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DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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SECTION A - Please complete all items online.

I Tomohiro Kukita (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 M2 (HEM-7117-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 — 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:

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

10) No Set button (Date and Time setting, Beeper ON/OFF setting).

11) No symbol for average of 3 readings in memory, no symbol for beeper ON/OFF, no symbol for date and time.

13) No average function (average of the latest 3 readings in memory), no beeper control function, no date and time function.

14) 21 memories instead of 42 memories.

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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 Tomohiro Kukita.

Name Tomohiro Kukita

Date 22 July 2010

Signature of Witness J. Meijer-Dul

Name Janet Meijer

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

Company Stamp/Seal

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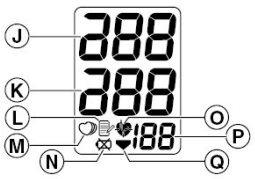
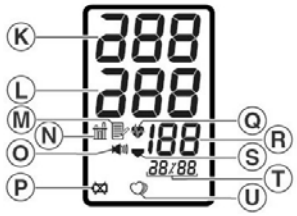
Comparison of the Omron M2 (HEM-7117-E) with the Omron M3 Intellisense (HEM-7051-E)

Devices	M2 (HEM-7117-E)	M3 Intellisense (HEM-7051-E)
Pictures		
Display	 J. Systolic blood pressure K. Diastolic blood pressure L. Memory symbol M. Irregular heartbeat symbol N. Battery low symbol O. Heartbeat symbol P. Pulse display Q. Deflation symbol	 K. Systolic blood pressure L. Diastolic blood pressure M. Memory symbol N. Average value symbol O. Buzzer symbol P. Battery low symbol Q. Heartbeat symbol R. Pulse display S. Deflation symbol T. Date/Time display U. Irregular heartbeat symbol
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 [Note 2] 8 Cuffs Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) [Query 3] 6 Large (Arm circ. 32-42 cm) (Optional) [Query 3] 6 Sensors Pressure sensor: capacitive 5 **Buttons/Switches** Power On/Off with Start/Stop (O/I Start Label) 10 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 Irregular heartbeat 11, 13 Measurement Records Memory icon [Query 4] 11 Power Low battery 11, 17 **Algorithms** Diagnostic Normotension/Hypertension 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13 **Case** Display Single screen display 10 Segment LCD 10 Power AC adapter (Optional) 17 Automatic switch-off when not used for 5 min 17	Automatic safety release valve [Note 2] 8 *Cuffs* Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) [Query 3] 6 Large (Arm circ. 32-42 cm) (Optional) [Query 3] 6 *Sensors* Pressure sensor: capacitive 5 ***Buttons/Switches*** *Power* On/Off with Start/Stop (O/I Start Label) 10 *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 Irregular heartbeat 11, 13 *Measurement Records* Memory icon 11 *Power* Low battery 11, 17 ***Algorithms*** *Diagnostic* Normotension/Hypertension 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13 ***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** Measurement Records Memory: 21 measurements 14	***Measurement*** *Measurement Records* Memory: 42 measurements 14

	Display/Symbols/Indicators Measurement Records Memory recall number (Replaces pulse rate momentarily) 11 **Case** Power 4 "AAA" batteries ~ 300 measurements 17	***Display/Symbols/Indicators*** *Date and Time* Date and Time (During memory recall) 11 ***Case*** *Power* 4 "AA" batteries ~ 1500 measurements 17
Device 2 Criteria		***Buttons/Switches*** *Settings* Set 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Audible pulse indicator during deflation (Optional) 18 Beeps after measurement (Optional) 18 *Post Measurement* Average symbol 11, 13 *Date and Time* Date and Time 11 *Settings* Audible pulse indicator mode active 11, 18 ***Algorithms*** *Averages* Last 3 measurements (within 10 min of each other) mean 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 M2. 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 M2 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.*
	Note 2	*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.
	Query 3	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 3	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 4	In the declaration for the M2, it is stated that there is no symbol for memory. The device does contain such a symbol. It will be overlooked as a minor error.
	Response 4	*Yes, this is an error. We will resend the correct declarations.*
	Comment 4	The new declaration was received.
	Query 5	One of the Omron websites describes an M2 device http://www.omron-healthcare.com.sg/products_bloodpressure_m2.htm which differs from that for which the application was supplied. There is no "HEM" model number for this on the site (and none in a manual for the M2 device available 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 5	*Mentioned device, M2 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 "M2" 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, to distinguish as like OMRON Healthcare Europe website in case we use same sales name at global market basis.*
Recommendation	The queries were adequately answered. Equivalence is recommended.	
Date	26/08/2010	