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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-746C (HEM-746C-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) Power ON button is added. Start button is used for measurement start only.

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

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

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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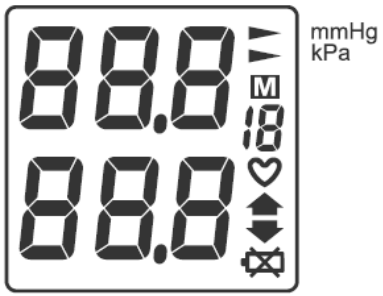
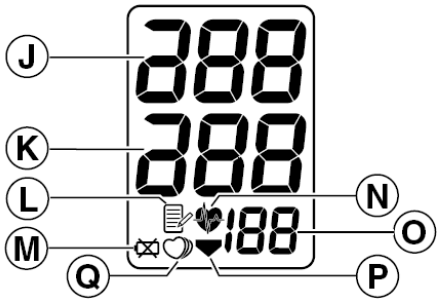
Comparison of the Omron HEM-746C (HEM-746C-SH) with the Omron M2_Compact (HEM-7102-E)

Devices	HEM-746C (HEM-746C-SH)	M2_Compact (HEM-7102-E)
Pictures		
Display		
Validation		ESH
Device 1 Criteria	***Measurement*** *Cuffs* Small (Arm circ. 17-22 cm) (Optional) 6 ***Display/Symbols/Indicators*** *Measurement Procedure* Inflation symbol 11 *Measurement Records* Memory recall number 11 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*	***Measurement*** *Accuracy* Pulse accuracy ± 5% 1, 5 *Method*

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	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	Pulse 40 bpm -180 bpm	1, 5, 8	Pulse 40 bpm -180 bpm	1, 5, 8
	Manually initiated measurements	13	Manually initiated measurements	13
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Inflation		*Inflation*	
	Inflation 0 mmHg - 299 mmHg	1, 5, 7	Inflation 0 mmHg - 299 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Press button if BP > 170 mmHg	7	Press button if BP > 170 mmHg	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
	Sensors		*Sensors*	
	Pressure sensor: capacitive	5	Pressure sensor: capacitive	5
	Measurement Records		*Measurement Records*	
	Memory: 14 measurements	14	Memory: 14 measurements	14
	Buttons/Switches		***Buttons/Switches***	
	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
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Segment LCD	10	Segment LCD	10
	Power		*Power*	
	AC adapter (Optional)	17	AC adapter (Optional)	17
	Automatic switch-off when not used for 5 min	17	Automatic switch-off when not used for 5 min	17
Comparable Criteria	***Measurement***		***Measurement***	
	Accuracy		*Accuracy*	
	BP accuracy ± 4 mmHg	1, 5	BP accuracy ± 3 mmHg	1, 5
	Cuffs		*Cuffs*	

	Medium 140 mm × 480 mm (Arm circ. 22 to 32 cm) Query 2 6 ***Buttons/Switches*** *Power* On/Off with Stop 10 Start 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error EE, E and E/E Query 3 11 *Measurement Records* Memory "M" symbol 11 ***Case*** *Power* 4 "AA" batteries ~ 300 measurements 17	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Query 2 6 ***Buttons/Switches*** *Power* On/Off with Start/Stop (O/I Label) 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error EE, E, E/E and E025 Query 3 11 *Measurement Records* Memory icon 11 ***Case*** *Power* 4 "AAA" batteries ~ 300 measurements 17
Device 2 Criteria		***Measurement*** *Cuffs* Large (Arm circ. 32-42 cm) (Optional) 6 ***Display/Symbols/Indicators*** *Post Measurement* Hypertension (Blinking heartbeat) 11, 13 Irregular heartbeat 11, 13, 18 ***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 HEM-746C, 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-746C (HEM-746C-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	The dimensions of the cuffs supplied with the HEM-746C 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 chart1 which explains the relation between the models and dimensions.*

Chart1 Models and cuff dimensions

Models	Dimensions (in manual)
M2 Compact	146 mm x 446 mm
HEM- 46C	140 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. Regarding to shorter dimension, HEM746C was measured different point from others. We consider this as cloth cover change (Fig2).

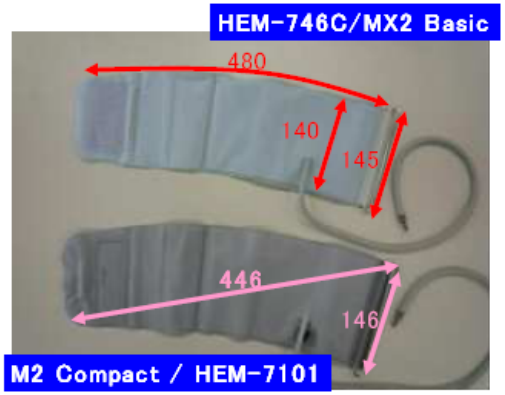

Fig2 Measurement point

However, this does not make any difference to measurement accuracy because the dimensions of bladder are all the same. In 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 HEM-746C 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

Model	Error codes			
M3 Intellisense	EE	E	E/E	Eo25
HEM-746C	EE/67	E/88	E/E	

Recommendation	The queries were adequately answered. A further query needs to be made regarding the accuracy ranges. Equivalence is recommended subject to an adequate response.
Date	26/08/2010