

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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### 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-E2)

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(1):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 checked="" type="checkbox"/>	No <input 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:

5) The pressure sensor is replaced to a piezo electric sensor (NPS) from a capacitive sensor (CPSU), but the accuracy of blood pressure measurement is equivalent between NPS and CPSU.

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. **Blood pressure level indicator is added.**

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 Tomohiro Kukita

Company Stamp/Seal

Name Tomohiro Kukita

Date 28 June, 2012.



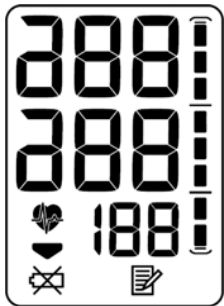

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Comparison of the Omron M2 Basic (HEM-7116-E2) with the Omron M3 Intellisense (HEM-7051-E)

Devices	M2 Basic (HEM-7116-E2)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	<p><b>Measurement</b></p> <p><i>Cuffs</i></p> <p>Universal (Arm circ. 22-42 cm) (Optional) 6</p>	
Same Criteria	<p><b>Measurement</b></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>Pulse 40 bpm -180 bpm 1, 5</p> <p>Measurements are from single inflations 13</p> <p>Manually initiated measurements 13, 14</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 299 mmHg 1, 5, 7</p>	<p><b>Measurement</b></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>Pulse 40 bpm -180 bpm 1, 5</p> <p>Measurements are from single inflations 13</p> <p>Manually initiated measurements 13, 14</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 299 mmHg 1, 5, 7</p>

Devices	M2 Basic (HEM-7116-E2)	M3 Intellisense (HEM-7051-E)		
<b>Same Criteria (continued)</b>	<b>Measurement (continued)</b>	<b>Measurement (continued)</b>		
	<i>Inflation (continued)</i>	<i>Inflation (continued)</i>		
	Automatic Inflation	7	Automatic Inflation	7
	Fuzzy Logic <sup>Query 1, Note 3</sup>	7	Fuzzy Logic <sup>Query 1, Note 3</sup>	7
	Press button if BP > 220 mmHg	7	Press button if BP > 220 mmHg	7
	Manually adjustable inflation pressure	7	Manually adjustable inflation pressure	7
	<i>Deflation</i>		<i>Deflation</i>	
	Automatic Deflation	8	Automatic Deflation	8
	Automatic safety release valve <sup>Query 1, Note 4</sup>	8	Automatic safety release valve <sup>Query 1, Note 4</sup>	8
	<i>Cuffs</i>		<i>Cuffs</i>	
	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) <sup>Note 2</sup>	6	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) <sup>Note 2</sup>	6
	Large (Arm circ. 32-42 cm) (Optional)	6	Large (Arm circ. 32-42 cm) (Optional)	6
	<b>Buttons/Switches</b>		<b>Buttons/Switches</b>	
	<i>Power</i>		<i>Power</i>	
	On/Off with Start/Stop (O/I Start Label)	10	On/Off with Start/Stop (O/I Start Label)	10
	<b>Display/Symbols/Indicators</b>		<b>Display/Symbols/Indicators</b>	
	<i>Measurement Procedure</i>		<i>Measurement Procedure</i>	
	Deflation symbol	11	Deflation symbol	11
	Heartbeat symbol during deflation	11	Heartbeat symbol during deflation	11
	<i>Post Measurement</i>		<i>Post Measurement</i>	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	<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
	<b>Algorithms</b>		<b>Algorithms</b>	
	<i>Diagnostic</i>		<i>Diagnostic</i>	
	Normotension/Hypertension	13	Normotension/Hypertension	13
135 / 85 mmHg thresholds	10, 11, 13	135 / 85 mmHg thresholds	10, 11, 13	
<b>Case</b>		<b>Case</b>		
<i>Display</i>		<i>Display</i>		
Single screen display	10	Single screen display	10	
Segment LCD	10	Segment LCD	10	
<i>Power</i>		<i>Power</i>		
AC adapter (Optional)	17	AC adapter (Optional)	17	
Automatic switch-off when not used for 5 min	17	Automatic switch-off when not used for 5 min	17	

Devices	M2 Basic (HEM-7116-E2)	M3 Intellisense (HEM-7051-E)
<b>Comparable Criteria</b>	<p><b>Measurement</b> <i>Sensors</i> Pressure sensor: piezo-resistive <sup>Note 1</sup> 5</p> <p><i>Measurement Records</i> Memory: 1 measurement 14</p> <p><b>Display/Symbols/Indicators</b> <i>Post Measurement</i> Measurement error <math>EE, E, E/E</math> and <math>E_r</math> <sup>Query 1, Note 5</sup> 11 Hypertension (Indicator strip) 11, 13</p> <p><b>Case</b> <i>Power</i> 4 “AAA” batteries ~ 300 measurements 17</p>	<p><b>Measurement</b> <i>Sensors</i> Pressure sensor: capacitive <sup>Note 1</sup></p> <p><i>Measurement Records</i> Memory: 42 measurements 14</p> <p><b>Display/Symbols/Indicators</b> <i>Post Measurement</i> Measurement error <math>EE, E, E/E</math> and <math>E/\sigma_{25}</math> <sup>Query 1, Note 5</sup> 11 Hypertension (Blinking heartbeat) 11, 13</p> <p><b>Case</b> <i>Power</i> 4 “AA” batteries ~ 1500 measurements 17</p>
<b>Device 2 Criteria</b>		<p><b>Buttons/Switches</b> <i>Measurement Records</i> Memory 10</p> <p><i>Settings</i> Set 10</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Procedure</i> Audible pulse indicator during deflation (Optional) 18 Beeps after measurement (Optional) 18</p> <p><i>Post Measurement</i> Irregular heartbeat 11, 13 Average symbol 11, 13</p> <p><i>Date and Time</i> Date and Time 11 Date and Time (During memory recall) 11</p> <p><i>Settings</i> Audible pulse indicator mode active 11, 18</p> <p><b>Algorithms</b> <i>Averages</i> Last 3 measurements (within 10 min of each other) mean 13</p> <p><i>Diagnostic</i> Irregular heartbeat detection 13</p>

<p><b>Query</b></p>	<p>1</p>	<p><b>Query</b> There are differences in the descriptions of the rapid air release, fuzzy logic and error codes between the manuals. Similar queries were raised previously but it is not possible to infer scientifically that answers can be applied in these instances also. Can you confirm that the rapid air release and fuzzy logic are used in both devices and that the mapping of the errors, as described previously for specific devices also applies to these?</p> <table border="1" data-bbox="616 319 1724 430"> <thead> <tr> <th></th> <th>Rapid Air Release</th> <th>Fuzzy Logic</th> <th colspan="4">Error Codes<sup>2</sup></th> </tr> </thead> <tbody> <tr> <td>M2 Basic (HEM-7116-E2)</td> <td>No</td> <td>No</td> <td>E</td> <td>EE</td> <td>E/E</td> <td>Er/?</td> </tr> <tr> <td>M3 Intellisense (HEM-7051-E)</td> <td>Yes<sup>1</sup></td> <td>Yes</td> <td>E</td> <td>EE</td> <td>E/E</td> <td>E/oP</td> </tr> </tbody> </table> <p>Note 1 This is not included in the manual but stated in a previous communication.                  Note 2 From previous communications, the errors are equivalent and grouped as shown and <i>P</i> refers to a pressure level. It is unclear from the manuals whether or not a pressure is shown for the HEM-7116-E2.</p> <p><b>Response</b> We confirm that rapid air release function and fuzzy logic are applied for all devices. Regarding to the error codes, please refer the document which we sent previously. For equivalent models of M3 Intellisense, a group1 error codes apply but we change the device error code from “Eo25” to “Er” in order to avoid confusion form our customers. (“25” is not pressure).</p> <p><b>Comment</b> The explanation is accepted</p>		Rapid Air Release	Fuzzy Logic	Error Codes <sup>2</sup>				M2 Basic (HEM-7116-E2)	No	No	E	EE	E/E	Er/?	M3 Intellisense (HEM-7051-E)	Yes <sup>1</sup>	Yes	E	EE	E/E	E/oP
		Rapid Air Release	Fuzzy Logic	Error Codes <sup>2</sup>																			
M2 Basic (HEM-7116-E2)	No	No	E	EE	E/E	Er/?																	
M3 Intellisense (HEM-7051-E)	Yes <sup>1</sup>	Yes	E	EE	E/E	E/oP																	
<p>2</p>	<p><b>Query</b> The declaration states that there is “No symbol for memory” but a memory symbol is present.</p> <p><b>Response</b> <i>This is an error. We will correct the declaration.</i></p> <p><b>Comment</b> The revised application is OK.</p>																						
<p><b>Notes</b></p>	<p>1</p>	<p>The Omron M2 Basic (HEM-7116-E) was approved as equivalent to the Omron M3 Intellisense (HEM-7051-E) on 26/08/2010. The Omron M2 Basic (HEM-7116-E2) is similar to the M2 Basic (HEM-7116-E) device except that</p> <ul style="list-style-type: none"> <li>a) The current pressure sensor (CPSU), a capacitive type, is changed to a new pressure sensor (NPS), a piezoelectric semiconductor type and</li> <li>b) An indicator is used to show hypertension rather than a blinking heartbeat.</li> </ul> <p>Details of comparatives tests between the sensors have been reviewed by dabl®Educational. Furthermore, the Omron M6 Comfort (HEM-7221-E8), which is the same as the Omron M6 Comfort (HEM-7221-E) except for a similar change in sensor, has been validated using the ESH-IP 2010 protocol and is recommended for use. Following a review of these documents, it was concluded that the change in sensor would not have a detrimental effect on the accuracy of the device.</p>																					
	<p>2</p>	<p>There is a change in the cloth used for the cuffs between those used for the Omron M2 Basic (HEM-7116-E2) [CM2-9513256-6 Medium, CL2-9513255-8 Large and CW-9520534-2 Universal] and those used for the Omron M3 Intellisense (HEM-7051-E) [CM-4997086-7 &amp; CM1-7935058-8 Medium and CL-4997065-4 Large]. The Omron M2 Basic (HEM-7116-E), approved for equivalence 26/08/2010 used CM2-9513256-6 &amp; CM1-9997578-9 Medium and CL2-9513255-8 &amp; CL1-9996760-3 Large.</p>																					

	3	<p>This note from the equivalence application for the HEM-7116-E is also applicable to the HEM-7116-E2.</p> <p><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>																							
	4	<p>This note from the equivalence application for the HEM-7116-E is also applicable to the HEM-7116-E2.</p> <p><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 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>																							
	5	<p>This note from Omron is applicable to the HEM-7116-E2.</p> <p><i>Regarding to Group1, when error appears in the device, the number in 2nd line indicates current air pressure. Therefore, EE and EE/0 indicates same error "cuff is under inflated" and also E and E/38 for measurement error. The number "0" and "38" means for "0mmHg" and "38mmHg". These are no more than example description for manual. However, in order not to confuse users, we are not using this description in manual any more. Regarding to Eo25 and Er25, these indicates same error "device error". These differences come from hardware limitation from LCD display. We consider these error codes have no difference and there is no algorithm change.</i></p> <p style="text-align: center;"><b>Group 1 Error Codes</b></p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Models</th> <th colspan="4">Error codes</th> <th>Ref</th> </tr> </thead> <tbody> <tr> <td>M3 Intellisense</td> <td>EE</td> <td>E</td> <td>E/E</td> <td>Eo25</td> <td>Z</td> </tr> <tr> <td>M2 Basic</td> <td>EE</td> <td>E</td> <td>E/E</td> <td>Eo25</td> <td>Z</td> </tr> <tr> <td>M3</td> <td>EE</td> <td>E/38</td> <td>E/E</td> <td>Er25</td> <td>Y</td> </tr> </tbody> </table>	Models	Error codes				Ref	M3 Intellisense	EE	E	E/E	Eo25	Z	M2 Basic	EE	E	E/E	Eo25	Z	M3	EE	E/38	E/E	Er25
Models	Error codes				Ref																				
M3 Intellisense	EE	E	E/E	Eo25	Z																				
M2 Basic	EE	E	E/E	Eo25	Z																				
M3	EE	E/38	E/E	Er25	Y																				
<b>Recommendation</b>	Equivalence is recommended.																								
<b>Date</b>	02/07/2012																								