dabl® Educational Trust

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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SECTION A - Please complete all items online.

I Takefumi Nakanishi (Name of a Company Director) Director of Omron Healthcare Europe B.V. (Company name)

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Omron M3 (HEM-7200-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 (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 ☐	No ☒
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐
	3	Artefact/Error Detection	Yes ☐	No ☒
	4	Microphone(s)	Yes ☐	No ☐
	5	Pressure Transducer	Yes ☐	No ☒
	6	Cuff or Bladder	Yes ☒	No ☐
	7	Inflation Mechanism	Yes ☐	No ☒
	8	Deflation Mechanism	Yes ☐	No ☒
Part II	9	Model Name or Number	Yes ☒	No ☐
	10	Casing	Yes ☒	No ☐
	11	Display	Yes ☒	No ☐
	12	Carrying/Mounting Facilities	Yes ☐	No ☐
	13	Software other than Algorithm	Yes ☒	No ☐
	14	Memory Capacity/Number of stored measurements	Yes ☒	No ☐
	15	Printing Facilities	Yes ☐	No ☐
	16	Communication Facilities	Yes ☐	No ☐
	17	Power Supply	Yes ☐	No ☒
	18	Other Facilities	Yes ☐	No ☒

Brief explanation of differences and further relevant details:

6) Outer cloth is changed, no change on the size, shape and material on bladder.

10) The up button and the down button are added.

11) 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 body movement and the function to guide cuff wrapping are added.

14) 60 memories instead of 42 memories.

*Informs to user if the cuff was incorrectly wrapped.

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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 _____ Company Stamp/Seal

Name Takefumi Nakanishi

Date 17 February 2010

Signature of Witness _____

Name Janet Meijer

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

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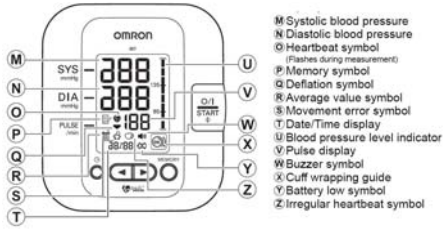
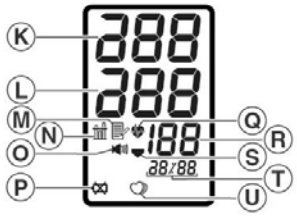
Comparison of the Omron M3 (HEM-7200-E) with the Omron M3 Intellisense (HEM-7051-E)

Devices	M3 (HEM-7200-E)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		
Validation		ESH
Device 1 Criteria	***Buttons/Switches*** *Settings* Up and down 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Correct cuff wrapping indicator 11, 13 *Post Measurement* Body movement error 3, 11, 13 ***Algorithms*** *Parameter Settings* Correct cuff wrapping detection 13 *Diagnostic* Body movement error detection 3, 13	
Same Criteria	**Measurement** Accuracy BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 Method Oscillometric measurement method 1, 5	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5

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	Pulse 40 bpm -180 bpm	1, 5	Pulse 40 bpm -180 bpm	1, 5
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Manually initiated measurements	13, 14	Manually initiated measurements	13, 14
	Inflation		*Inflation*	
	Inflation 0 mmHg - 299 mmHg	1, 5, 7	Inflation 0 mmHg - 299 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Fuzzy Logic	7	Fuzzy Logic	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
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Automatic safety release valve Note 1	8	Automatic safety release valve Note 1	8
	Cuffs		*Cuffs*	
	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Query 2	6	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Query 2	6
	Large (Arm circ. 32-42 cm) (Optional) Query 2	6	Large (Arm circ. 32-42 cm) (Optional) Query 2	6
	Sensors		*Sensors*	
	Pressure sensor: capacitive	5	Pressure sensor: capacitive	5
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (O/I Start Label)	10	On/Off with Start/Stop (O/I Start Label)	10
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	Settings		*Settings*	
	Set	10	Set	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Deflation symbol	11	Deflation symbol	11
	Heartbeat symbol during deflation	11	Heartbeat symbol during deflation	11
	Audible pulse indicator during deflation (Optional)	18	Audible pulse indicator during deflation (Optional)	18
	Beeps after measurement (Optional)	18	Beeps after measurement (Optional)	18
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Irregular heartbeat	11, 13	Irregular heartbeat	11, 13
	Average symbol	11, 13	Average symbol	11, 13
	Measurement Records		*Measurement Records*	
	Memory icon	11	Memory icon	11
	Date and Time		*Date and Time*	
	Date and Time	11	Date and Time	11

	Date and Time (During memory recall) 11 Power Low battery 11, 17 Settings Audible pulse indicator mode active 11, 18 **Algorithms** Averages Last 3 measurements (within 10 min of each other) mean 13 Diagnostic Normotension/Hypertension 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13 **Case** Display Single screen display 10 Segment LCD 10 Power 4 “AA” batteries ~ 1500 measurements 17 AC adapter (Optional) 17 Automatic switch-off when not used for 5 min 17	Date and Time (During memory recall) 11 *Power* Low battery 11, 17 *Settings* Audible pulse indicator mode active 11, 18 ***Algorithms*** *Averages* Last 3 measurements (within 10 min of each other) mean 13 *Diagnostic* Normotension/Hypertension 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13 ***Case*** *Display* Single screen display 10 Segment LCD 10 *Power* 4 “AA” batteries ~ 1500 measurements 17 AC adapter (Optional) 17 Automatic switch-off when not used for 5 min 17
Comparable Criteria	**Measurement** Measurement Records Memory: 60 measurements 14 **Display/Symbols/Indicators** Post Measurement Measurement error EE, E, E/E and Er/25 Query 3 11 Hypertension (Indicator strip) 11, 13	***Measurement*** *Measurement Records* Memory: 42 measurements 14 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error EE, E, E/E and E025 Query 3 11 Hypertension (Blinking heartbeat) 11, 13
Device 2 Criteria		
Web link		http://www.omron-healthcare.com/sitepreview.php?SiteID=227

Comments	Note 1	*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.*

<table>
<tr><td></td><td>
Query 2 There appear to be some differences in the cuffs supplied with the monitors.
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 2 a) These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.
b) These cuffs have no differences except cloth covers.
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.
Response 3 Regarding to Chart 1, when error appears in the device, the number in 2nd line indicates current air pressure. Regarding to Eo25 and Er25, these indicates same error "device error". These differences come from hardware limitation from LCD display.
Chart 1 Error Codes
<table>
<tr><th>Model</th><th colspan="4">Error codes</th></tr>
<tr><td>M3 Intellisense</td><td>EE</td><td>E</td><td>E/E</td><td>Eo25</td></tr>
<tr><td>M3</td><td>EE</td><td>E</td><td>E/E</td><td>Er25</td></tr>
</table>
Query 4 One of the Omron websites describes an M3 device http://www.omron-healthcare.com.sg/products_bloodpressure_m3.htm which differs from that for which the application was supplied. There is no “HEM” model number for this on the site. Therefore, it is difficult to distinguish them from the similarly named applicant devices. How can this device be distinguished from that for which the application is made?
Response 4 Mentioned device, M3 on http://www.omron-healthcare.com.sg, do not have “HEM” model so far. When this device was marketed, we have communicated by using only “M3” without mentioning “HEM” model. However as dabl pointed out, this confuses user to identify which model. From now on, the new device will be described with HEM model numbers, for example M3(HEM-7200-E), to distinguish as like OMRON Healthcare Europe website. (http://www.omron-healthcare.com/en/product/blood_pressure_monitors/M3.html) in case we use same sales name (e.g. M3) at global market basis.
</td></tr>
<tr><td>Recommendation</td><td>The queries were adequately answered. Equivalence is recommended.</td></tr>
<tr><td>Date</td><td>26/08/2010</td></tr>
</table>