

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items online.

I Takefumi Nakanishi 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

Omron M1 (HEM-4030-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M1 Plus (HEM-4011C-E)
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the International protocol, the results of which were published as follows

Belghazi J, El Feghali RN, Moussalem T, Rejdych M, Asmar RG
Authors(s)

Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension:

Vascular Health and Risk Management 2007; 3(4): 389-400
Title Publication Year Volume Pages

The only differences between the devices involve the following components:

(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences below.)

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input 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"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	Yes <input checked="" type="checkbox"/>	No <input 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 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"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

Brief explanation of differences and further relevant details:

6) Outer cloth is changed, no change on the size, shape and material on bladder.

10) No "SET" button.

11) No symbol for date or time, no symbol for average of 3 readings in memory, no symbol for beeper ON/OFF, no symbol for irregular heart beat. The symbol for memory number is added.

13) No function to detect irregular heartbeat, no function to average of memories (average of the latest 3 measurements) and no beeper function.

14) 14 memories instead of 21 memories.



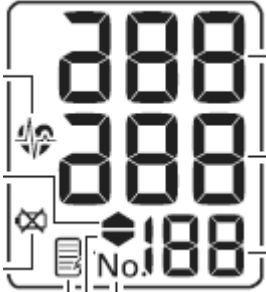
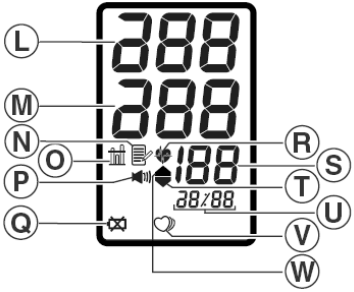
17) Two "AAA" manganese or alkaline batteries instead of four.



SECTION B - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director	<u>T. Nakanishi</u>	Company Stamp/Seal
Name	<u>Takefumi Nakanishi</u>	OMRON HEALTHCARE EUROPE B.V. [†]
Date	<u>17 February 2010</u>	Kruisweg 577
Signature of Witness	<u>J. Meijer</u>	NL-2132 NA Hoofddorp
Name	<u>Janet Meijer</u>	P.O. Box 2150 NL- 2130 GL Hoofddorp
Address	<u>Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands</u>	Tel. +31 - 20 354 82 00
		Fax +31 - 20 354 82 01

Comparison of the Omron M1 (HEM-4030-E) with the Omron M1 Plus (HEM-4011C-E)

Devices	Omron M1 (HEM-4030-E)	Omron M1 Plus (HEM-4011C-E)
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Display/Symbols/Indicators</p> <p>Measurement Records</p> <p>Memory recall number (Replaces pulse rate momentarily) 11</p>	
Same Criteria	<p>Measurement</p> <p>Accuracy</p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy $\pm 5\%$ 1, 5</p> <p>Method</p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p>Inflation</p> <p>Inflation 0 mmHg - 299 mmHg 1, 5, 7</p>	<p>Measurement</p> <p>Accuracy</p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy $\pm 5\%$ 1, 5</p> <p>Method</p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p>Inflation</p> <p>Inflation 0 mmHg - 299 mmHg 1, 5, 7</p>

Manual (bulb) Inflation	7	Manual (bulb) Inflation	7
<i>Deflation</i>		<i>Deflation</i>	
Automatic Deflation	8	Automatic Deflation	8
<i>Cuffs</i>		<i>Cuffs</i>	
Large (Arm circ. 32-42 cm) (Optional) ^{Query 1}	6	Large (Arm circ. 32-42 cm) (Optional) ^{Query 1}	6
Medium 152 mm × 600 mm (Arm circ. 22 to 32 cm) ^{Query 1}	6	Medium 152 mm × 600 mm (Arm circ. 22 to 32 cm) ^{Query 1}	6
Small (Arm circ. 17-22 cm) (Optional) ^{Query 1}	6	Small (Arm circ. 17-22 cm) (Optional) ^{Query 1}	6
<i>Sensors</i>		<i>Sensors</i>	
Pressure sensor: capacitive	5	Pressure sensor: capacitive	5
Buttons/Switches		Buttons/Switches	
<i>Power</i>		<i>Power</i>	
On/Off with Stop (I/O Label)	10	On/Off with Stop (I/O Label)	10
<i>Measurement Records</i>		<i>Measurement Records</i>	
Memory	10	Memory	10
<i>Manual</i>		<i>Manual</i>	
Air release	10	Air release	10
Display/Symbols/Indicators		Display/Symbols/Indicators	
<i>Preparation</i>		<i>Preparation</i>	
Zero cuff pressure check	11, 13, 18	Zero cuff pressure check	11, 13, 18
<i>Measurement Procedure</i>		<i>Measurement Procedure</i>	
Re-inflation symbol (insufficient manual inflation)	11	Re-inflation symbol (insufficient manual inflation)	11
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 EE , E , E/E and $E_{\alpha 25}$	11	Measurement error EE , E , E/E and $E_{\alpha 25}$	11
Hypertension (Blinking heartbeat)	11, 13	Hypertension (Blinking heartbeat)	11, 13
<i>Measurement Records</i>		<i>Measurement Records</i>	
Memory icon	11	Memory icon	11
<i>Power</i>		<i>Power</i>	
Low battery	11, 17	Low battery	11, 17
Algorithms		Algorithms	
<i>Diagnostic</i>		<i>Diagnostic</i>	
Normotension/Hypertension	13	Normotension/Hypertension	13
135 / 85 mmHg thresholds	13	135 / 85 mmHg thresholds	13
Case		Case	
<i>Display</i>		<i>Display</i>	
Single screen display	10	Single screen display	10
Segment LCD	10	Segment LCD	10

	<i>Power</i> 2 “AAA” batteries ~ 1500 measurements 17 Automatic switch-off when not used for 5 min 17	<i>Power</i> 4 “AAA” batteries ~ 1500 measurements 17 Automatic switch-off when not used for 5 min 17
Comparable Criteria	Measurement <i>Measurement Records</i> Memory: 14 measurements 14 Case <i>Power</i> 2 “AAA” batteries ~ 1500 measurements 17	Measurement <i>Measurement Records</i> Memory: 21 measurements 14 Case <i>Power</i> 4 “AAA” batteries ~ 1500 measurements 17
Device 2 Criteria		Buttons/Switches <i>Settings</i> Set 10 Display/Symbols/Indicators <i>Measurement Procedure</i> Audible pulse indicator during deflation (Optional) 18 Beeps after measurement (Optional) 18 <i>Post Measurement</i> Average icon 11, 13, 14 Irregular heartbeat 11, 13, 18 <i>Settings</i> Audible pulse indicator mode active 11, 18 <i>Date and Time</i> Date and Time 11 Date and Time (During memory recall) 11 Algorithms <i>Averages and Differences</i> Last 3 measurements (within 10 min of each other) mean 13 <i>Diagnostic</i> Irregular heartbeat detection 13
Web link		http://www.

Comments	<p>Query 1 There appear to be some differences in the cuffs supplied with the monitors.</p> <p> a) There are different part numbers between those listed for the devices. These match the declaration of the different cloth covers. No difference is made in the declaration. It is taken that there are no changes.</p> <p> b) It is understood that the cloth changes apply to the large cuffs also.</p> <p>Response 1 a) <i>These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.</i></p> <p> b) <i>These cuffs have no differences except cloth covers.</i></p>
Recommendation	The queries were adequately answered. Equivalence is recommended.
Date	26/08/2010