	164	98	172	102	170	100	156	96	158	98
150	120	152	118	162	116	160	118	160	116	160	118
160	108	156	106	148	100	150	102	150	106	152	104
146	110	148	110	148	100	150	102	150	102	150	102
130	82	126	80	134	80	130	80	126	78	128	80
110	76	110	76	108	76	106	74	108	74	108	74
140	80	140	80	134	82	132	82	132	82	132	82
112	72	110	70	112	70	114	70	110	70	110	70
146	78	146	76	136	72	136	72	134	76	136	76
136	88	134	90	136	92	136	90	138	94	138	94
108	64	108	62	108	68	106	68	104	56	104	54
106	70	104	70	110	72	110	70	104	70	104	70
136	86	134	86	132	80	132	80	122	80	122	80
116	66	116	66	100	60	98	60	98	58	96	58
162	92	164	90	156	88	158	88	156	88	156	88
158	88	158	88	140	78	142	78	130	68	132	68
120	64	122	66	120	70	120	70	118	70	120	70
160	114	160	112	158	112	160	110	156	106	158	104
164	96	166	96	154	96	154	96	160	90	160	90
158	106	160	106	160	110	160	110	150	102	152	104
180	110	178	108	182	104	180	106	178	102	174	102
162	110	160	110	166	110	168	108	152	108	150	106
140	98	140	98	136	94	138	94	140	104	140	102

BP7-S obs1	BP7-D obs1	BP7-S obs2	BP7-D obs2	BP2-S dev	BP2-D dev	BP4-S dev	BP4-D dev	BP6-S dev	BP6-D dev	BPA-S obs2	BPA-D obs2
108	76	108	74	109	58	111	64	106	64	110	78
162	88	160	86	178	85	169	85	164	90	170	86
104	68	100	66	103	61	111	63	108	57	100	62
110	70	112	72	117	70	119	71	109	69	110	68
156	86	158	88	163	83	159	84	164	81	162	86
152	98	150	98	168	95	156	99	158	102	154	98
152	86	156	86	169	83	152	87	148	84	176	80
120	82	120	80	125	80	120	76	120	71	124	86
148	108	146	104	146	101	152	104	155	105	156	108
180	68	182	70	174	71	169	69	180	71	178	70
164	104	160	102	163	95	153	96	161	94	162	102
160	118	160	118	149	105	150	107	157	110	154	118
154	108	152	106	155	108	155	102	157	106	148	106
150	110	150	108	145	107	140	102	148	108	152	108
130	78	130	80	137	82	128	74	130	75	122	80
110	76	110	74	110	74	113	75	111	75	124	74
142	82	140	80	143	81	138	78	141	74	144	84
110	70	112	70	114	60	119	66	115	64	112	72
126	70	128	72	144	71	139	72	138	70	154	86
140	94	140	94	131	91	135	95	137	93	132	90
108	60	106	58	111	65	105	59	108	61	110	62
102	74	100	74	109	65	116	67	106	76	110	72
126	82	128	80	132	77	134	77	131	75	146	86
90	56	90	56	109	60	101	57	100	56	114	70
152	92	152	92	165	87	162	87	160	90	164	90
132	70	130	70	146	76	141	67	128	70	164	96
118	70	120	70	125	69	130	76	115	73	122	64
160	110	160	108	163	107	162	102	159	105	162	110
158	90	158	90	168	96	163	95	153	92	174	100
160	104	160	106	158	106	166	107	160	104	166	102
182	108	182	108	178	109	176	104	168	111	178	112
142	106	144	106	164	103	149	102	145	100	158	104
150	104	150	104	141	96	141	89	147	102	142	108

BPA-S obs1: Entry systolic BP taken by Observer1.
BPA-D obs1: Entry diastolic BP taken by Observer1.
BPA-S obs2: Entry SBP taken by Observer2.
BPA-D obs2: Entry DBP taken by Observer2.
BPB-S dev: Device detection SBP given by Omron M6 device.
BPB-D dev: Device detection DBP given by Omron M6 device.
BP1-S obs1: SBP first measurement taken by Observer1.
BP1-D obs1: DBP first measurement taken by Observer1.
BP1-S obs2: SBP first measurement taken by Observer2.
BP1-D obs2: DBP first measurement taken by Observer2.
BP3-S obs1: SBP second measurement taken by Observer1.
BP3-D obs1: DBP second measurement taken by Observer1.
BP3-S obs2: SBP second measurement taken by Observer2.
BP3-D obs2: DBP second measurement taken by Observer2.
BP5-S obs1: SBP third measurement taken by Observer1.
BP5-D obs1: DBP third measurement taken by Observer1.
BP5-S obs2: SBP third measurement taken by Observer2.
BP5-D obs2: DBP third measurement taken by Observer2.
BP7-S obs1: SBP fourth measurement taken by Observer1.
BP7-D obs1: DBP fourth measurement taken by Observer1.
BP7-S obs2: SBP fourth measurement taken by Observer2.
BP7-D obs 2: DBP fourth measurement taken by Observer2.
BP2S dev: SBP first measurement given by Omron M6 device.
BP2D dev: DBP first measurement given by Omron M6 device.
BP4S dev: SBP second measurement given by Omron M6 device.
BP4D dev: DBP second measurement given by Omron M6 device.
BP6S dev: SBP third measurement given by Omron M6 device.
BP6D dev: DBP third measurement given by Omron M6 device.