

**DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE**

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

**SECTION A** - Please complete all items.

I **Andre van Gils**,  
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 Man.** Address **Binh Duong Province, Vietnam**  
**Vietnam Co., LTD**

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> **M3 (HEM-7154-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 Man.** Address **Binh Duong Province, Vietnam**  
**Vietnam Co., LTD**

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> **M6 AC (HEM-7322-E)**

Existing validated blood pressure measuring device.

which has previously passed the **ESH 2010** protocol, the results of which were published as follows:

dablEducational Trust; 2014 Jan 22. 4 p. Available from: [ESH-IP 2010 Validation of Omron M6 AC \(HEM-7322-E\).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 checked="" 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 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 type="checkbox"/>	N/A <sup>g</sup> <input checked="" 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.

In an attached document. DET9 Form.

**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
- Completed DET9 Form
- 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@dableeducational.org.

Signature of Director 

Name Lucia Prada

Date 16 August, 2019

Signature of Witness 

Name Hideki Kondo

Address 16 August, 2019

Company Stamp/Seal

OMRON HEALTHCARE EUROPE BV  
Scorpius 33  
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TEL +31-23 5544700  
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Comparison of the Omron M3 (HEM-7154-E) with the Omron M6 AC (HEM-7322-E)

Devices – Item 9	Omron M3 (HEM-7154-E)	Omron M6 AC (HEM-7322-E)
Pictures		
Display Image		
Validation	(equivalence)	ESH 2010
Category	Upper Arm Devices for Self-measurement of Blood Pressure	Upper Arm Devices for Self-measurement of Blood Pressure
Casing – Item 10	<p><b>Casing</b></p> <p><i>Dimensions</i> Approximately 105 mm (w) × 87 mm (h) × 153 mm (l) (not including the Arm cuff)</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i> On/Off with START/STOP</p>	<p><b>Casing</b></p> <p><i>Dimensions</i> Approximately 124 mm (w) × 90 mm (h) × 161 mm (l) (not including the Arm cuff)</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i> On/Off with START/STOP</p>

	<p><i>Measurement Records</i></p> <p>Memory</p> <p><i>Functions</i></p> <p>Back/Forward</p> <p>User ID select</p> <p>Date/Time setting</p>	<p><i>Measurement Records</i></p> <p>Memory</p> <p><i>Functions</i></p> <p>Back/Forward</p> <p>User ID select</p> <p>Date/Time setting</p> <p>Weekly average</p>
<b>Display – Item 11</b>	<p><b><i>Display/Symbols/Indicators</i></b></p> <p><i>Measurement Procedure</i></p> <p>Deflation symbol</p> <p>Heartbeat symbol</p> <p>User ID symbol</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse</p> <p>Date and Time</p> <p>Irregular heartbeat symbol</p> <p>Cuff wrap guide symbol (OK, loose)</p> <p>Body Movement error symbol</p> <p>Measurement error “E1 E2 E3 E4 E5 Er”</p> <p><i>Power</i></p> <p>Battery symbol (low, depleted)</p> <p><i>Measurement Records</i></p> <p>Memory symbol</p> <p>Memory recall number (replaces pulse rate momentarily)</p> <p><i>Date and Time</i></p> <p>Date and Time (During memory recall)</p> <p><i>Function</i></p> <p>Blood pressure level symbol</p> <p>Average value symbol</p>	<p><b><i>Display/Symbols/Indicators</i></b></p> <p><i>Measurement Procedure</i></p> <p>Deflation symbol</p> <p>Heartbeat symbol</p> <p>User ID symbol</p> <p>During Measurement: Blood Pressure Level</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse</p> <p>Date and Time</p> <p>Irregular heartbeat symbol</p> <p>Cuff wrap guide symbol (OK, loose) and Cuff wrap OK lamp</p> <p>Body Movement error symbol</p> <p>Measurement error “E1 E2 E3 E4 E5 Er”</p> <p><i>Power</i></p> <p>Battery symbol (low, depleted)</p> <p><i>Measurement Records</i></p> <p>Memory symbol</p> <p>Memory recall number (replaces pulse rate momentarily)</p> <p><i>Date and Time</i></p> <p>Date and Time (During memory recall)</p> <p><i>Function</i></p> <p>Blood pressure level indicator</p> <p>Average value symbol</p> <p>Blood pressure colour indicator</p> <p>Morning average symbol</p> <p>Evening average symbol</p> <p>Morning hypertension symbol</p>
<b>Carrying/Mounting Facilities – Item 12</b>	<p><i>Carrying/Mounting Facilities</i></p> <p>Storage Case</p>	<p><i>Carrying/Mounting Facilities</i></p> <p>Storage Case</p>
<b>Software other than Algorithm – Item 13</b>	<p><b><i>Software other than Algorithm</i></b></p> <p><i>Averages and Differences</i></p> <p>Average (Last 3 measurements value within 10 min)</p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection</p> <p>Blood Pressure classification</p> <p><i>Functions</i></p> <p>Correct cuff wrapping detection</p> <p>Body movement error detection</p>	<p><b><i>Software other than Algorithm</i></b></p> <p><i>Averages and Differences</i></p> <p>Average (Last 3 measurements value within 10 min)</p> <p>Morning/Evening Weekly Average</p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection</p> <p>Blood Pressure classification</p> <p><i>Functions</i></p> <p>Correct cuff wrapping detection</p> <p>Body movement error detection</p>

<b>Memory Capacity Item 14</b>	<i>Number of stored measurements</i> 60 measurements per user	<i>Number of stored measurements</i> 100 measurements per user
<b>Same Criteria</b>	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>Blood Pressure accuracy <math>\pm 3</math> mmHg 1,5</p> <p>Pulse accuracy <math>\pm 5\%</math> 1,5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1,5</p> <p>Manually initiated measurements 13</p> <p><i>Ranges</i></p> <p>Cuff Pressure range 0 to 299 mmHg 1,5,7,8</p> <p>Blood Pressure measurement SYS 60 to 260 mmHg 1,5,7,8</p> <p>Blood Pressure measurement DIA 40 to 215 mmHg 1,5,7,8</p> <p>Pulse measurement 40 to 180 beats / min. 1,5,7,8</p> <p><i>Inflation</i></p> <p>Inflation 0 to 299 mmHg 1,5,7</p> <p>Automatic Inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Arm Cuff HEM-FL31 (Arm circumference 22 cm to 44 cm) Type BF 6</p> <p><i>Sensors</i></p> <p>The electric pressure sensor 5</p> <p><i>Measurements other than Blood Pressure</i></p> <p>Pulse 40 to 180 beat / min. 1,5,8</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>Heartbeat symbol 11</p> <p>During Measurement: Blood Pressure Level 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Irregular heartbeat symbol 11</p> <p>Cuff wrap guide symbol (OK, loose) 11</p> <p>Measurement error "E1 E2 E3 E4" 11</p> <p><i>Power</i></p> <p>Battery symbol (low, depleted) 11</p> <p><b>Software other than Algorithm</b></p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p><i>Functions</i></p> <p>Correct cuff wrapping detection 13</p> <p>Body movement error detection 13</p> <p><b>Power Supply</b></p> <p><i>Power</i></p> <p>4 "AA" batteries 17</p> <p>AC adapter (HHP-CM01 / HHP-BFH01) 17</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>Blood Pressure accuracy <math>\pm 3</math> mmHg 1,5</p> <p>Pulse accuracy <math>\pm 5\%</math> 1,5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1,5</p> <p>Manually initiated measurements 13</p> <p><i>Ranges</i></p> <p>Cuff Pressure range 0 to 299 mmHg 1,5,7,8</p> <p>Blood Pressure measurement SYS 60 to 260 mmHg 1,5,7,8</p> <p>Blood Pressure measurement DIA 40 to 215 mmHg 1,5,7,8</p> <p>Pulse measurement 40 to 180 beats / min. 1,5,7,8</p> <p><i>Inflation</i></p> <p>Inflation 0 to 299 mmHg 1,5,7</p> <p>Automatic Inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Arm Cuff HEM-FL31 (Arm circumference 22 cm to 44 cm) Type BF 6</p> <p><i>Sensors</i></p> <p>The electric pressure sensor 5</p> <p><i>Measurements other than Blood Pressure</i></p> <p>Pulse 40 to 180 beat / min. 1,5,8</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>Heartbeat symbol 11</p> <p>During Measurement: Blood Pressure Level 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Irregular heartbeat symbol 11</p> <p>Cuff wrap guide symbol (OK, loose) 11</p> <p>Measurement error "E1 E2 E3 E4" 11</p> <p><i>Power</i></p> <p>Battery symbol (low, depleted) 11</p> <p><b>Software other than Algorithm</b></p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p><i>Functions</i></p> <p>Correct cuff wrapping detection 13</p> <p>Body movement error detection 13</p> <p><b>Power Supply</b></p> <p><i>Power</i></p> <p>4 "AA" batteries 17</p> <p>AC adapter (HHP-CM01 / HHP-BFH01) 17</p>

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<b>Comments</b>		
<b>Recommendation</b>	<b>Recommended</b>	
<b>Date</b>	<b>September 2019</b>	