

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I **Daisuke Nozaki**,
Name of a Company Director

a Director of **Omron Healthcare Europe B.V.**,
Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker^a **Omron Healthcare Co., Ltd.** **Address** **53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan**
Manufacturer^b **Omron Healthcare Co., Ltd.** **Address** **53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan**
Brand^c **Omron** **Model^d** **HBP-1100**

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the validated blood pressure measuring device

Maker^a **Omron Healthcare Co., Ltd.** **Address** **53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan**
Manufacturer^b **Omron Healthcare Co., Ltd.** **Address** **53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan**
Brand^c **Omron** **Model^d** **HBP-1300**

Existing validated blood pressure measuring device.

which has previously passed the **ESH2010** protocol, the results of which were published as follows:

dablEducational Trust; 2014 May 22. 4 p. Available from: <http://www.dableducational.org/Publications/2014/ESH-IP-2010-Validation-of-Omron-HBP-1300.pdf>

Full reference

The only differences between the devices involve the following components:

Tick one box for each item 1–18.

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^g <input type="checkbox"/>

An explanation of each item ticked "Yes" must be included in **Section B** or on a separate sheet.

- Notes:
- a Provide the name and address of the actual maker of the device.
 - b Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
 - c Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
 - d Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
 - e Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
 - f Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
 - g Only tick N/A (Not Applicable) if neither device provides printing, communication or other facilities, as appropriate.

SECTION B An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

9) The model number is changed to HBP-1100 (HBP-1100-E) from HBP-1300 (HBP-1300-E).

10) [Power On/OFF] button, [STRAT/STOP] button and [Auscultation] button are added to HBP-1100.

There are no [MODE] button, Right-POINTING TRIANGLE and Left-POINTING TRIANGLE button, and [START/STOP] button (Power ON/OFF) on HBP-1100.

11) Zero indicator icon and Battery replacement icon are added to HBP-1100.

There are no Memory icon, Battery charge level icon, Charge icon, and Inflation setting icon on HBP-1100

13) There is no function of setting initial inflation pressure value on HBP-1100.

14) There is no memory storage function on HBP-1100.

17) There is no rechargeable battery on HBP-1100.

SECTION C Please check that the following are included with the application

- A manual for the validated device
- A manual for the device for which equivalence is being sought
- An image of the validated device
- An image of the device for which equivalence is being sought
- An image of the screen layout of validated device*
- An image of the screen layout of the device for which equivalence is being sought*

* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

SECTION D Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dableducational.org.

Signature of Director 

Company Stamp/Seal

Name Daisuke Nozaki

Date 23 May 2014



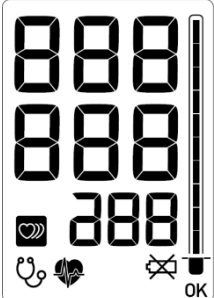
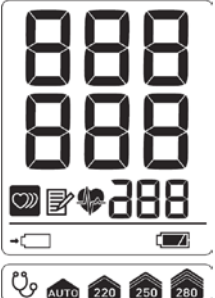
Signature of Witness 

Name Tomohiro Kukita

Address 23 May 2014

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Comparison of the Omron HBP-1100 with the Omron HBP-1300

Devices	Omron HBP-1100	Omron HBP-1300
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy $\pm 5\%$ 1, 5</p> <p>Calibration facility 18</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>SBP 60 mmHg – 250 mmHg, DBP 40 mmHg – 200 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm – 200 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p>Press button to note SBP & DBP (Auscultation mode) 18</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy $\pm 5\%$ 1, 5</p> <p>Calibration facility 18</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>SBP 60 mmHg – 250 mmHg, DBP 40 mmHg – 200 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm – 200 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p>Press button to note SBP & DBP (Auscultation mode) 18</p>

Devices	Omron HBP-1100	Omron HBP-1300
Same Criteria	<p>Measurement</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg – 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Manual Inflation option 7</p> <p>Zero pressure check before inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Extra Large (Arm circ. 42 to 50 cm) (Optional) GS CUFF XL 6</p> <p>Large (Arm circ. 32 to 42 cm) (Optional) GS CUFF L 6</p> <p>Medium (Arm circ. 22 to 32 cm) GS CUFF M 6</p> <p>Small (Arm circ. 17-22 cm) (Optional) GS CUFF S 6</p> <p>Extra Small (Arm circ. 12-18 cm) (Optional) GS CUFF SS 6</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Auscultation mode icon 11, 14</p> <p><i>Measurement Procedure</i></p> <p>Manual Inflation 11</p> <p>During Measurement: BP Level & Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error E1, E2, E3 & E9 11</p> <p>Technical Alarm Condition error (Flashing measurement) 11</p> <p>Body movement error (''' ↔ == symbol) 3, 11, 13, 18</p> <p>Irregular heartbeat 11, 13, 18</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p>Body movement error detection 3, 13</p> <p>Casing</p> <p><i>Display</i></p> <p>Segment LCD 10</p>	<p>Measurement</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg – 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Manual Inflation option 7</p> <p>Zero pressure check before inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Extra Large (Arm circ. 42 to 50 cm) (Optional) GS CUFF XL 6</p> <p>Large (Arm circ. 32 to 42 cm) (Optional) GS CUFF L 6</p> <p>Medium (Arm circ. 22 to 32 cm) GS CUFF M 6</p> <p>Small (Arm circ. 17-22 cm) (Optional) GS CUFF S 6</p> <p>Extra Small (Arm circ. 12-18 cm) (Optional) GS CUFF SS 6</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Auscultation mode icon 11, 14</p> <p><i>Measurement Procedure</i></p> <p>Manual Inflation 11</p> <p>During Measurement: BP Level & Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error E1, E2, E3 & E9 + alarm LED 11</p> <p>Technical Alarm Condition error (Flashing measurement) 11</p> <p>Body movement error (''' ↔ == symbol) 3, 11, 13, 18</p> <p>Irregular heartbeat 11, 13, 18</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p>Body movement error detection 3, 13</p> <p>Casing</p> <p><i>Display</i></p> <p>Segment LCD 10</p>

Devices	Omron HBP-1100	Omron HBP-1300
Comparable Criteria	<p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off (Power Label) 10</p> <p>Start/Stop (Start/Stop Label) 10</p> <p><i>Function</i></p> <p>Auscultation mode 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Zero pressure check (bar and OK) 11, 14</p> <p><i>Post Measurement</i></p> <p>Measurement error E1, E2, E3 & E9 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Power error E40 11</p> <p>Casing</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 200 measurements 17</p> <p>AC adapter (S 60240HW5SW) 17</p>	<p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start/Stop Label) 10</p> <p><i>Function</i></p> <p>Backward & Forward 10</p> <p>Mode 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Zero pressure check (□/□) 11, 14</p> <p><i>Post Measurement</i></p> <p>Measurement error E1, E2, E3 & E9 + alarm LED 11</p> <p><i>Power</i></p> <p>Full, Low, Exhausted, Charging & Charged battery 11, 17</p> <p>Power error E40, E41 & E42 + alarm LED 11</p> <p>Casing</p> <p><i>Display</i></p> <p>Dual screen display 10</p> <p><i>Power</i></p> <p>Rechargeable battery pack 17</p> <p>AC adapter (ADAPTER-E1600/ ADAPTER-UK1600) 17</p>
Device 2 Criteria		<p>Measurement</p> <p><i>Inflation</i></p> <p>Optional inflation target pressures 7</p> <p><i>Measurement Records</i></p> <p>Memory: 1 measurement (last measurement) 14</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Inflation target selection x 4 11</p> <p><i>Measurement Records</i></p> <p>Memory icon 11</p> <p>Casing</p> <p><i>Power</i></p> <p>Automatic switch-off when not used for 5 or 10 min 17</p> <p><i>Features</i></p> <p>Wall mount kit (Optional) WMKIT-1300 10</p>

Comments	<p>Both of these devices are intended for professional use. The main difference is that the HBP-1100 does not have a facility to select one three set target pressures (220 mmHg, 250 mmHg or 280 mmHg). The HBP-1300 also stores the last measurement and has a selectable automatic stitch-off facility. The HBP-1300 uses a battery pack and has extra error codes relating to that. It also lights an LED whenever there is an error.</p> <p>Both devices perform a zero-pressure check before taking a measurement. The HBP-1100 displays this on a special indicator bar and OK symbol whereas the HBP-1300 just uses the same 7-segment sections as used to display SBP and DBP.</p>
Recommendation	Equivalence is Recommended
Date	27 May 2014