

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

HEM-7051 (HEM-7051-SH)

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

Publication

2010; 15:49-54

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 type="checkbox"/>	No <input checked="" 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 checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input checked="" 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:

10) No clock setting button.

11) The symbols for irregular heartbeat detection and hypertension indicator are removed. Clock function is removed. The symbol for mmHg/kPa is added.

13) The functions of irregular heartbeat detection and hypertension indicator are removed. Beeper is removed. Clock function is removed. The function of switching mmHg/kPa is added.




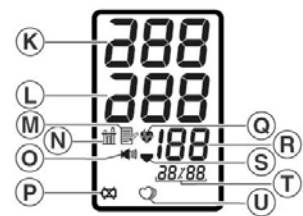
14) Stores 21 readings instead of 42, without time stamp.



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>08 Feb 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 HEM-7051 (HEM-7051-SH) with the Omron M3 Intellisense (HEM-7051-E)

Devices	HEM-7051 (HEM-7051-SH)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Display/Symbols/Indicators Settings Current unit (kPa / mmHg) marker 11</p> <p>Algorithms Parameter Settings Unit conversion (kPa / mmHg) 13</p>	
Same Criteria	<p>Measurement Accuracy Pulse accuracy ± 5% 1, 5</p> <p>Method Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5 Measurements are from single inflations 13 Manually initiated measurements 13, 14</p> <p>Inflation Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Fuzzy Logic 7</p>	<p>Measurement Accuracy Pulse accuracy ± 5% 1, 5</p> <p>Method Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5 Measurements are from single inflations 13 Manually initiated measurements 13, 14</p> <p>Inflation Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 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 8</p> <p>Cuffs</p> <p>Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) ^{Query 2} 6</p> <p>Sensors</p> <p>Pressure sensor: capacitive 5</p> <p>Buttons/Switches</p> <p>Measurement Records</p> <p>Memory 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 $E_{0.25}$ ^{Query 3} 11</p> <p>Measurement Records</p> <p>Memory icon 11</p> <p>Power</p> <p>Low battery 11, 17</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>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 ^{Query 1} 8</p> <p>Cuffs</p> <p>Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) ^{Query 2} 6</p> <p>Sensors</p> <p>Pressure sensor: capacitive 5</p> <p>Buttons/Switches</p> <p>Measurement Records</p> <p>Memory 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 $E_{0.25}$ ^{Query 3} 11</p> <p>Measurement Records</p> <p>Memory icon 11</p> <p>Power</p> <p>Low battery 11, 17</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>Accuracy</p> <p>BP accuracy ± 4 mmHg 1, 5</p> <p>Measurement Records</p> <p>Memory: 21 measurements 14</p> <p>Buttons/Switches</p> <p>Power</p> <p>On/Off with Start/Stop (Start/Stop Label) 10</p>		<p>Measurement</p> <p>Accuracy</p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Measurement Records</p> <p>Memory: 42 measurements 14</p> <p>Buttons/Switches</p> <p>Power</p> <p>On/Off with Start/Stop (O/I Start Label) 10</p>

	<p>Display/Symbols/Indicators Measurement Records Memory recall number (Replaces pulse rate momentarily) 11</p> <p>Case Power 4 “AAA” batteries ~ 300 measurements 17</p>	<p>Display/Symbols/Indicators <i>Date and Time</i> Date and Time (During memory recall) 11</p> <p>Case <i>Power</i> 4 “AA” batteries ~ 1500 measurements 17</p>
Device 2 Criteria		<p>Measurement <i>Cuffs</i> Large (Arm circ. 32-42 cm) (Optional) 6</p> <p>Buttons/Switches <i>Settings</i> Set 10</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i> Audible pulse indicator during deflation (Optional) 18 Beeps after measurement (Optional) 18</p> <p><i>Post Measurement</i> Hypertension (Blinking heartbeat) 11, 13 Irregular heartbeat 11, 13 Average symbol 11, 13</p> <p><i>Date and Time</i> Date and Time 11</p> <p><i>Settings</i> Audible pulse indicator mode active 11, 18</p> <p>Algorithms <i>Averages</i> Last 3 measurements (within 10 min of each other) mean 13</p> <p><i>Diagnostic</i> Normotension/Hypertension 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13</p>
Web link		http://www.omron-healthcare.com/sitepreview.php?SiteID=227

Comments	<p>Query 1 Rapid pressure release: The manual, for the HEM-7051, include two deflation entries. In addition to the regular deflation, there is an automatic exhaust valve for rapid pressure release. This is understood to be a safety feature. It appears not to be available for the M3 Intellisense. There is no reference to this difference in the declaration. Please explain.</p>
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	<p>Response 1 <i>The fact we have is that the M3 Intellisense (HEM-7051-E) and the HEM-7051 (HEM-7051-SH) 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> <p>Query 2 There appear to be some differences in the cuffs supplied with the monitors.</p> <p>There are different part numbers between those listed for the devices. No part numbers are provided for the HEM-7051 and no difference is made in the declaration. It is taken that there are no changes.</p> <p>Response 2 <i>These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.</i></p> <p>Query 3 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.</p> <p>Response 3 <i>Regarding to Chart 1, 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.</i></p> <p style="text-align: center;">Chart 1 Error Codes</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">Model</th> <th colspan="4" style="text-align: center;">Error codes</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">M3 Intellisense</td> <td style="text-align: center;">EE</td> <td style="text-align: center;">E</td> <td style="text-align: center;">E/E</td> <td style="text-align: center;">Eo25</td> </tr> <tr> <td style="text-align: center;">HEM-7051</td> <td style="text-align: center;">EE/0</td> <td style="text-align: center;">E/38</td> <td style="text-align: center;">E/E</td> <td style="text-align: center;">Eo25</td> </tr> </tbody> </table>	Model	Error codes				M3 Intellisense	EE	E	E/E	Eo25	HEM-7051	EE/0	E/38	E/E	Eo25
Model	Error codes															
M3 Intellisense	EE	E	E/E	Eo25												
HEM-7051	EE/0	E/38	E/E	Eo25												
Recommendation	The queries were adequately answered. A further query needs to be made regarding the accuracy ranges. Equivalence is recommended subject to an adequate response.															
Date	26/08/2010															