

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

A SIGNED COPY WILL BE POSTED ON THE 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^a Omron Healthcare Man. Address Binh Duong Province, Vietnam
Vietnam Co., LTD
 Manufacturer^b Omron Healthcare Co., Ltd. Address 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan
 Brand^c Omron Model^d M6 Comfort (HEM-7360-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^a Omron Healthcare Man. Address Binh Duong Province, Vietnam
Vietnam Co., LTD
 Manufacturer^b Omron Healthcare Co., Ltd. Address 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan
 Brand^c Omron Model^d M6 Comfort (HEM-7321-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 Comfort (HEM-7321-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 ^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 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 type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <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@dableducational.org.

Signature of Director 
 Name Lucia Prada
 Date 16 September, 2019
 Signature of Witness 
 Name Hideki Kondo
 Address 16 September, 2019

Company Stamp/Seal
 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 M6 Comfort (HEM-7360-E) with the Omron M6 Comfort (HEM-7321-E)

Devices – Item 9	Omron M6 Comfort (HEM-7360-E)	Omron M6 Comfort (HEM-7321-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>Casing <i>Dimensions</i> Approximately 191 mm (w) × 85 mm (h) × 120 mm (l) (not including the Arm cuff)</p> <p>Buttons/Switches <i>Power</i> On/Off with START/STOP</p>	<p>Casing <i>Dimensions</i> Approximately 124 mm (w) × 90 mm (h) × 161 mm (l) (not including the Arm cuff)</p> <p>Buttons/Switches <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>Morning/Evening Weekly Average</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>
Display – Item 11	<p><i>Display/Symbols/Indicators</i></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 E6 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>Morning average symbol</p> <p>Evening average symbol</p> <p>AFib indicator symbol</p> <p>Prior Measurement reading</p> <p>SBP, DBP, Pulse, Date and Time,</p> <p>Irregular heart beat, Cuff wrap guide, Body movement,</p> <p>Blood pressure level and AFib indicator</p>	<p><i>Display/Symbols/Indicators</i></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>Morning average symbol</p> <p>Evening average symbol</p> <p>Blood pressure colour indicator</p> <p>Morning hypertension symbol</p>
Carrying/Mounting Facilities – Item 12	<p><i>Carrying/Mounting Facilities</i></p> <p>Storage Case</p>	<p><i>Carrying/Mounting Facilities</i></p> <p>Storage Case</p>
Software other than Algorithm – Item 13	<p><i>Software other than Algorithm</i></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>Software other than Algorithm</i></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> Irregular heartbeat detection Blood Pressure classification</p> <p><i>Functions</i> Correct cuff wrapping detection Body movement error detection AFib detection</p>	<p><i>Diagnostic</i> Irregular heartbeat detection Blood Pressure classification</p> <p><i>Functions</i> Correct cuff wrapping detection Body movement error detection</p>
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i> Blood Pressure accuracy ± 3 mmHg 1,5 Pulse accuracy ± 5% 1,5</p> <p><i>Method</i> Oscillometric measurement method 1,5 Manually initiated measurements 13</p> <p><i>Ranges</i> Cuff Pressure range 0 to 299 mmHg 1,5,7,8 Blood Pressure measurement SYS 60 to 260 mmHg 1,5,7,8 Blood Pressure measurement DIA 40 to 215 mmHg 1,5,7,8 Pulse measurement 40 to 180 beats / min. 1,5,7,8</p> <p><i>Inflation</i> Inflation 0 to 299 mmHg 1,5,7 Automatic Inflation 7</p> <p><i>Deflation</i> Automatic Deflation 8</p> <p><i>Cuffs</i> Arm Cuff HEM-FL31 (Arm circumference 22 cm to 44 cm) Type BF 6</p> <p><i>Sensors</i> The electric pressure sensor 5</p> <p><i>Measurements other than Blood Pressure</i> Pulse 40 to 180 beat / min. 1,5,8</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i> Heartbeat symbol 11 During Measurement: Blood Pressure Level 11</p> <p><i>Post Measurement</i> SBP, DBP and Pulse 11 Irregular heartbeat symbol 11 Cuff wrap guide symbol (OK, loose) 11 Measurement error “E1 E2 E3 E4” 11</p> <p><i>Power</i> Battery symbol (low, depleted) 11</p> <p>Software other than Algorithm</p> <p><i>Diagnostic</i> Irregular heartbeat detection 13</p> <p><i>Functions</i> Correct cuff wrapping detection 13 Body movement error detection 13</p>	<p>Measurement</p> <p><i>Accuracy</i> Blood Pressure accuracy ± 3 mmHg 1,5 Pulse accuracy ± 5% 1,5</p> <p><i>Method</i> Oscillometric measurement method 1,5 Manually initiated measurements 13</p> <p><i>Ranges</i> Cuff Pressure range 0 to 299 mmHg 1,5,7,8 Blood Pressure measurement SYS 60 to 260 mmHg 1,5,7,8 Blood Pressure measurement DIA 40 to 215 mmHg 1,5,7,8 Pulse measurement 40 to 180 beats / min. 1,5,7,8</p> <p><i>Inflation</i> Inflation 0 to 299 mmHg 1,5,7 Automatic Inflation 7</p> <p><i>Deflation</i> Automatic Deflation 8</p> <p><i>Cuffs</i> Arm Cuff HEM-FL31 (Arm circumference 22 cm to 44 cm) Type BF 6</p> <p><i>Sensors</i> The electric pressure sensor 5</p> <p><i>Measurements other than Blood Pressure</i> Pulse 40 to 180 beat / min. 1,5,8</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i> Heartbeat symbol 11 During Measurement: Blood Pressure Level 11</p> <p><i>Post Measurement</i> SBP, DBP and Pulse 11 Irregular heartbeat symbol 11 Cuff wrap guide symbol (OK, loose) 11 Measurement error “E1 E2 E3 E4” 11</p> <p><i>Power</i> Battery symbol (low, depleted) 11</p> <p>Software other than Algorithm</p> <p><i>Diagnostic</i> Irregular heartbeat detection 13</p> <p><i>Functions</i> Correct cuff wrapping detection 13 Body movement error detection 13</p>

	<p>Memory Capacity <i>Number of stored measurements</i> 100 measurements per user</p> <p>Power Supply <i>Power</i> 4 "AA" batteries AC adapter (HHP-CM01 / HHP-BFH01)</p>	<p>14</p> <p>17</p> <p>17</p>	<p>Memory Capacity <i>Number of stored measurements</i> 100 measurements per user</p> <p>Power Supply <i>Power</i> 4 "AA" batteries AC adapter (HHP-CM01 / HHP-BFH01)</p>	<p>14</p> <p>17</p> <p>17</p>
--	--	-------------------------------	--	-------------------------------

Comments	
Recommendation	Recommended
Date	September 2019