

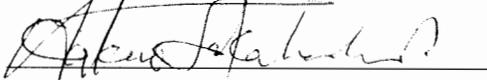
Please complete Section 1 to Section 5 of this form and return it to dabl[®] Educational Trust with copies of the validation plots. In Section 3 to Section 5, complete all boxes except where a study is stopped after Phase 1 – in that case, leave Phase 2 boxes empty. The requirements for each of these sections are detailed below the respective table.

Study Ref.
Do Not Fill

Brand Omron

Model HEM-1020

Investigator Takahashi H, Yoshika M, Yokoi T.

Signed 

Date Dec 7, 2012

Section 1: Checklist

- Observer Training Method used: BHS
- Familiarisation Session
- Validation Environment Suitable
- Analysis
 - All boxes in Section 3 to Section 5 completed
 - Plots completed according to protocol
 - SBP X-axis: Range 80 mmHg to 190 mmHg, reference lines at 130 mmHg and 160 mmHg
 - Y-axis: Range -30 mmHg to 30 mmHg; reference lines every 5 mmHg from -15 mmHg to 15 mmHg
 - DBP X-axis: Range 30 mmHg to 140 mmHg, reference lines at 80 mmHg and 100 mmHg
 - Y-axis: Range -30 mmHg to 30 mmHg; reference lines every 5 mmHg from -15 mmHg to 15 mmHg

Section 2: Procedure

Please outline any adjustment to the protocol due to validation in a non-general population or any other exceptional issues relating to the study. If the protocol was followed as written, this section should be left blank.

This form is intended for use only in connection with blood pressure monitor validation studies carried out in accordance with the protocol of the European Society of Hypertension: O'Brien E et al. International protocol for validation of blood pressure measuring devices in adults. Blood Press Monit 2002;7:3-17

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Section 3: Screening and Recruitment Details

Screening and Recruitment		Phase 2 Recruitment Ranges (mmHg)	
Total Screened	44 1	Low (90 – 129)	11 11
Why Eliminated		SBP	
Ranges Complete	12 2	Medium (130 – 160)	11 12
BP out of Range	1 3	High (161 – 180)	11 13
Arrhythmias	3 4		
Poor Quality Sounds	5 5	DBP	
Other Reasons*	7 6	Low (40 – 79)	11 14
Total Eliminated	28 7	Medium (80 – 100)	11 15
		High (101 – 130)	11 16
Total Recruited	82 8		
Subjects with both SBP and DBP used	22 9		
Subjects with one of SBP or DBP used	22 10		
*Explanation	Body motion (4), Arm Circumference out of Range (2), Abort of measurement (1)		17

- Legend:
- Box 1 The total number of subjects screened, regardless of whether or not they were included in the study.
 - Box 2 The number eliminated because both SBP and DBP fell into ranges for which there were already 11 subjects included.
 - Box 3 The number eliminated because (a) SBP was out of range (< 90 mmHg or > 180 mmHg) and DBP fell into a range for which there were already 11 subjects included. (b) DBP was out of range (< 40 mmHg or > 130 mmHg) and SBP fell into a range for which there were already 11 subjects included (c) both SBP and DBP were out of range.
 - Box 4 The number eliminated due to arrhythmias.
 - Box 5 The number eliminated due to an inability to auscultate their BP accurately due to poor quality sounds regardless of the reason for the lack of quality.
 - Box 6 The number eliminated for reasons not covered in boxes 2 to 5. An explanation must be provided in Box 17.
 - Box 7 The total number eliminated. This equals the sum of boxes 2 to 6
 - Box 8 The total recruited equals the number screened (Box 1) less the number eliminated (Box 7). Box 8 also equals Box 9 plus Box 10.
 - Box 9 The number of subjects where both SBP and DBP fell into recruitment ranges with less than 11 subjects already included
 - Box 10 The number of subjects where only one of SBP or DBP fell into recruitment ranges with less than 11 subjects already included but where the other pressure either fell into a range for which there were already 11 subjects included or where it was out of range. Box 9 plus half Box 10 must equal 33.
 - Boxes 11-16 These must each equal 11 in a completed study. They may be less if a device is eliminated at Phase 1.
 - Box 17 An explanation of those listed as excluded in Box 6.

Section 4: Subject Details

		Phase	2 18
		SBP	DBP
Sex	Male:Female	16:17 19	17:16 20
Age (years)	Range (Low:High)	34-85 21	34-85 22
	Mean (SD)	63(13) 23	60(14) 24
Arm Circumference (cm)	Range (Low:High)	22:31 25	22:31 26
	Mean (SD)	27(2) 27	27(3) 28
Cuff	Standard	33 29	33 30
	Large (> 35 cm)	0 31	0 32
Recruitment BP (mmHg)	Range (Low:High)	108:176 33	51:120 34
	Mean (SD)	144(22) 35	88(17) 36

If the study was terminated at Phase 1, please complete this table for those 15 subjects only; otherwise complete it for all included subjects. If the same subjects are used for both SBP and DBP in all cases, then the DBP and SBP columns will be the same for boxes 19 to 32. The values in this table refer only to the 15 (Phase 1) or 33 (Phase 2) subjects analysed for the respective pressure. Eliminated subjects are not included. Subjects in whom only one pressure is analysed are included only for that pressure.

- Legend:
- Box 18 Enter the phase at which the study was completed.
 - Boxes 19-20 Enter the number of males, a colon and the number of females e.g. 16:17. They should total 15, if the final phase is Phase 1, or 33, if it is Phase 2.
 - Boxes 21-22 Enter the age of the youngest subject, a colon and the age of the oldest subject e.g. 31:74.
 - Boxes 23-24 Enter the mean and, in parentheses, the SD of the subject ages. Values should be rounded to the nearest integer. e.g. 52 (12).
 - Boxes 25-26 Enter the smallest arm circumference, a colon and the largest arm circumference e.g. 24:34.
 - Boxes 27-28 Enter the mean and, in parentheses, the SD of the subject arm circumferences. Values should be rounded to the nearest integer. e.g. 29 (3).
 - Boxes 29-30 Enter the number of subjects on whom a standard cuff was used.
 - Boxes 31-32 Enter the number of subjects on whom a large cuff was used. If no large cuff was supplied these boxes should contain an "X". If a large cuff was supplied but not used, these boxes should contain a zero.
 - Boxes 33-34 Enter the lowest pressure, a colon and the highest pressure from Observer A measurements only e.g. 104:180.
 - Boxes 35-36 Enter the mean and, in parentheses, the SD of the subject pressures from Observer A measurements only. Values should be rounded to the nearest integer. e.g. 140 (20)

Section 5: Validation Results

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Phase 1 Result														
Required	One of	25	35	40															
Achieved	SBP	<table border="1"><tr><td>38</td><td>37</td></tr></table>	38	37	<table border="1"><tr><td>44</td><td>39</td></tr></table>	44	39	<table border="1"><tr><td>45</td><td>41</td></tr></table>	45	41	<table border="1"><tr><td>Continue</td><td>43</td></tr></table>		Continue	43					
	38	37																	
44	39																		
45	41																		
Continue	43																		
DBP	<table border="1"><tr><td>37</td><td>38</td></tr></table>	37	38	<table border="1"><tr><td>45</td><td>40</td></tr></table>	45	40	<table border="1"><tr><td>45</td><td>42</td></tr></table>	45	42	<table border="1"><tr><td>Continue</td><td>44</td></tr></table>		Continue	44						
37	38																		
45	40																		
45	42																		
Continue	44																		
Phase 2.1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Phase 2.1 Result	Mean	SD												
Required	Two of	65	80	95															
	All of	60	75	90															
Achieved	SBP	<table border="1"><tr><td>76</td><td>45</td></tr></table>	76	45	<table border="1"><tr><td>95</td><td>47</td></tr></table>	95	47	<table border="1"><tr><td>98</td><td>49</td></tr></table>	98	49	<table border="1"><tr><td>Pass</td><td>51</td></tr></table>	Pass	51	<table border="1"><tr><td>-1.9</td><td>53</td></tr></table>	-1.9	53	<table border="1"><tr><td>4.7</td><td>55</td></tr></table>	4.7	55
	76	45																	
95	47																		
98	49																		
Pass	51																		
-1.9	53																		
4.7	55																		
DBP	<table border="1"><tr><td>77</td><td>46</td></tr></table>	77	46	<table border="1"><tr><td>93</td><td>48</td></tr></table>	93	48	<table border="1"><tr><td>96</td><td>50</td></tr></table>	96	50	<table border="1"><tr><td>Pass</td><td>52</td></tr></table>	Pass	52	<table border="1"><tr><td>-1.5</td><td>54</td></tr></table>	-1.5	54	<table border="1"><tr><td>5.2</td><td>56</td></tr></table>	5.2	56	
77	46																		
93	48																		
96	50																		
Pass	52																		
-1.5	54																		
5.2	56																		
Phase 2.2		$2/3 \leq 5 \text{ mmHg}$		$0/3 \leq 5 \text{ mmHg}$	Phase 2.2 Result	Overall Result													
Required		≥ 22		≤ 3															
Achieved	SBP	<table border="1"><tr><td>28</td><td>57</td></tr></table>		28	57	<table border="1"><tr><td>0</td><td>59</td></tr></table>	0	59	<table border="1"><tr><td>Pass</td><td>61</td></tr></table>	Pass	61	<table border="1"><tr><td>Pass</td><td>63</td></tr></table>		Pass	63				
	28	57																	
0	59																		
Pass	61																		
Pass	63																		
DBP	<table border="1"><tr><td>26</td><td>58</td></tr></table>		26	58	<table border="1"><tr><td>2</td><td>60</td></tr></table>	2	60	<table border="1"><tr><td>Pass</td><td>62</td></tr></table>	Pass	62	<table border="1"><tr><td>Pass</td><td>64</td></tr></table>		Pass	64					
26	58																		
2	60																		
Pass	62																		
Pass	64																		

- Legend:
- Boxes 37-42 Enter the number of absolute differences between observer and device measurements from Phase 1 falling within 5 mmHg, 10 mmHg and 15 mmHg respectively. Each is at most 45.
 - Box 43 If boxes 37, 39 and 41 fulfil the requirements, then this is "Continue"; otherwise it is "Stop".
 - Box 44 If boxes 38, 40 and 42 fulfil the requirements, then this is "Continue"; otherwise it is "Stop".
 - Boxes 45-50 Enter the number of absolute differences between observer and device measurements from Phase 2 falling within 5 mmHg, 10 mmHg and 15 mmHg respectively. Each is at most 99
 - Box 51 If boxes 45, 47 and 49 fulfil the requirements, then this is "Pass"; otherwise it is "Fail".
 - Box 52 If boxes 46, 48 and 50 fulfil the requirements, then this is "Pass"; otherwise it is "Fail".
 - Boxes 53-54 Enter the mean of the 99 differences between observer and device measurements. (Observer measurements are subtracted from device measurements.) Values should be rounded to one decimal place. e.g. -2.3
 - Boxes 55-56 Enter the standard deviation of 99 differences between observer and device measurements. Values should be rounded to one decimal place. e.g. 4.5
 - Boxes 57-58 Enter the number of subjects with two or three of the absolute differences between observer and device measurements within 5 mmHg. Each is at most 33.
 - Boxes 59-60 Enter the number of subjects with none of the absolute differences between observer and device measurements within 5 mmHg. Each is at most 33.
 - Box 61 If boxes 57 and 59 fulfil the requirements, then this is "Pass"; otherwise it is "Fail".
 - Box 62 If boxes 58 and 60 fulfil the requirements, then this is "Pass"; otherwise it is "Fail".
 - Box 63 If boxes 51 and 61 are both "Pass", then this is "Pass"; otherwise it is "Fail".
 - Box 64 If boxes 52 and 62 are both "Pass", then this is "Pass"; otherwise it is "Fail".