

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-E8)

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 memory, 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 Tomohiro Kukita

Company Stamp/Seal

Name Tomohiro Kukita

Date 29 June 2011



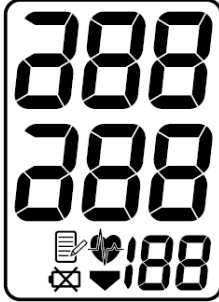

Signature of Witness J. Meijer

Name Janet Meijer

Address Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands

OMRON HEALTHCARE EUROPE B.V.
Kruisweg 577
NL-2132 NA Hoofddorp
P.O. Box 2150 NL- 2130 GL Hoofddorp
Tel. +31 - 20 354 82 00
Fax +31 - 20 354 82 01

Comparison of the Omron M2 Basic (HEM-7116-E8) with the Omron M3 Intellisense (HEM-7051-E)

Devices	M2 Basic (HEM-7116-E8)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria		
Same Criteria	<p>Measurement</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>Automatic Inflation 7</p> <p>Fuzzy Logic^{Note 2} 7</p>	<p>Measurement</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>Automatic Inflation 7</p> <p>Fuzzy Logic^{Note 2} 7</p>

Devices	M2 Basic (HEM-7116-E8)	M3 Intellisense (HEM-7051-E)	
Same Criteria (continued)	Measurement (continued)	Measurement (continued)	
	<i>Inflation (continued)</i>	<i>Inflation (continued)</i>	
	Press button if BP > 220 mmHg	7	Press button if BP > 220 mmHg
	Manually adjustable inflation pressure	7	Manually adjustable inflation pressure
	<i>Deflation</i>		<i>Deflation</i>
	Automatic Deflation	8	Automatic Deflation
	Automatic safety release valve ^{Note 3}	8	Automatic safety release valve ^{Note 3}
	<i>Cuffs</i>		<i>Cuffs</i>
	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) ^{Note 4}	6	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) ^{Note 4}
	Large (Arm circ. 32-42 cm) (Optional)	6	Large (Arm circ. 32-42 cm) (Optional)
	Buttons/Switches		Buttons/Switches
	<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)
	Display/Symbols/Indicators		Display/Symbols/Indicators
	<i>Measurement Procedure</i>		<i>Measurement Procedure</i>
	Deflation symbol	11	Deflation symbol
	Heartbeat symbol during deflation	11	Heartbeat symbol during deflation
	<i>Post Measurement</i>		<i>Post Measurement</i>
	SBP, DBP and Pulse	11	SBP, DBP and Pulse
	Measurement error EE , E , E/E and $E_{\alpha 25}$	11	Measurement error EE , E , E/E and $E_{\alpha 25}$
	Hypertension (Blinking heartbeat)	11, 13	Hypertension (Blinking heartbeat)
	<i>Measurement Records</i>		<i>Measurement Records</i>
	Memory icon	11	Memory icon
	<i>Power</i>		<i>Power</i>
	Low battery	11, 17	Low battery
	Algorithms		Algorithms
	<i>Diagnostic</i>		<i>Diagnostic</i>
	Normotension/Hypertension	13	Normotension/Hypertension
135 / 85 mmHg thresholds	10, 11, 13	135 / 85 mmHg thresholds	
Case		Case	
<i>Display</i>		<i>Display</i>	
Single screen display	10	Single screen display	
Segment LCD	10	Segment LCD	
<i>Power</i>		<i>Power</i>	
AC adapter (Optional)	17	AC adapter (Optional)	
Automatic switch-off when not used for 5 min	17	Automatic switch-off when not used for 5 min	

Devices	M2 Basic (HEM-7116-E8)	M3 Intellisense (HEM-7051-E)
Comparable Criteria	<p>Measurement</p> <p><i>Sensors</i></p> <p>Pressure sensor: piezo-resistive ^{Note 1} 5</p> <p><i>Measurement Records</i></p> <p>Memory: 1 measurement 14</p> <p>Case</p> <p><i>Power</i></p> <p>4 “AAA” batteries ~ 300 measurements 17</p>	<p>Measurement</p> <p><i>Sensors</i></p> <p>Pressure sensor: capacitive ^{Note 1} 5</p> <p><i>Measurement Records</i></p> <p>Memory: 42 measurements 14</p> <p>Case</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 1500 measurements 17</p>
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 memory zone mean 13</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>

<p>Queries</p>	<p>1</p>	<p>Query Even though the application is for equivalence against the Omron M3 Intellisense (HEM-7051-E), the fact that the Omron M2 Basic (HEM-7116-E) was previously approved against the same device is an important consideration. The only expected difference in the applications would therefore be the change in sensor.</p> <p>The appears to be a change in the console according to the respective manuals</p> <table border="1" data-bbox="694 319 1646 446"> <thead> <tr> <th></th> <th>Dimensions (mm)</th> <th>Weight (g)</th> </tr> </thead> <tbody> <tr> <td>Omron M2 Basic (HEM-7116-E)</td> <td>104 × 57 × 129</td> <td>260</td> </tr> <tr> <td>Omron M2 Basic (HEM-7116-E8)</td> <td>104 × 64 × 129</td> <td>245</td> </tr> </tbody> </table> <p>Response <i>We corrected the specification in the manual of Omron M2 Basic (HEM-7116-E8) because we found that the previous Omron M2 Basic (HEM-7116-E) was not correct.</i></p> <p>Comment The explanation is accepted</p>		Dimensions (mm)	Weight (g)	Omron M2 Basic (HEM-7116-E)	104 × 57 × 129	260	Omron M2 Basic (HEM-7116-E8)	104 × 64 × 129	245
	Dimensions (mm)	Weight (g)									
Omron M2 Basic (HEM-7116-E)	104 × 57 × 129	260									
Omron M2 Basic (HEM-7116-E8)	104 × 64 × 129	245									
	<p>2</p>	<p>Query</p> <p>a) The cuffs for the Omron M2 Basic (HEM-7116-E8) are the same as those for the Omron M2 Basic (HEM-7116-E). In the equivalence application for the Omron M2 Basic (HEM-7116-E) on 22/07/2010, a change in the cloth was declared. The equivalence for the Omron M2 Basic (HEM-7116-E8) is against the same device. Yet this difference is not included. Please explain.</p> <p>b) The publication cited is an abstract. Abstracts are not recognises by dablEducational as full evidence of validation. The correct reference is the paper Asmar R, Khabouth J, Topouchian J, El Feghali R, Mattar J. 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). <i>Blood Press Monit</i> 2010;15(1):49-54</p> <p>Response</p> <p>a) <i>This was mistake. Please confirm the revised application.</i></p> <p>b) <i>This was mistake. Please confirm the revised application.</i></p> <p>Comment The revised application is OK.</p>									
<p>Notes</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-E8) is identical to the M2 Basic (HEM-7116-E) device except that the current pressure sensor (CPSU), a capacitive type, is changed to a new pressure sensor (NPS), a piezoelectric semiconductor type. Details of comparatives tests 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>The manual for the HEM-7116-E was updated to refer to the HEM-7116-E and HEM-7116-E8. The main difference was the removal of the pressure detection item in the technical data section. The optional AC adapter has also changed.</p>									

2	This query from the equivalence application for the HEM-7116-E is also applicable to the HEM-7116-E8.	
	Query	Fuzzy logic: The manual, for the Omron M3 Intellisense (HEM-7051-E), states that fuzzy logic is used. It appears not to be available for the Omron M2 Basic (HEM-7116-E). There is no reference to this difference in the declaration. Please explain.
	Response	<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>
	Comment	The explanation is accepted
3	This note from the equivalence application for the HEM-7116-E is also applicable to the HEM-7116-E8.	
	<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>	
4	This query from the equivalence application for the HEM-7116-E is also applicable to the HEM-7116-E8.	
	Query	There appear to be some differences in the cuffs supplied with the monitors.
		<ul style="list-style-type: none"> 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. b) It is understood that the cloth changes apply to the large cuffs also.
	Response	<ul style="list-style-type: none"> a) <i>These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.</i> b) <i>These cuffs have no differences except cloth covers.</i>
	Comment	The explanation is accepted
Recommendation		Equivalence is recommended.
Date		02/07/2012