

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

### SECTION A - Please complete all items.

I **Tomohiro Kukita,**  
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<sup>a</sup> **OMRON Healthcare Co., Ltd.** Address **53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan**

Manufacturer<sup>b</sup> **OMRON Healthcare Co., Ltd** Address **53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan**

Brand<sup>c</sup> **OMRON** Model<sup>d</sup> **780-BT (HEM-7081-ITE)**

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<sup>a</sup> **OMRON Healthcare Co., Ltd.** Address **53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan**

Manufacturer<sup>b</sup> **OMRON Healthcare Co., Ltd.** Address **53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan**

Brand<sup>c</sup> **OMRON** Model<sup>d</sup> **M7 (HEM-780-E)**

Existing validated blood pressure measuring device.

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

**Andrew Colemana, Stephen Steela, Paul Freemana, Annemarie de Greeffb, Andrew Shennanb.** Validation of the Omron M7 (HEM-780-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol. Blood Pressure Monitoring 2008, Vol 13 No 1; 49-54

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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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 <sup>f</sup> <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 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 <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A <sup>g</sup> <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. Model name 780-BT (HEM-7081-ITE)

10. No start button, No on/off button, No date and time set button, O/I Start button, User ID selection switch, Bluetooth upload button, Set button.

11. No Average value symbol, No inflation symbol, User ID(A/B) and guest symbol, Date/Time display and movement error symbol and irregular heartbeat symbol. The bluetooth upload symbol. The bluetooth upload symbol blinks and the unit starts transferring the data. The bluetooth result symbol will blink when the pairing result. The DATA/FULL symbol is not displayed when only 0 to 66 measurements results are stored, or if the results have already been sent (when 67 or more results are stored).

13. No function of Average value, Movement error and irregular heartbeat detection.

14. 84 memories for each user (A and B).

16. Includes the bluetooth communication.

**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 Tomohiro Kukita

Company Stamp/Seal

Name Tomohiro Kukita

Date 2 April 2013





Signature of Witness Nozaki Daisuke

Name Nozaki Daisuke

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Comparison of the Omron 708-BT (HEM-7081-ITE) with the Omron M7 (HEM-780-E)

Devices	Omron 708-BT (HEM-7081-ITE)	Omron M7 (HEM-780-E)
Pictures		
Display		
Validation		BHS AAMI
Device 1 Criteria	<p><b>Buttons/Switches</b></p> <ul style="list-style-type: none"> <li>Measurement Records</li> <li>User ID Slider 10</li> </ul> <p><b>Communication</b></p> <ul style="list-style-type: none"> <li>Bluetooth 10</li> </ul> <p><b>Display/Symbols/Indicators</b></p> <p><i>Post Measurement</i></p> <ul style="list-style-type: none"> <li>Body movement error 3, 11, 13, 18</li> <li>Irregular heartbeat 11, 13, 18</li> </ul> <p><i>Measurement Records</i></p> <ul style="list-style-type: none"> <li>Memory recall number (Replaces pulse rate momentarily) 11</li> <li>User (A, B or G [guest]) 11</li> </ul> <p><i>Communication</i></p> <ul style="list-style-type: none"> <li>Bluetooth connection 11, 16</li> <li>Bluetooth transmission reminder (<i>Data Full</i>) 11, 16</li> </ul>	

Devices	Omron 708-BT (HEM-7081-ITE)	Omron M7 (HEM-780-E)
<b>Device 1 Criteria (continued)</b>	<p><b>Display/Symbols/Indicators (continued)</b> <i>Communication (continued)</i></p> <p>Bluetooth transmission result (OK or Err) 11, 16</p> <p><b>Algorithms</b> <i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p>Body movement error detection 3, 13</p>	
<b>Same Criteria</b>	<p><b>Measurement</b> <i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg – 299 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Fuzzy Logic 7</p> <p>Press button if BP &gt; 220 mmHg 7</p> <p>Manually adjustable inflation pressure 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Sensors</i></p> <p>Pressure sensor: capacitive 5</p> <p><b>Buttons/Switches</b> <i>Measurement Records</i></p> <p>Memory × 2 10</p> <p><i>Settings</i></p> <p>(Date/Time) Set <sup>Query 3</sup> 10</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Procedure</i></p> <p>Deflation symbol 11</p> <p>During Measurement: BP Level &amp; Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p>	<p><b>Measurement</b> <i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg – 299 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Fuzzy Logic 7</p> <p>Press button if BP &gt; 220 mmHg 7</p> <p>Manually adjustable inflation pressure 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Sensors</i></p> <p>Pressure sensor: capacitive 5</p> <p><b>Buttons/Switches</b> <i>Measurement Records</i></p> <p>Memory × 2 10</p> <p><i>Settings</i></p> <p>Date/Time set <sup>Query 3</sup> 10</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Procedure</i></p> <p>Deflation symbol 11</p> <p>During Measurement: BP Level &amp; Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p>

Devices	Omron 708-BT (HEM-7081-ITE)	Omron M7 (HEM-780-E)
Same Criteria (continued)	<p><b>Display/Symbols/Indicators (continued)</b></p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low/Exhausted battery 11, 17</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 300 measurements 17</p> <p>AC adapter (Optional – R-Adapter 9997695-0) 17</p>	<p><b>Display/Symbols/Indicators (continued)</b></p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 300 measurements 17</p> <p>AC adapter (Optional) 17</p>
Comparable Criteria	<p><b>Measurement</b></p> <p><i>Cuffs</i></p> <p>Single (Arm circ. 22 to 42 cm) (Comfort Cuff 9956685-4)<sup>Query 1</sup> 6</p> <p><i>Measurement Records</i></p> <p>Memory: 84 measurements × 2 users 14</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Start Label) 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Post Measurement</i></p> <p>Measurement error <math>EE, E, E/E</math> and <math>E_r \geq 5</math><sup>Query 2</sup> 11</p> <p><i>Measurement Records</i></p> <p>Memory icon 11</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p><i>Power</i></p> <p>Automatic switch-off when not used for 2 min 17</p>	<p><b>Measurement</b></p> <p><i>Cuffs</i></p> <p>Single 150 mm × 582 mm (Circ. 22 to 42 cm) (HEM-CUFF-P)<sup>Query 1</sup> 6</p> <p><i>Measurement Records</i></p> <p>Memory: 90 measurements 14</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Stop (O/I Label) 10</p> <p>Start 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Post Measurement</i></p> <p>Measurement error <math>EE, E, E/E</math> and <math>E_r</math><sup>Query 2</sup> 11</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 11</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Dual screen display 10</p> <p><i>Power</i></p> <p>Automatic switch-off when not used for 5 min 17</p>
Device 2 Criteria		<p><b>Measurement</b></p> <p><i>Inflation</i></p> <p>Zero pressure check before inflation 7</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Preparation</i></p> <p>Zero cuff pressure check 11, 13, 18</p>

Devices	Omron 708-BT (HEM-7081-ITE)	Omron M7 (HEM-780-E)
Device 2 Criteria (continued)		<p><b>Measurement (continued)</b></p> <p><i>Measurement Procedure</i></p> <p>Inflation symbol 11</p> <p><i>Post Measurement</i></p> <p>Average "AVG" symbol 11, 13, 14</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p>

Queries	1	<p>Query The declaration firm indicates that there are no differences between the cuffs for the two devices. According to the respective manuals, the cuff for the 708-BT (HEM-7081-ITE) is the <i>Comfort Cuff 9956685-4</i>, while that for the M7 (HEM-780-E) is the <i>HEM-CUFF-P</i>. Please explain this anomaly.</p> <p>Response <i>These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.</i></p> <p>Comment The explanation is accepted.</p>
	2	<p>Query Is the error code Er25 (Device error) in the 708-BT triggered for the same reasons as the error code Er (Abnormal memory function) in the M7?</p> <p>Response <i>Yes, these indicate same error "device error".</i></p> <p>Comment The explanation is accepted</p>
	3	<p>Query According to the declaration, the 708-BT has "no date and time set button", as in the M7, but does have a "set button". However, from the manuals, the respective buttons appear to have identical functions. Why is a difference in buttons, as distinct from a difference in a button name, declared?</p> <p>Response <i>The difference is only the name of the button. The function itself is same. We will correct the declaration if necessary.</i></p> <p>Comment The explanation is accepted; a new declaration is unnecessary.</p>
Note	1	Though the styles of the two devices are different, that if the 708-BT (HEM-7081-ITE) is similar to other devices in the same family as the M7 (HEM-780-E). These too have the newer cloth covers for the cuffs. The main differences are the removal of the averaging feature and the introduction of the irregular heartbeat detection, body movement detection and a facility to transmit data via Bluetooth to a device set up to read the transmitted data. None of these features affects blood pressure measurement.
Recommendation	The queries were adequately answered. Equivalence is recommended.	
Date	03/05/2013	