



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
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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 M6 (HEM-7211-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron 705IT (HEM-759-E)
Existing validated blood pressure measuring device

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

Coleman A, Freeman P, Steel S, Shennan A
Authors(s)

Validation of the Omron 705IT (HEM-759-E) oscillometric blood pressure monitoring

device according to the British Hypertension Society protocol

Blood pressure monitoring 2006;11:27-32
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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" 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 power button (the start button is used for power on and measurement start.). No adjust button. No USB port. The up button and down button and the LED for dual check system* are added.

11) No symbol for inflation. The symbol for average of 3 readings in memory, the symbol for irregular heart beat, the symbol for body movement, the symbol for cuff wrapping guide** and the indicator for blood pressure level are added.

13) The function to detect irregular heart beat, the function to detect body movement, the function to average of memories (average of the latest 3 measurements), the function to guide cuff wrapping, the function of hypertension indicator, the function to check sensor (dual check system) are added.

14) 90 memories instead of 28 memories.

15) No printing facility.

16) No communication facility.

*Main sensor takes the measurement, sub sensor checks if the device works.




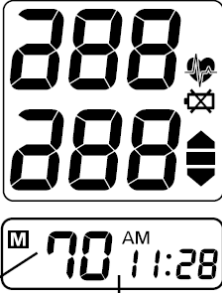
**Informs to user if the cuff was incorrectly wrapped.



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		Fax +31 - 20 354 82 01

Comparison of the Omron M6 (HEM-7211-E) with the Omron 705IT (HEM-759-E)

Devices	Omron M6 (HEM-7211-E)	Omron 705IT (HEM-759-E)
Pictures		
Display		
Validation		ESH BHS AAMI
Device 1 Criteria	<p>Measurement</p> <p><i>Sensors</i></p> <p>Pressure sensor: 2nd sensor for dual check 5</p> <p>Buttons/Switches</p> <p><i>Settings</i></p> <p>Up and down 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Correct cuff wrapping indicator 11, 13, 18</p> <p><i>Post Measurement</i></p> <p>Hypertension (Indicator strip) 11, 13</p> <p>Average icon 11, 13, 14</p> <p>Body movement error 3, 11, 13, 18</p> <p>Irregular heartbeat 11, 13, 18</p> <p><i>Settings</i></p>	

	Sensor cross check (LED) 5, 18 Algorithms <i>Averages and Differences</i> Last 3 measurements (within 10 min of each other) mean 13 <i>Diagnostic</i> Normotension/Hypertension 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13 Body movement error detection 3, 13 <i>Parameter Settings</i> Correct cuff wrapping detection 13 Sensor cross check 5, 18	
Same Criteria	Measurement <i>Accuracy</i> BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 <i>Method</i> Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 <i>Inflation</i> Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Fuzzy Logic 7 Press button if BP > 220 mmHg 7 Manually adjustable inflation pressure 7 <i>Deflation</i> Automatic Deflation 8 <i>Cuffs</i> Large (Arm circ. 32-42 cm) (Optional) ^{Query 1} 6 Small (Arm circ. 17-22 cm) (Optional) ^{Query 1} 6 <i>Sensors</i> Pressure sensor: capacitive 5 Buttons/Switches <i>Measurement Records</i> Memory 10 Display/Symbols/Indicators	Measurement <i>Accuracy</i> BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 <i>Method</i> Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 <i>Inflation</i> Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Fuzzy Logic 7 Press button if BP > 220 mmHg 7 Manually adjustable inflation pressure 7 <i>Deflation</i> Automatic Deflation 8 <i>Cuffs</i> Large (Arm circ. 32-42 cm) (Optional) ^{Query 1} 6 Small (Arm circ. 17-22 cm) (Optional) ^{Query 1} 6 <i>Sensors</i> Pressure sensor: capacitive 5 Buttons/Switches <i>Measurement Records</i> Memory 10 Display/Symbols/Indicators

	<p><i>Measurement Procedure</i></p> <p>Deflation symbol 11</p> <p>During Measurement: BP Level & Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Case</p> <p><i>Display</i></p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>AC adapter (Optional) 17</p>	<p><i>Measurement Procedure</i></p> <p>Deflation symbol 11</p> <p>During Measurement: BP Level & Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Case</p> <p><i>Display</i></p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>AC adapter (Optional) 17</p>
Comparable Criteria	<p>Measurement</p> <p><i>Cuffs</i></p> <p>Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm)^{Query 1} 6</p> <p><i>Measurement Records</i></p> <p>Memory: 90 measurements 14</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p><i>Settings</i></p> <p>Date/Time set 10</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>Measurement error E_1, E_2, E_3, E_4, E_5 and E_r^{Query 2} 11</p> <p><i>Measurement Records</i></p> <p>Memory icon 11</p> <p>Case</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 1500 measurements 17</p> <p>Automatic switch-off when not used for 2 min 17</p>	<p>Measurement</p> <p><i>Cuffs</i></p> <p>Medium 140 mm × 480 mm (Arm circ. 22 to 32 cm)^{Query 1} 6</p> <p><i>Measurement Records</i></p> <p>Memory: 28 measurements 14</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Stop (O/I Label) 10</p> <p>Start 10</p> <p><i>Settings</i></p> <p>Adjust 10</p> <p>Set 10</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>Measurement error E and E_r^{Query 2} 11</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 11</p> <p>Case</p> <p><i>Display</i></p> <p>Dual screen display 10</p> <p><i>Power</i></p> <p>4 “AA” (LR6) batteries ~ 300 measurements 17</p> <p>Automatic switch-off when not used for 5 min 17</p>

Device 2 Criteria		<p>Display/Symbols/Indicators <i>Measurement Procedure</i> Inflation symbol 11</p> <p>Case <i>Ports</i> USB/Printer port 15 USB port, cable and PC software 16, 18</p> <p><i>Features</i> Optional printer 15</p>
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>c) The dimensions of the cuff supplied with the M6 differ from that supplied with the 705-IT, with which it is being compared. However, the declaration declares only a change in the outer cloth and that there is no change in size. Please explain.</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> <p>c) <i>Please confirm chart1 which explains the relation between the models and dimensions.</i></p> <p style="text-align: center;">Chart1 Models and cuff dimensions</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Models</th> <th>Dimensions (in manual)</th> </tr> </thead> <tbody> <tr> <td>705IT</td> <td>140 mm x 480 mm</td> </tr> <tr> <td>M6</td> <td>146 mm x 446 mm</td> </tr> </tbody> </table> <p style="text-align: center;"><i>The actual size of these cuffs is same (Fig1).</i></p>	Models	Dimensions (in manual)	705IT	140 mm x 480 mm	M6	146 mm x 446 mm
Models	Dimensions (in manual)						
705IT	140 mm x 480 mm						
M6	146 mm x 446 mm						



Fig1 Size comparison

The dimensions in manual were different because the measurement point was different. (Fig4)

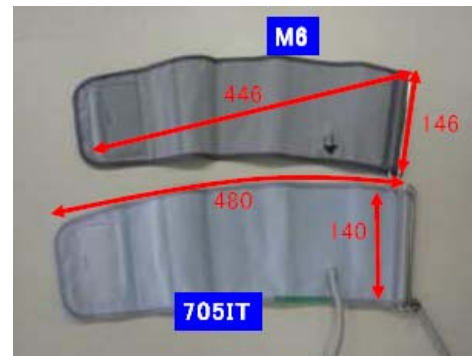


Fig2 Measurement point

However, this does not make any difference to measurement accuracy because the dimensions of bladder are all the same. In order not to confuse users, we will standardize the measurement point of cuff and describe the standardize dimensions in the manual.

Query 2 There appear to be some differences in the error codes (apart from the extra features) which would not be expected if there were no algorithm changes. In the list, a slash indicates a line break where the error code is on two lines. Please explain.

Response 2 *Regarding to Chart 2, the 705IT error code E had subdivide to E1, E2, E3, E4 and E5. For our software, error codes consist of several error judgment conditions. We had a limitation to show enough information on the display in the past due to technical restriction on hardware. For now, the hardware performance has advanced to display more error code. Therefore, we reconsidered the constitution of the error judgment conditions and changed the expression to make it more easy to understand for users, starting from M6 (HEM-7211-E) and M6 Comfort (HEM-7221-E).*

		Chart 2 Error Codes					
		Model	Error codes				
		705IT	E				Er
		M6	E1	E2	E3	E2	E5
		<p>The diagram consists of two boxes. The left box is titled '705IT error code' and contains two items: 'E' and 'Er'. The right box is titled 'M6 error code' and contains five items: 'E1', 'E2', 'E3', 'E4', and 'E5' stacked vertically, and 'Er' at the bottom. Arrows point from 'E' in the 705IT box to each of the five items (E1-E5) in the M6 box. An arrow points from 'Er' in the 705IT box to 'Er' in the M6 box.</p>					
Recommendation	The queries were adequately answered. Equivalence is recommended.						
Date	26/08/2010						