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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 HEM-7101 (HEM-7101-SH)
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) No AC adapter port.

11) No symbol for irregular heart beat. The symbol for mmHg/kPa is added.

13) No function to detect irregular heart beat. The function of switching mmHg/kPa is added.

14) Stores 21 readings instead of 14.

17) AC adapter is not available.

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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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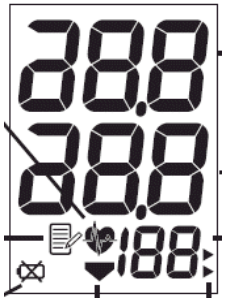
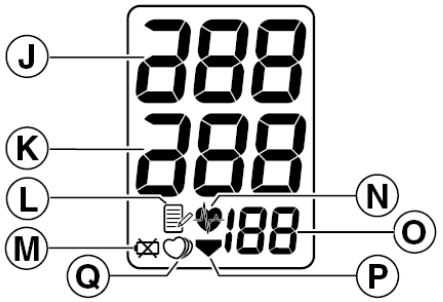
Comparison of the Omron HEM-7101 (HEM-7101-SH) with the Omron M2_Compact (HEM-7102-E)

Devices	HEM-7101 (HEM-7101-SH)	M2_Compact (HEM-7102-E)
Pictures		
Display		
Validation		ESH
Device 1 Criteria	**Display/Symbols/Indicators** Settings Current unit (kPa / mmHg) marker 11 **Algorithms** *Parameter Settings* Unit conversion (kPa / mmHg) 13	
Same Criteria	***Measurement*** *Accuracy* Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7	***Measurement*** *Accuracy* Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7

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	Automatic Inflation	7	Automatic Inflation	7
	Manually adjustable inflation pressure	7	Manually adjustable inflation pressure	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Automatic safety release valve	8	Automatic safety release valve Query 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
	Sensors		*Sensors*	
	Pressure sensor: capacitive	5	Pressure sensor: capacitive	5
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop	10	On/Off with Start/Stop (O/I Label)	10
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Deflation symbol	11	Deflation symbol	11
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Measurement error EE, E, E/E and Eo25	11	Measurement error EE, E, E/E and Eo25	11
	Hypertension (Blinking heartbeat)	11, 13	Hypertension (Blinking heartbeat)	11, 13
	Measurement Records		*Measurement Records*	
	Memory icon	11	Memory icon	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		***Algorithms***	
	Diagnostic		*Diagnostic*	
	Normotension/Hypertension	13	Normotension/Hypertension	13
	135 / 85 mmHg thresholds	13	135 / 85 mmHg thresholds	13
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Segment LCD	10	Segment LCD	10
	Power		*Power*	
	4 “AAA” batteries ~ 300 measurements	17	4 “AAA” batteries ~ 300 measurements	17
	Automatic switch-off when not used for 5 min	17	Automatic switch-off when not used for 5 min	17

Comparable Criteria	***Measurement*** *Accuracy* BP accuracy ± 4 mmHg 1, 5 *Inflation* Press button if BP > 220 mmHg 7 *Measurement Records* Memory: 21 measurements 14	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 *Inflation* Press button if BP > 170 mmHg 7 *Measurement Records* Memory: 14 measurements 14
Device 2 Criteria		***Measurement*** *Cuffs* Large (Arm circ. 32-42 cm) (Optional) 6 ***Display/Symbols/Indicators*** *Post Measurement* Irregular heartbeat 11, 13, 18 ***Algorithms*** *Diagnostic* Irregular heartbeat detection 13 ***Case*** *Power* AC adapter (Optional) 17
Web link		http://www.

Comments	Query 1	Rapid pressure release: The manual, for the HEM-7101, 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 HEM-7101 (HEM-7101-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.*
	Query 2	There appear to be some differences in the cuffs supplied with the monitors. There are different part numbers between those listed for the devices. No part numbers is provided for the HEM-7101 and no difference is made in the declaration. It is taken that there are no changes.
	Response 2	These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.

Recommendation	The queries were adequately answered. Further queries need to be made regarding the accuracy ranges and the BP above which a manually initiated boost is required. Equivalence is recommended subject to an adequate responses.
Date	26/08/2010