

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 **M7 Intelli IT (HEM-7322T-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.Available from: [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 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 checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input 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 M7 Intelli IT (HEM-7322T-E) from M6 Comfort (HEM-7321-E).

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

- The connection button is available in the M7 Intelli IT (HEM-7322T-E)
- The Date/Time setting button is removed from M6 Comfort (HEM-7321-E)

11) The connect symbol, the OK symbol, the DATA/FULL symbol are implemented (compared to M6 Comfort).

13) The software which sends device to smartphone the Data of blood pressure and pulse rate is implemented.

16) The data (measurement results of blood pressure and pulse rate) is transferred user's smartphone using bluetooth.

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



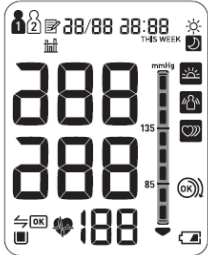
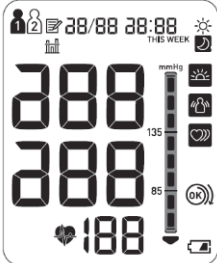
Date 22 June ,2016

Signature of Witness 

Name Atsushi Kawano

Address 22 June,2016

Comparison of the Omron M7 Intelli IT (HEM-7322T-E) with the Omron M6 Comfort (HEM-7321-E)

Devices	Omron M7 Intelli IT (HEM-7322T-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		
Device 2 Criteria	<p><i>Details on Equivalent device that are different to Validated device</i></p> <p>Buttons/Switches</p> <p>Connection button 10</p> <p>Display/Symbols/Indicators</p> <p>Function</p> <p>DATA/FULL symbol 11,13</p> <p>OK symbol 11,13</p> <p>Connection symbol 11,13</p> <p>Algorithms</p> <p>Communication</p> <p>The data (measurement results of blood pressure and pulse rate) is</p>	

	transferred user's smartphone using Bluetooth.	13,16	
Same Criteria	Measurement		Measurement
	<i>Accuracy</i>		<i>Accuracy</i>
	BP accuracy \pm 3 mmHg	1,5	BP accuracy \pm 3 mmHg
	Pulse accuracy \pm 5%	1,5	Pulse accuracy \pm 5%
	<i>Method</i>		<i>Method</i>
	Oscillometric measurement method	1,5	Oscillometric measurement method
	Manually initiated measurements	13	Manually initiated measurements
	Measurements are from single inflations	13	Measurements are from single inflations
	<i>Ranges</i>		<i>Ranges</i>
	BP 0 mmHg to 299 mmHg	1,5,7,8	BP 0 mmHg to 299 mmHg
	Pulse 40 bpm to 180 bpm	1,5,8	Pulse 40 bpm to 180 bpm
	<i>Inflation</i>		<i>Inflation</i>
	Inflation 0 mmHg to 299 mmHg	1,5,7	Inflation 0 mmHg to 299 mmHg
	Automatic Inflation	7	Automatic Inflation
	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 (Please state sizes and materials used)</i>		<i>Cuffs (Please state sizes and materials used)</i>
	Arm Cuff (Arm circ. 22 cm to 42 cm) No.HEM-FL31		Arm Cuff (Arm circ. 22 cm to 42 cm) No.HEM-FL31
	<i>Sensors</i>		<i>Sensors</i>
	Piezo sensor	5	Piezo sensor
	<i>Measurement Records</i>		<i>Measurement Records</i>
Memory: 100 measurements for each of 2 users	14	Memory: 100 measurements for each of 2 users	
<i>Measurements other than Blood Pressure</i>		<i>Measurements other than Blood Pressure</i>	
Pulse 40 bpm to 180 bpm	1,5,8	Pulse 40 bpm to 180 bpm	
Buttons/Switches		Buttons/Switches	
<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	
Weekly Average button	10	Weekly Average button	
<i>Function</i>		<i>Function</i>	
Date/Time setting	10	Date/Time setting	
User ID selection	10	User ID selection	
Up/Down	10	Up/Down	

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
Morning Average symbol	11,13,14	Morning Average symbol	11,13,14
Evening Average symbol	11,13,14	Evening Average symbol	11,13,14
Morning Hypertension symbol	11,13	Morning Hypertension symbol	11,13
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
Weekly Average (morning and evening measurements value within 8weeks)	13	Weekly Average (morning and evening measurements value within 8weeks)	13
<i>Diagnostic</i>		<i>Diagnostic</i>	
BP classification	13	BP classification	13
Irregular heartbeat detection	13	Irregular heartbeat detection	13

	<p><i>Functions</i></p> <p>Body movement error detection 13</p> <p>Correct cuff wrapping detection 13</p> <p><i>Communication</i></p> <p>Casing</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Ports</i></p> <p>Air Jack 10</p> <p>AC Adapter jack 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><i>Features</i></p> <p>Blood pressure colour indicator 10</p>	<p><i>Functions</i></p> <p>Body movement error detection 13</p> <p>Correct cuff wrapping detection 13</p> <p><i>Communication</i></p> <p>Casing</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Ports</i></p> <p>Air Jack 10</p> <p>AC Adapter jack 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><i>Features</i></p> <p>Blood pressure colour indicator 10</p>
Comparable Criteria		

Comments	
Recommendation	Recommended
Date	15 July 2016
Date Approved	29 July 2016