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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

SEM-1 (HEM-7051-C12)
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; 15:49-54
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 clock setting button.

11) The symbol for irregular heartbeat detection is removed. Clock function is removed.

13) The function of irregular heartbeat detection is removed. Beeper is removed. Clock function is removed.

14) Stores 21 readings instead of 42.

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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 _____

Name Takefumi Nakanishi

Date 08 Feb 2010

Signature of Witness _____

Name Janet Meijer

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

Company Stamp/Seal

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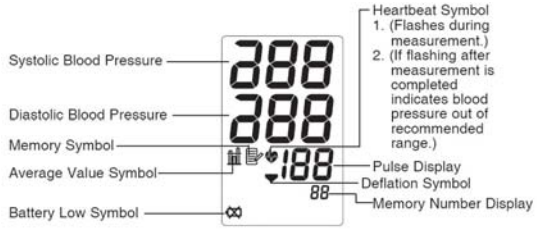
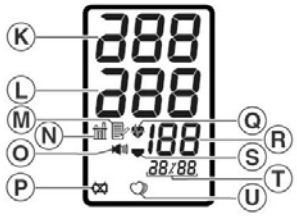
Comparison of the Omron SEM-1 (HEM-7051-C12) with the Omron M3 Intellisense (HEM-7051-E)

Devices	SEM-1 (HEM-7051-C12)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		
Validation		ESH
Device 1 Criteria		
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 Measurements are from single inflations 13 Manually initiated measurements 13, 14 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Fuzzy Logic [Query 1] 7 Press button if BP > 220 mmHg 7 Manually adjustable inflation pressure 7 *Deflation* Automatic Deflation 8	***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 Measurements are from single inflations 13 Manually initiated measurements 13, 14 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Fuzzy Logic 7 Press button if BP > 220 mmHg 7 Manually adjustable inflation pressure 7 *Deflation* Automatic Deflation 8

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	Automatic safety release valve 8 *Cuffs* Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Query 3 6 *Sensors* Pressure sensor: capacitive 5 ***Buttons/Switches*** *Measurement Records* Memory 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Deflation symbol 11 Heartbeat symbol during deflation 11 *Post Measurement* SBP, DBP and Pulse 11 Measurement error EE, E, E/E and E025 11 Hypertension (Blinking heartbeat) 11, 13 Average symbol 11, 13 *Measurement Records* Memory icon 11 *Power* Low battery 11, 17 ***Algorithms*** *Diagnostic* Normotension/Hypertension 13 135 / 85 mmHg thresholds 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	Automatic safety release valve Query 2 8 *Cuffs* Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Query 3 6 *Sensors* Pressure sensor: capacitive 5 ***Buttons/Switches*** *Measurement Records* Memory 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Deflation symbol 11 Heartbeat symbol during deflation 11 *Post Measurement* SBP, DBP and Pulse 11 Measurement error EE, E, E/E and E025 11 Hypertension (Blinking heartbeat) 11, 13 Average symbol 11, 13 *Measurement Records* Memory icon 11 *Power* Low battery 11, 17 ***Algorithms*** *Diagnostic* Normotension/Hypertension 13 135 / 85 mmHg thresholds 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: 21 measurements 14 ***Buttons/Switches*** *Power* On/Off with Start/Stop (Start/Stop Label) 10	***Measurement*** *Measurement Records* Memory: 42 measurements 14 ***Buttons/Switches*** *Power* On/Off with Start/Stop (O/I Start Label) 10

	Display/Symbols/Indicators *Measurement Records* Memory recall number 11 ***Algorithms*** *Averages* Last 3 measurements mean 13	***Display/Symbols/Indicators*** *Date and Time* Date and Time (During memory recall) 11 ***Algorithms*** *Averages* Last 3 measurements (within 10 min of each other) mean 13
Device 2 Criteria		***Measurement*** *Cuffs* Large (Arm circ. 32-42 cm) (Optional) 6 ***Buttons/Switches*** *Settings* Set 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Audible pulse indicator during deflation (Optional) 18 Beeps after measurement (Optional) 18 *Post Measurement* Irregular heartbeat 11, 13 *Date and Time* Date and Time 11 *Settings* Audible pulse indicator mode active 11, 18 ***Algorithms*** *Diagnostic* Irregular heartbeat detection 13
Web link		http://www.omron-healthcare.com/sitepreview.php?SiteID=227

Comments	Query 1	Fuzzy logic: The manual, for the M3 Intellisense, states that fuzzy logic is used. It appears not to be available for the SEM1. There is no reference to this difference in the declaration. Please explain.
	Response 1	*The equivalent group of M3 Intellisense (HEM-7051-E) has the function of "Fuzzy logic", then SEM-1 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.*
	Query 2	Rapid pressure release: The manual, for the SEM1, 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. Response 2 *The fact we have is that the M3 Intellisense (HEM-7051-E) and the SEM1 (HEM-7051-C12) 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 3 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 are provided for the SEM1 and no difference is made in the declaration. It is taken that there are no changes. Response 3 *These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.*
Recommendation	The queries were adequately answered. Equivalence is recommended.
Date	26/08/2010