

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 **Andre van Gils,** a Director of **Omron Healthcare Europe B.V.,**
Name of a Company Director 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** **M3 Comfort (HEM-7134-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 .4p.Availablefrom: [http://www.dableducational.org/Publications/2014/ESH-IP 2010 Validation of Omron M6 Comfort \(HEM-7321-E\).pdf](http://www.dableducational.org/Publications/2014/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 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 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.

9) The model number is changed to M3 Comfort (HEM-7134-E) from M6 Comfort (HEM-7321-E).

10) The following differences are implemented (compared to M6 Comfort):

- Smaller casing (Blood Pressure Module inside is the same for both models)
- The weekly average button is not available in the M3 Comfort (HEM-7134-E)
- The LCD display is smaller to fit the smaller casing

11) The morning average symbol, the evening average symbol, the morning hypertension symbol are removed (compared to M6 Comfort).

13) The software to calculate average of week, morning and night value and the morning hypertension detection function are removed from the M6 Comfort.

14) The M3 Comfort automatically stores up to 60 sets for each of the 2 users (compared to 100 sets for each of the 2 users in M6 Comfort).

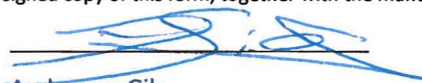
SECTION C Please check that the following are included with the application

- 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 Andre van Gils

Date 13 July ,2015



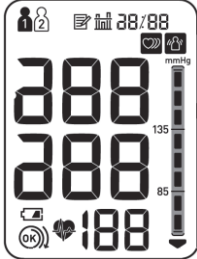
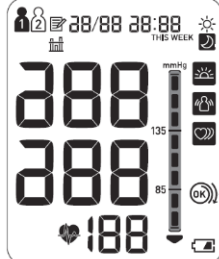
Signature of Witness Atsushi Kawano



Name Atsushi Kawano

Address 13 July ,2015

Comparison of the Omron M3 Comfort (HEM-7134-E) with the Omron M6 Comfort (HEM-7321-E)

Devices	Omron M3 Comfort (HEM-7134-E)	Omron M6 Comfort (HEM-7321-E)
Pictures		
Display		
Validation		ESH 2010
Category	Upper Arm Devices for Self-measurement of Blood Pressure	Upper Arm Devices for Self-measurement of Blood Pressure
Device 1 Criteria		<p><i>Details on validated device that are different to Equivalent device</i></p> <p>Buttons/Switches</p> <p><i>Analysis</i></p> <p>Weekly Average button 10</p> <p>Display/Symbols/Indicators</p> <p><i>Function</i></p> <p>Morning Average symbol 11,13,14</p> <p>Evening Average symbol 11,13,14</p> <p>Morning Hypertension symbol 11,13</p> <p>Casing</p> <p><i>Features</i></p> <p>Casing and LCD bigger than Equivalent device 10</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Weekly Average 13</p>

		(morning and evening measurements value within 8weeks)
Device 2 Criteria	<i>Details on Equivalent device that are different to Validated device</i>	
Same Criteria	<p>Measurement</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>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Ranges</i></p> <p>BP 0 mmHg to 299 mmHg 1,5,7,8</p> <p>Pulse 40 bpm to 180 bpm 1,5,8</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg to 299 mmHg 1,5,7</p> <p>Automatic Inflation 7</p> <p>Fuzzy Logic 7</p> <p>Press button if BP > 210 mmHg 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>Arm Cuff (Arm circ. 22 cm to 42 cm) No.HEM-FL31</p> <p><i>Sensors</i></p> <p>Piezo sensor 5</p> <p><i>Measurement Records</i></p> <p><i>Measurements other than Blood Pressure</i></p> <p>Pulse 40 bpm to 180 bpm 1,5,8</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start/Stop Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p><i>Function</i></p> <p>Date/Time setting 10</p> <p>User ID selection 10</p> <p>Up/Down 10</p> <p><i>Analysis</i></p>	<p>Measurement</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>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Ranges</i></p> <p>BP 0 mmHg to 299 mmHg 1,5,7,8</p> <p>Pulse 40 bpm to 180 bpm 1,5,8</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg to 299 mmHg 1,5,7</p> <p>Automatic Inflation 7</p> <p>Fuzzy Logic 7</p> <p>Press button if BP > 210 mmHg 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>Arm Cuff (Arm circ. 22 cm to 42 cm) No.HEM-FL31</p> <p><i>Sensors</i></p> <p>Piezo sensor 5</p> <p><i>Measurement Records</i></p> <p><i>Measurements other than Blood Pressure</i></p> <p>Pulse 40 bpm to 180 bpm 1,5,8</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start/Stop Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p><i>Function</i></p> <p>Date/Time setting 10</p> <p>User ID selection 10</p> <p>Up/Down 10</p> <p><i>Analysis</i></p>

<i>Event Marking</i>		<i>Event Marking</i>	
<i>Communication</i>		<i>Communication</i>	
Display/Symbols/Indicators		Display/Symbols/Indicators	
<i>Preparation</i>		<i>Preparation</i>	
<i>Measurement Procedure</i>		<i>Measurement Procedure</i>	
Deflation symbol	11	Deflation symbol	11
During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
<i>Post Measurement</i>		<i>Post Measurement</i>	
SBP,DBP and Pulse	11	SBP,DBP and Pulse	11
Measurement error E1 E2 E3 E4 E5 Er	11	Measurement error E1 E2 E3 E4 E5 Er	11
Hypertension (indicator strip)	11,13	Hypertension (indicator strip)	11,13
Irregular heartbeat	11,13,18	Irregular heartbeat	11,13,18
Body Movement error	3, 11,13,18	Body Movement error	3, 11,13,18
Correct cuff wrap indicator	11,13,18	Correct cuff wrap indicator	11,13,18
User ID	11,13,14	User ID	11,13,14
Blood pressure colour indicator	11,13	Blood pressure colour indicator	11,13
<i>Measurement Records</i>		<i>Measurement Records</i>	
Memory icon	11	Memory icon	11
Memory recall number (Replaces pulse rate momentarily)	11	Memory recall number (Replaces pulse rate momentarily)	11
<i>Date and Time</i>		<i>Date and Time</i>	
Date and Time (During memory recall)	11	Date and Time (During memory recall)	11
<i>Power</i>		<i>Power</i>	
Low & Exhausted battery	11,17	Low & Exhausted battery	11,17
<i>Function</i>		<i>Function</i>	
Average	11,13,14	Average	11,13,14
<i>Communication</i>		<i>Communication</i>	
<i>Features</i>		<i>Features</i>	
<i>Not described</i>		<i>Not described</i>	
Algorithms		Algorithms	
<i>Averages and Differences</i>		<i>Averages and Differences</i>	
Average (Last 3 measurements value within 10 min)	13	Average (Last 3 measurements value within 10 min)	13
<i>Diagnostic</i>		<i>Diagnostic</i>	

	BP classification 13 Irregular heartbeat detection 13 <i>Functions</i> Body movement error detection 13 Correct cuff wrapping detection 13 <i>Communication</i> Casing <i>Display</i> Single screen display 10 Segment LCD 10 <i>Ports</i> Air Jack 10 AC Adapter jack 10 <i>Power</i> 4"AA"batteries~1000 measurements 17 AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17 Automatic switch-off when not used for 2 min 17 Rechargeable batteries not permitted 17 <i>Features</i> Blood pressure colour indicator 10	BP classification 13 Irregular heartbeat detection 13 <i>Functions</i> Body movement error detection 13 Correct cuff wrapping detection 13 <i>Communication</i> Casing <i>Display</i> Single screen display 10 Segment LCD 10 <i>Ports</i> Air Jack 10 AC Adapter jack 10 <i>Power</i> 4"AA"batteries~1000 measurements 17 AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17 Automatic switch-off when not used for 2 min 17 Rechargeable batteries not permitted 17 <i>Features</i> Blood pressure colour indicator 10
Comparable Criteria	Measurement <i>Measurement Records</i> Memory: 60 measurements for each of 2 users 14 Display/Symbols/Indicators <i>Date and Time</i> Date and Time (alternating) 11	Measurement <i>Measurement Records</i> Memory: 100 measurements for each of 2 users 14 Display/Symbols/Indicators <i>Date and Time</i> Date and Time 11

Comments		

Recommendation	<i>Recommended</i>	
Date	21 st October 2015	