

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 Tomohiro Kukita 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 M2 Basic (HEM-7116-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M3 Intellisense (HEM-7051-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

Asmar R, Khabouth J, Topouchian J, El Feghali R, Mattar J
Authors(s)

Validation of three automatic devices for self-measurement of blood pressure according to the International Protocol: The Omron M3 Intellisense (HEM-7051-E), the Omron M2

Compact (HEM 7102-E), and the Omron R3-I Plus (HEM 6022-E)

Title
Blood Pressure Monitoring 2010; 15:49-54
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 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 Set button (Date and Time setting, Beeper ON/OFF setting), no Memory button.

11) No symbol for average of 3 readings in memory, no symbol for beeper ON/OFF, no symbol for date and time, no symbol for irregular heartbeat symbol.

13) No average function (average of the latest 3 readings in memory), no beeper control function, no date and time function, no function to detect irregular heartbeat.



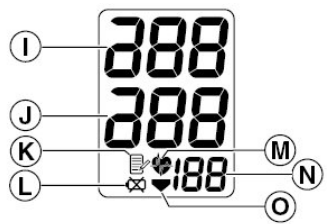
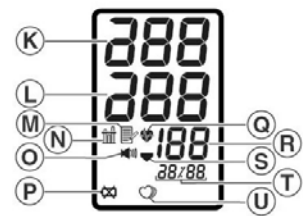
14) Previous memory instead of 42 memories.



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>Tomohiro Kukita</u>	Company Stamp/Seal
Name	<u>Tomohiro Kukita</u>	OMRON HEALTHCARE EUROPE B.V.
Date	<u>22 July 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>	

Comparison of the Omron M2_Basic (HEM-7116-E) with the Omron M3 Intellisense (HEM-7051-E)

Devices	M2_Basic (HEM-7116-E)	M3 Intellisense (HEM-7051-E)
Pictures		
Display	 <ul style="list-style-type: none"> I. Systolic blood pressure J. Diastolic blood pressure K. Memory symbol L. Battery low symbol M. Heartbeat symbol N. Pulse display O. Deflation symbol 	 <ul style="list-style-type: none"> K. Systolic blood pressure L. Diastolic blood pressure M. Memory symbol N. Average value symbol O. Buzzer symbol P. Battery low symbol Q. Heartbeat symbol R. Pulse display S. Deflation symbol T. Date/Time display U. Irregular heartbeat symbol
Validation		ESH
Device 1 Criteria		
Same Criteria	<p>Measurement</p> <p>Accuracy</p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p>Method</p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5</p> <p>Measurements are from single inflations 13</p> <p>Manually initiated measurements 13, 14</p> <p>Inflation</p> <p>Inflation 0 mmHg - 299 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Fuzzy Logic^{Query 1} 7</p> <p>Press button if BP > 220 mmHg 7</p> <p>Manually adjustable inflation pressure 7</p> <p>Deflation</p> <p>Automatic Deflation 8</p>	<p>Measurement</p> <p>Accuracy</p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p>Method</p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5</p> <p>Measurements are from single inflations 13</p> <p>Manually initiated measurements 13, 14</p> <p>Inflation</p> <p>Inflation 0 mmHg - 299 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Fuzzy Logic 7</p> <p>Press button if BP > 220 mmHg 7</p> <p>Manually adjustable inflation pressure 7</p> <p>Deflation</p> <p>Automatic Deflation 8</p>

	<p>Automatic safety release valve ^{Note 2} 8</p> <p>Cuffs</p> <p>Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) ^{Query 3} 6</p> <p>Large (Arm circ. 32-42 cm) (Optional) 6</p> <p>Sensors</p> <p>Pressure sensor: capacitive 5</p> <p>Buttons/Switches</p> <p>Power</p> <p>On/Off with Start/Stop (O/I Start Label) 10</p> <p>Display/Symbols/Indicators</p> <p>Measurement Procedure</p> <p>Deflation symbol 11</p> <p>Heartbeat symbol during deflation 11</p> <p>Post Measurement</p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error EE, E, E/E and E_{a25} 11</p> <p>Hypertension (Blinking heartbeat) 11, 13</p> <p>Measurement Records</p> <p>Memory icon ^{Query 4} 11</p> <p>Power</p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p>Diagnostic</p> <p>Normotension/Hypertension 13</p> <p>135 / 85 mmHg thresholds 10, 11, 13</p> <p>Case</p> <p>Display</p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p>Power</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 5 min 17</p>		<p>Automatic safety release valve ^{Note 2} 8</p> <p>Cuffs</p> <p>Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) ^{Query 3} 6</p> <p>Large (Arm circ. 32-42 cm) (Optional) 6</p> <p>Sensors</p> <p>Pressure sensor: capacitive 5</p> <p>Buttons/Switches</p> <p>Power</p> <p>On/Off with Start/Stop (O/I Start Label) 10</p> <p>Display/Symbols/Indicators</p> <p>Measurement Procedure</p> <p>Deflation symbol 11</p> <p>Heartbeat symbol during deflation 11</p> <p>Post Measurement</p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error EE, E, E/E and E_{a25} 11</p> <p>Hypertension (Blinking heartbeat) 11, 13</p> <p>Measurement Records</p> <p>Memory icon 11</p> <p>Power</p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p>Diagnostic</p> <p>Normotension/Hypertension 13</p> <p>135 / 85 mmHg thresholds 10, 11, 13</p> <p>Case</p> <p>Display</p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p>Power</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 5 min 17</p>
Comparable Criteria	<p>Measurement</p> <p>Measurement Records</p> <p>Memory: 1 measurement 14</p> <p>Case</p> <p>Power</p> <p>4 “AAA” batteries ~ 300 measurements 17</p>		<p>Measurement</p> <p>Measurement Records</p> <p>Memory: 42 measurements 14</p> <p>Case</p> <p>Power</p> <p>4 “AA” batteries ~ 1500 measurements 17</p>

Devices	M2_Basic (HEM-7116-E)	M3 Intellisense (HEM-7051-E)
Device 2 Criteria		<p>Buttons/Switches</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p><i>Settings</i></p> <p>Set 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Audible pulse indicator during deflation (Optional) 18</p> <p>Beeps after measurement (Optional) 18</p> <p><i>Post Measurement</i></p> <p>Irregular heartbeat 11, 13</p> <p>Average symbol 11, 13</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>Settings</i></p> <p>Audible pulse indicator mode active 11, 18</p> <p>Algorithms</p> <p><i>Averages</i></p> <p>Last 3 measurements (within 10 min of each other) mean 13</p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p>
Web link		http://www.omron-healthcare.com/sitepreview.php?SiteID=227

Comments	<p>There were three queries and a note that became known as a result of queries relating to similar devices.</p> <p>Query 1 Fuzzy logic: The manual, for the M3 Intellisense, states that fuzzy logic is used. It appears not to be available for the M2 Basic. There is no reference to this difference in the declaration. Please explain.</p> <p>Response 1 <i>The equivalent group of M3 Intellisense (HEM-7051-E) has the function of "Fuzzy logic", then M2 Basic (HEM-7116-E) also has Fuzzy logic as well in this case. However in our recent marketing approach some of models mention Fuzzy logic in the manual, some models do not mention, although all models in this group have Fuzzy logic. However we put the explanation of automatic inflation in each instruction manual for users to understand the function in spite of using the word of Fuzzy logic. As Fuzzy logic is related to Inflation mechanism, we checked "no differences" on the Part I - Item 7 of declaration forms.</i></p> <p>Note 2 <i>The fact we have is that the group of M3 Intellisense (HEM-7051-E) have same deflation mechanism. They have same valves for deflation system, as you mentioned, which are the regular deflation valve (slow deflation during measurement) and the rapid</i></p>
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	<p><i>exhaust valve (release pressure rapidly from air system in the device after measurement to make comfortable and safe patients). Also these 2 valves are operated by automatic. In some device's manual e.g. M3 Intellisense (HEM-7051-E), we mention only "Deflation: Automatic pressure release valve" as one function of automatic deflation so that we could provide easy explanation to end users.</i></p> <p>Query 3 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 3 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>Query 4 In the declaration for the M2 Basic, it is stated that there is no symbol for memory. The device does contain such a symbol. It will be overlooked as a minor error.</p> <p>Response 4 <i>Yes, this is an error. We will resend the correct declarations.</i></p> <p>Comment 4 The new declaration was received.</p>
Recommendation	The queries were adequately answered. Equivalence is recommended.
Date	26/08/2010