

**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>** M2 (HEM-7121-E)

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>** HEM-7130

Existing validated blood pressure measuring device.

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

dablEducational Trust; 2013 Nov 14. 4 p. Available from: <http://www.dableducational.org/Publications/2013/ESH-IP-2010-Validation-of-Omron-HEM-7130.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 <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 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 <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" 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) The model number is changed to M2 (HEM-7121-E) from HEM-7130.
- 10) The Up/Down buttons and the Date/Time setting button are removed from the M2.
- 11) The Average value symbol, the Date/Time display and the movement error symbol are removed from the M2.
- 13) The average reading recently 3times with 10minutes function, the body movement detection function and the clock function are removed from the M2.
- 14) The memory capacity has 1 user 30sets.

**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](mailto:info@dableducational.org).

Signature of Director Tomohiro Kukita

Company Stamp/Seal

Name Tomohiro Kukita

Date 17 Mar, 2014



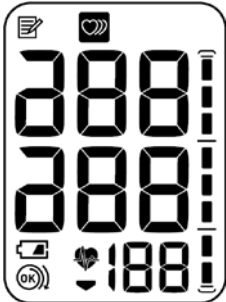

Signature of Witness Anita Kecskes

Name Anita Kecskes

Address 17 Mar, 2014

OMRON HEALTHCARE EUROPE BV  
Scorpius 33  
NL-2132 LR Hoofddorp  
P.O.BOX 2050 NL-2130 GL Hoofddorp  
TEL +31-23 5544700  
FAX +31-23 5544701

Comparison of the Omron M2 (HEM-7121-E) with the Omron HEM-7130 (Japanese model)

Devices	Omron M2 (HEM-7121-E)	Omron HEM-7130 (Japanese model) <sup>Query 4</sup>
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		
Same Criteria	<p><b>Measurement</b></p> <p><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>BP 0 mmHg to 299 mmHg <sup>Query 1</sup> 1, 5, 7, 8</p> <p>Pulse 40 bpm to 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 to 299 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p>	<p><b>Measurement</b></p> <p><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>BP 0 mmHg to 299 mmHg <sup>Query 1</sup> 1, 5, 7, 8</p> <p>Pulse 40 bpm to 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 to 299 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p>

Devices	Omron M2 (HEM-7121-E)	Omron HEM-7130 (Japanese model) <sup>Query 4</sup>	
<b>Same Criteria (continued)</b>	<b>Measurement (continued)</b>	<b>Measurement (continued)</b>	
	<i>Inflation (continued)</i>	<i>Inflation (continued)</i>	
	Fuzzy Logic	7	Fuzzy Logic
	Press button if BP > 210 mmHg	7	Press button if BP > 210 mmHg
	<i>Deflation</i>		<i>Deflation</i>
	Automatic Deflation	8	Automatic Deflation
	<i>Cuffs</i>		<i>Cuffs</i>
	Large (Arm circ. 22 cm to 42 cm) No. HEM-RML31 (Optional)	6	Large (Arm circ. 22 cm to 42 cm) No. HEM-RML31 (Optional) <sup>Query 2</sup>
	Medium (Arm circ. 22 cm to 32 cm) No. HEM-CR24	6	Medium (Arm circ. 22 cm to 32 cm) No. HEM-CR24 <sup>Query 2</sup>
	Small (Arm circ. 17 cm to 22 cm) No. HEM-CS24 (Optional) <sup>Query 2</sup>	6	Small (Arm circ. 17 cm to 22 cm) No. HEM-CS24 (Optional) <sup>Query 2</sup>
	<b>Buttons/Switches</b>		<b>Buttons/Switches</b>
	<i>Power</i>		<i>Power</i>
	On/Off with Start/Stop (Start/Stop Label)	10	On/Off with Start/Stop (Start/Stop Label)
	<i>Measurement Records</i>		<i>Measurement Records</i>
	Memory	10	Memory
	<b>Display/Symbols/Indicators</b>		<b>Display/Symbols/Indicators</b>
	<i>Measurement Procedure</i>		<i>Measurement Procedure</i>
	Deflation symbol	11	Deflation symbol
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat
	<i>Post Measurement</i>		<i>Post Measurement</i>
	SBP, DBP and Pulse	11	SBP, DBP and Pulse
	Measurement error E1 E2 E3 E4 E5 Er	11	Measurement error E1 E2 E3 E4 E5 Er
	Hypertension (Indicator strip) <sup>Query 3</sup>	11, 13	Hypertension (Indicator strip) <sup>Query 3</sup>
	Irregular heartbeat	11, 13, 18	Irregular heartbeat
	Correct cuff wrapping indicator	11, 13, 18	Correct cuff wrapping indicator
	<i>Measurement Records</i>		<i>Measurement Records</i>
	Memory icon	11	Memory icon
	Memory recall number (Replaces pulse rate momentarily)	11	Memory recall number (Replaces pulse rate momentarily)
<i>Power</i>		<i>Power</i>	
Low & Exhausted battery	11, 17	Low & Exhausted battery	
<b>Algorithms</b>		<b>Algorithms</b>	
<i>Diagnostic</i>		<i>Diagnostic</i>	
BP classification <sup>Query 3</sup>	13	BP classification <sup>Query 3</sup>	
Irregular heartbeat detection	13	Irregular heartbeat detection	
<i>Functions</i>		<i>Functions</i>	
Correct cuff wrapping detection	13	Correct cuff wrapping detection	

Devices	Omron M2 (HEM-7121-E)	Omron HEM-7130 (Japanese model) <sup>Query 4</sup>
<b>Same Criteria (continued)</b>	<p><b>Casing</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 1000 measurements 17</p> <p>AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17</p> <p>Automatic switch-off when not used for 2 min 17</p> <p>Rechargeable batteries not permitted 17</p>	<p><b>Casing</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 1000 measurements 17</p> <p>AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17</p> <p>Automatic switch-off when not used for 2 min 17</p> <p>Rechargeable batteries not permitted 17</p>
<b>Comparable Criteria</b>	<p><b>Measurement</b></p> <p><i>Measurement Records</i></p> <p>Memory: 30 measurements 14</p>	<p><b>Measurement</b></p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements (Guest not recorded) 14</p>
<b>Device 2 Criteria</b>		<p><b>Measurement</b></p> <p><i>Method</i></p> <p>Prevent storing of result (Guest mode) 13, 14</p> <p><b>Buttons/Switches</b></p> <p><i>Function</i></p> <p>Date/Time set 10</p> <p>Up and down 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Post Measurement</i></p> <p>Average 11, 13, 14</p> <p>Body movement error 3, 11, 13, 18</p> <p><i>Date and Time</i></p> <p>Date and Time (alternating) 11</p> <p>Date and Time (During memory recall) 11</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements (within 10 min of each other) mean 13</p> <p><i>Diagnostic</i></p> <p>Body movement error detection 3, 13</p>

<p><b>Queries</b></p>	<p>1</p>	<p><b>Query</b> Each of the manuals states that the blood pressure measurement range is 0 mmHg to 299 mmHg. They also state that the monitor will not inflate above 299 mmHg. This means that the measurement ranges must be below this.</p> <p>According to ISO 80601-2-30 (2009), the device must be capable (in non-neonatal mode) of indicating at least 60 mmHg to 230 mmHg for SBP and 40 mmHg to 130 mmHg for DBP (201.12.1.103), so specifying these separately is necessary. It also requires that the pressure ranges provided are the rated pressures (201.7.9.2.9 h and 201.12.1.101) and that those measurements that are outside of these ranges trigger a technical alarm (201.12.1.106).</p> <p>a) What are the SBP and DBP rated ranges for each of the devices? b) Are there technical alarm ranges for each of the devices?</p> <p><b>Response</b> a) There is no SBP and DBP rated ranges because we have not defined the rated range of cuff pressure which is actually limited by measurement range of the pressure (not blood pressure) 0 to 299 mmHg. The capability to measure the required SBP and DBP range (201.12.1.103) are confirmed by technical validation test. b) There is no technical alarm because of the reason above.</p> <p><b>Query</b> The rated ranges for SBP and DBP are simply the ranges, within the inflation range, for which SBP and DBP values are displayed. Where a pulse is detected close to the maximum inflation pressure or the wave envelope suggests SBP as being close to the maximum inflation pressure, it may be rejected an unreliable estimate of SBP. DBP estimates close to zero can be similarly rejected. These are the technical alarm conditions.</p> <p>The reply suggests that there are no upper or lower limits to either SBP or DBP i.e. <math>299 \text{ mmHg} \geq \text{SBP} &gt; \text{DBP} \geq 0 \text{ mmHg}</math>. Is this correct?</p> <p><b>Response</b> Yes, this is correct.</p> <p><b>Comment</b> The reply answers the query fully.</p>
	<p>2</p>	<p><b>Query</b></p> <p>a) What are the numbers of the cuffs supplied with the HEM-7130? b) Why is the small cuff (HEM-CS24; arm circ. 17 cm to 32 cm) not provided as an option for the M2 (HEM-7121-E)? c) Why is the large cuff (arm circ. 32 cm to 42 cm), optionally available for the HEM-7130, different from the large cuff large cuff (No. HEM-RML31; arm circ. 22 cm to 42 cm) optionally available for the M2 (HEM-7121-E)?</p> <p><b>Response</b> a) The HEM-7130 is supplied with a medium cuff (HEM-CR24; arm circ. 22 cm to 32 cm). A large cuff (HEM-RML31; arm circ. 22 cm to 42 cm) is optional. b) The small cuff option is currently missing from the manual. We are now working to add it. c) It is the same large cuff (No. HEM-RML31; arm circ. 22 cm to 42 cm) that is available for both devices. However, in Japan, it is marketed as being for arm circumferences 32 cm to 42 cm.</p> <p><b>Comment</b> The reply answers the query fully.</p>

	3	<p><b>Query</b> Both devices have vertical indicator strips. Each strip contains 8 sections with a 135 mmHg mark between the 3<sup>rd</sup> and 4<sup>th</sup> sections and an 85 mmHg mark between the 6<sup>th</sup> and 7<sup>th</sup> sections. From the diagrams in the respective manuals, their function appears to be to display the pulse pressure, with a series of sections lit from one indicating a range of SBP values to one indicating a range of DBP values. However, no explanation is provided in either manual. What range of pressure does each section represent and are they the same for both devices?</p> <p><b>Response</b> Please find the range of the pressure for each section as shown. These are same for both devices.</p> <p><b>Comment</b> The reply answers the query fully.</p>	
	4	<p><b>Query</b> The image of the HEM-7130 available from <a href="http://www.healthcare.omron.co.jp">www.healthcare.omron.co.jp</a> matches that in the validation paper and in the manuals available from <a href="http://www.healthcare.omron.co.jp">www.healthcare.omron.co.jp</a> and <a href="http://healthcare.omron.co.in">healthcare.omron.co.in</a>. However, the images available from <a href="http://omronhealthcare.com.au">omronhealthcare.com.au</a> and <a href="http://healthcare.omron.co.in">healthcare.omron.co.in</a> have an extra OK LED on the case. Please explain.</p> <div style="display: flex; justify-content: space-around; text-align: center;"> <div data-bbox="649 686 985 957"> <p>Japan</p> </div> <div data-bbox="1052 686 1321 957"> <p>Australia</p> </div> <div data-bbox="1388 686 1702 957"> <p>India</p> </div> </div> <p><b>Response</b> The model in <a href="http://www.healthcare.omron.co.jp">www.healthcare.omron.co.jp</a> is the correct one to which we are referring. This is Japan model. The model in <a href="http://omronhealthcare.com.au">omronhealthcare.com.au</a> has the same model name but is a different regional model for Australia and India.</p> <p><b>Query</b> Have they distinguishing names or alternative names?</p> <p><b>Response</b> These have the same model name but we distinguish them by a rating label on the unit. For example, there is “IN” for the rating label of the India model and “AU” for the Australia model. Please find the rating labels as shown. From the top, it is Japan, India, and Australia.</p> <p><b>Comment</b> The query relates to how we distinguish the particular HEM-7130 model in the assessments and on the website. Given that they are distinguished by rating labels only, we will simply use <i>HEM-7130 (Japanese model)</i>.</p>	

<b>Note</b>	1	The M2 (HEM-7121-E) has the same blood pressure measuring facilities as the HEM-7130 (Japanese model). However, it is a trimmed down version; there are no features provided on the M2 (HEM-7121-E) that are not available on the HEM-7130. It does not have the date & time, the averaging and the body-movement detection features of the HEM-7130. It stores up to 30, rather than 60 measurements and it does not have a "guest mode" feature.
<b>Recommendation</b>	Equivalence is Recommended	
<b>Date</b>	20 March 2014	