

Validation of the G-CARE ELECTRONICS SP-800 Vital Signs Monitor
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 G-CARE ELECTRONICS® SP-800 Vital Signs Monitor 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 G-CARE ELECTRONICS® SP-800 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 automatic by a micro pump. Deflation is automatic by constant air release solenoid valve. The unit weighs approximately 1.4 kg (3 hours quick charge for 8 hours normal ward operation). The included cuff is applicable to arm circumferences ranging from 230 to 330 mm. Optional small cuffs (211 – 266 mm), adult cuffs (254 – 343 mm), and large adult cuffs (270 – 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 20 to 300 mmHg and pulse from 40 to 200 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 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 G-CARE ELECTRONICS® SP-800 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:

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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 0.56 ± 4.16 mmHg and -0.13 ± 3.37 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 sustained arrhythmia.

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Table 1: characteristics of the subjects:

Number of subjects	33
Age (years)	48 ± 11
Arm circumference (cm)	30 ± 3
Gender (M/F)	18/15

Arm circumference range for the 33 subjects was 23 – 37 cm so the standard cuff was used in 28 of them and the large cuff in the other 5.

Mean BP for all retained measures obtained by standard mercury sphygmomanometer was 139.65 ± 22.31 mmHg and 85.98 ± 16.37 mmHg for the SBP and the DBP respectively.

Mean BP for all measures obtained by the G-CARE Electronics device was 140.20 ± 22.92 mmHg and 85.82 ± 16.42 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	39	43	45	Continue
	DBP	43	45	45	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	82	96	99	Pass	0.6	4.2
	DBP	88	98	99	Pass	-0.2	3.4

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	31	1	Pass
	DBP	31	0	Pass

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3. Discussion

The objective of the study was to assess the accuracy of the G-CARE ELECTRONICS® SP-800 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 G-CARE ELECTRONICS® SP-800 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 G-CARE Electronics 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

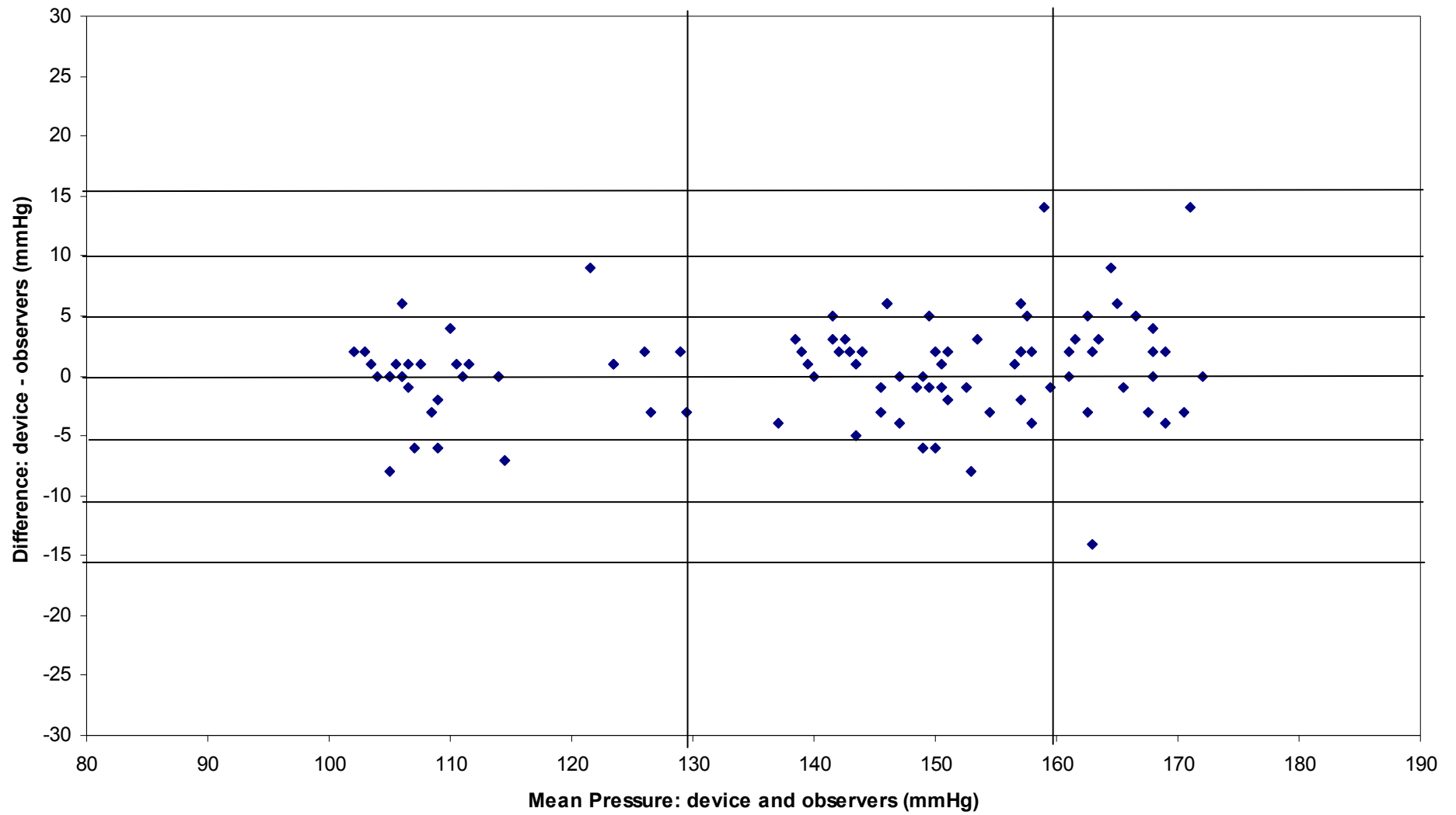
The G-CARE ELECTRONICS® SP-800 Vital Signs Monitor device fulfils the recommendations of the international validation protocol.

References

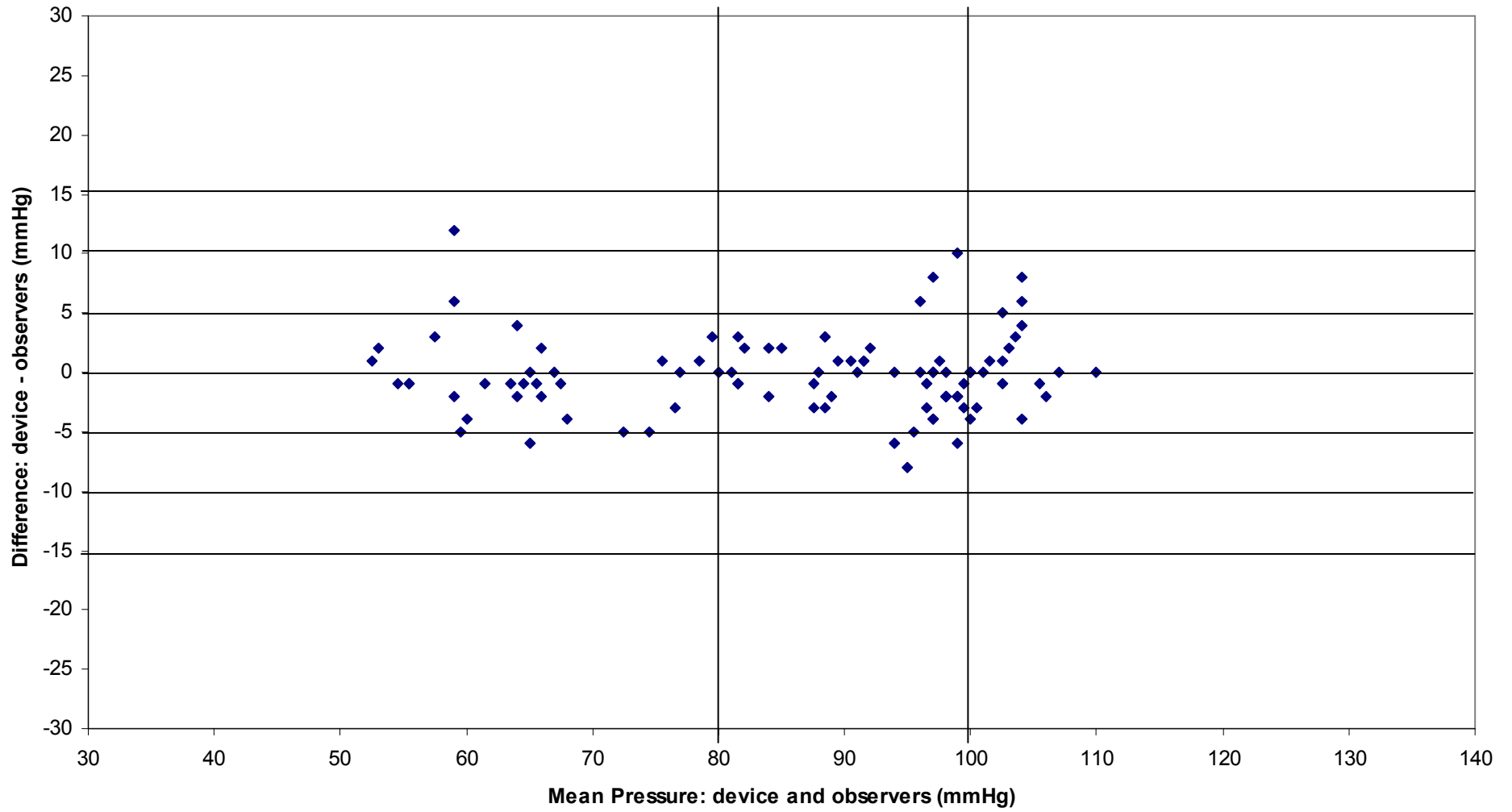
- (1) O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, Mengden T, Imai Y, Waeber B, Palatini P. Working Group on Blood Pressure Monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; 7:3-17.
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**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	37	2	30	116	72	122	73	110	78
2	2	78	2	28	110	76	109	66	106	68
3	3	51	1	31	126	94	122	99	134	94
4	4	59	2	30	144	88	146	90	150	94
5	5	46	1	30	146	90	154	95	150	90
6	7	59	2	29	160	88	163	91	154	84
7	8	45	2	27	154	76	153	82	150	76
8	10	49	2	32	144	100	158	95	142	94
9	21	34	1	26	124	78	125	80	126	78
10	23	71	2	29	110	64	112	66	110	66
11	24	49	1	33	170	102	163	101	170	102
12	25	56	2	32	160	104	169	102	164	102
13	26	53	1	33	164	102	167	96	164	102
14	27	42	2	32	170	102	166	100	164	102
15	28	54	2	30	174	106	168	100	172	102
16	9	58	2	33	172	88	161	93	162	88
17	11	47	1	28	158	88	152	92	152	86
18	14	57	2	31	162	100	160	97	160	102
19	15	41	2	31	164	94	157	99	160	98
20	19	55	2	32	150	98	145	98	140	98
21	20	47	1	30	158	94	154	94	154	90
22	29	55	2	31	162	102	162	101	180	102
23	30	50	1	30	168	104	167	102	158	92
24	31	47	2	37	162	104	160	101	140	102
25	32	56	1	32	158	102	165	95	146	106
26	34	47	2	31	142	104	152	98	148	100
27	35	57	1	27	152	106	157	99	154	104
28	36	32	1	23	102	58	108	61	102	60
29	37	33	1	25	114	56	111	59	114	46
30	38	31	2	30	114	60	108	57	110	52
31	39	42	1	26	100	62	93	66	94	64
32	40	31	1	25	122	54	117	60	120	52
33	41	30	1	24	104	64	103	73	110	68

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
110	78	108	78	108	80	108	76	108	78	116	74
106	68	106	70	106	70	102	68	100	66	104	66
134	94	128	94	128	94	136	96	138	96	132	98
152	96	144	80	142	82	138	82	140	84	150	88
150	90	140	90	140	88	144	88	142	88	142	90
156	84	146	80	146	80	146	86	148	88	132	80
150	76	150	78	148	78	148	74	146	74	150	76
142	92	142	90	144	90	136	96	138	94	136	92
124	76	122	78	122	78	124	80	122	80	126	80
110	64	114	70	114	70	110	68	110	66	114	64
168	102	180	100	180	98	170	104	170	102	162	98
164	102	160	100	160	100	168	106	166	106	168	108
164	102	174	110	176	110	168	110	166	110	168	106
164	100	156	98	158	98	160	102	160	102	154	102
174	100	170	102	172	102	172	108	172	106	174	106
162	90	156	90	156	92	158	90	156	90	172	90
150	88	150	86	150	84	142	84	140	80	148	84
160	102	154	100	156	100	152	100	152	102	156	100
160	96	158	98	158	98	152	90	154	90	158	94
140	96	138	100	140	100	140	100	142	100	142	98
152	90	152	92	152	90	154	92	154	90	146	90
178	102	160	100	160	102	162	96	162	98	160	100
160	94	166	100	166	100	160	98	162	98	162	100
138	100	150	104	150	102	154	100	152	102	162	100
148	104	150	102	150	102	156	100	156	100	148	100
150	100	140	100	142	100	138	98	138	100	134	100
154	102	150	102	152	102	152	98	152	100	150	100
104	60	102	62	104	62	106	62	104	62	106	66
114	48	112	56	112	56	110	50	110	52	110	52
110	52	106	62	106	62	106	52	104	52	110	56
94	64	102	62	102	62	108	70	106	70	108	72
120	52	118	54	118	52	110	56	112	56	114	52
110	68	104	68	106	68	104	64	106	66	104	68

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
118	76	111	75	112	72	126	70	116	70
106	66	106	67	103	65	105	65	110	74
130	98	130	104	125	94	128	96	126	96
148	88	150	83	149	81	144	85	146	88
142	90	140	86	145	87	144	88	146	90
134	82	141	86	152	90	147	90	160	90
148	74	145	81	148	79	144	76	154	78
136	88	149	99	145	88	140	87	146	100
126	80	127	77	124	83	124	80	126	78
114	66	107	67	114	67	114	65	110	66
160	96	166	103	156	97	161	96	168	102
168	106	178	105	163	99	168	105	162	104
168	108	169	99	169	110	170	107	164	100
154	100	161	101	169	93	159	104	168	100
174	106	167	98	172	105	169	102	176	104
170	90	158	90	159	91	149	91	170	86
150	80	149	83	144	81	151	81	158	90
156	100	162	100	160	98	158	98	162	100
156	92	156	91	152	95	147	101	164	96
142	100	143	97	140	100	144	97	148	98
146	90	146	92	150	93	145	92	158	96
160	100	165	106	164	98	156	97	162	100
162	98	165	105	170	108	165	98	166	104
162	100	135	102	151	102	168	107	162	102
148	100	152	98	157	100	153	98	158	100
134	100	149	100	143	97	140	91	144	102
152	98	160	96	155	95	166	95	152	106
106	66	109	58	104	58	105	61	102	60
108	52	106	55	104	55	101	53	114	56
110	54	107	54	106	57	105	54	112	60
108	72	104	63	108	66	106	66	98	62
112	54	111	65	111	62	112	59	122	54
104	68	108	62	106	64	104	63	102	66

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 G-CARE Electronics SP-800 device.
BPB-D dev: Device detection DBP given by G-CARE Electronics SP-800 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 G-CARE Electronics SP-800 device.
BP2D dev: DBP first measurement given by G-CARE Electronics SP-800 device.
BP4S dev: SBP second measurement given by G-CARE Electronics SP-800 device.
BP4D dev: DBP second measurement given by G-CARE Electronics SP-800 device.
BP6S dev: SBP third measurement given by G-CARE Electronics SP-800 device.
BP6D dev: DBP third measurement given by G-CARE Electronics SP-800 device.