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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 MX2 Basic (HEM-742-E2)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M2 Compact (HEM-7102-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 ☐	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:

10) Power ON button is added. Start button is used for measurement start only. No memory button.

11) No symbol for irregular heart beat and memory.

13) No function to detect irregular heart beat and no function to detect hypertension.

14) No memory function.

17) 4 x AA batteries instead of 4 x AAA batteries

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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 T. Nakanishi

Name Takefumi Nakanishi

Date 04 February 2010

Signature of Witness J. Meijer

Name Janet Meijer

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

Company Stamp/Seal

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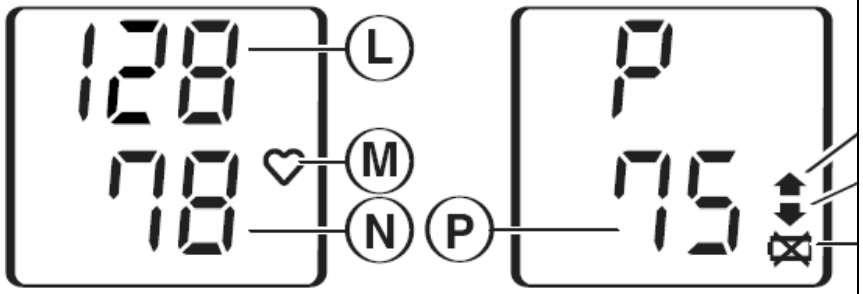
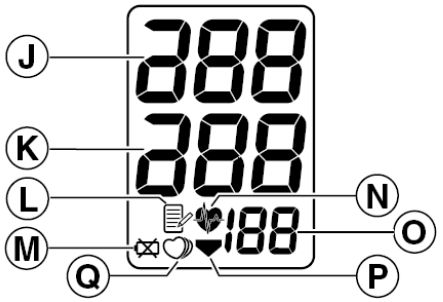
Comparison of the Omron MX2_Basic (HEM-742-E2) with the Omron M2_Compact (HEM-7102-E)

Devices	MX2_Basic (HEM-742-E2)	M2_Compact (HEM-7102-E)
Pictures		
Display		
Validation		ESH
Device 1 Criteria	***Measurement*** *Inflation* Zero pressure check before inflation 7 ***Display/Symbols/Indicators*** *Preparation* Zero cuff pressure check 11, 13, 18 *Measurement Procedure* Inflation symbol 11	
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13

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	Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Press button if BP > 170 mmHg 7 Manually adjustable inflation pressure 7 *Deflation* Automatic Deflation 8 Automatic safety release valve 8 *Cuffs* Large (Arm circ. 32-42 cm) (Optional) Query 2 6 *Sensors* Pressure sensor: capacitive 5 ***Display/Symbols/Indicators*** *Measurement Procedure* Deflation symbol 11 During Measurement: BP Level & Heartbeat 11 *Post Measurement* SBP, DBP and Pulse 11 *Power* Low battery 11, 17 ***Case*** *Display* Single screen display 10 Segment LCD 10 *Power* AC adapter (Optional) 17 Automatic switch-off when not used for 5 min 17	Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Press button if BP > 170 mmHg 7 Manually adjustable inflation pressure 7 *Deflation* Automatic Deflation 8 Automatic safety release valve Query 1 8 *Cuffs* Large (Arm circ. 32-42 cm) (Optional) Query 2 6 *Sensors* Pressure sensor: capacitive 5 ***Display/Symbols/Indicators*** *Measurement Procedure* Deflation symbol 11 During Measurement: BP Level & Heartbeat 11 *Post Measurement* SBP, DBP and Pulse 11 *Power* Low battery 11, 17 ***Case*** *Display* Single screen display 10 Segment LCD 10 *Power* AC adapter (Optional) 17 Automatic switch-off when not used for 5 min 17
Comparable Criteria	***Measurement*** *Cuffs* Medium 145 mm × 480 mm (Arm circ. 22 to 32 cm) Query 2 6 ***Buttons/Switches*** *Power* On/Off with Stop (O/I Label) 10 Start 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error EE, E and E/E Query 3 11 ***Case***	***Measurement*** *Cuffs* Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Query 2 6 ***Buttons/Switches*** *Power* On/Off with Start/Stop (O/I Start Label) 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error EE, E, E/E and E025 Query 3 11 ***Case***

	Power 4 “AA” batteries ~ 300 measurements 17	*Power* 4 “AAA” batteries ~ 300 measurements 17
Device 2 Criteria		***Measurement*** *Measurement Records* Memory: 14 measurements 14 ***Buttons/Switches*** *Measurement Records* Memory 10 ***Display/Symbols/Indicators*** *Post Measurement* Hypertension (Blinking heartbeat) 11, 13 Irregular heartbeat 11, 13, 18 *Measurement Records* Memory icon 11 ***Algorithms*** *Diagnostic* Normotension/Hypertension 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13
Web link		http://www.

Comments	Query 1	Rapid pressure release: The manual, for the MX2 Basic, 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 M2 Compact. There is no reference to this difference in the declaration. Please explain.
	Response 1	*The fact we have is that the M2 Compact (HEM-7102-E) and the MX2 Basic (HEM-742-E2) 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.*
	Query 2	The dimensions of the cuffs supplied with the HEM-746C and MX2 Basic differ from those supplied with the M2 Compact, with which they are being compared, but no differences are declared. Please explain.
	Response 2	*Please confirm Chart 1 which explains the relation between the models and dimensions.*

Chart 1 Models and cuff dimensions

Models	Dimensions (in manual)
M2 Compact	146 mm x 446 mm
MX2 Basic	145 mm x 480 mm

The actual size of these cuffs is same (Fig1).

Fig1 Size comparison

Regarding to longer dimension, the measurement point was different. For difference between M2 Compact / HEM-7101 and MX2 Basic, the 1mm difference is caused by treatment of edge of cuff. We consider this as cloth cover change (Fig2).

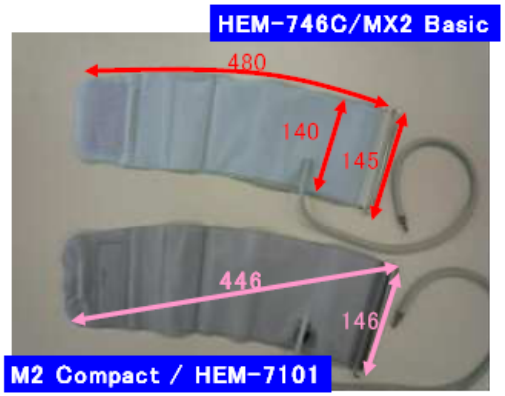

Fig2 Measurement point

However, this does not make any difference to measurement accuracy because the dimensions of bladder are all the same. In

<table>
<tr><td></td><td>
order not to confuse users, we will standardize the measurement point of cuff and describe the standardize dimensions in the manual.
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 2, when error appears in the device, the number in 2nd line indicates current air pressure. Therefore, EE and EE/67 indicates same error "cuff is under inflated" and also E and E/88 for measurement error. The number “67” and “88” means for “67mmHg” and “88mmHg”. These are no more than example description for manual. The MX2 Basic has the error code Eo25, but it is not described at manual. We consider these error codes have no difference and there is no algorithm change.
Chart 2 Error Codes
<table>
<tr><th>Model</th><th colspan="4">Error codes</th></tr>
<tr><td>M2 Compact</td><td>EE</td><td>E</td><td>E/E</td><td>Eo25</td></tr>
<tr><td>MX2 Basic</td><td>EE/67</td><td>E/88</td><td>E/E</td><td></td></tr>
</table>
</td></tr>
<tr><td>Recommendation</td><td>The queries were adequately answered. A further query needs to be made regarding the zeroing prior to measurement. Equivalence is recommended subject to an adequate response.</td></tr>
<tr><td>Date</td><td>26/08/2010</td></tr>
</table>