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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 M6 Comfort (HEM-7221-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M7 (HEM-780-E)
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the BHS protocol, the results of which were published as follows

Coleman A, Steel S, Freeman P, de Greeff A, Shennan A
Authors(s)
Validation of the Omron M7 (HEM-780-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol
Title
Blood pressure monitoring (Publication) 2008;13(1):49-54 (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 power button (the start button is used for power on and measurement start.). The memory button and the LED for dual check system* are added.

11) No symbol for inflation. The symbol for irregular heart beat, the symbol for body movement, the symbol for cuff wrapping guide** and the indicator for blood pressure level are added.

13) The function to detect irregular heart beat, the function to detect body movement, the function of hypertension indicator, the function to guide cuff wrapping, the function to check sensor (dual check system) are added.

*Main sensor takes the measurement, sub sensor checks if the device works.

**Informs to user if the cuff was incorrectly wrapped.

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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 17 February 2010

Signature of Witness M. Meijer-Dul

Name Janet Meijer

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

Company Stamp/Seal

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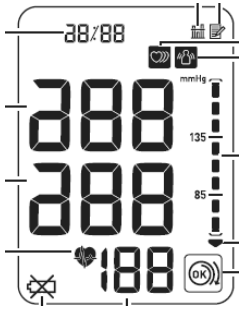
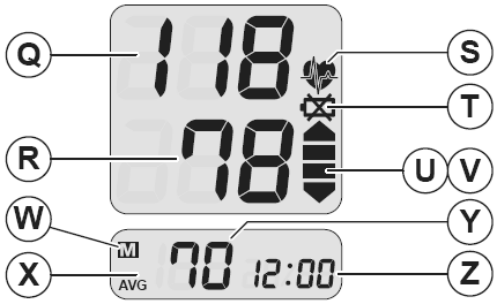
Comparison of the Omron M6 Comfort (HEM-7221-E) with the Omron M7 (HEM-7221-E)

Devices	Omron M6 Comfort (HEM-7221-E)	Omron M7 (HEM-7221-E)
Pictures		
Display		
Validation		BHS AAMI
Device 1 Criteria	***Measurement*** *Sensors* Pressure sensor: 2nd sensor for dual check 5 ***Display/Symbols/Indicators*** *Preparation* Correct cuff wrapping indicator 11, 13, 18 *Post Measurement* Hypertension (Indicator strip) 11, 13 Body movement error 3, 11, 13, 18 Irregular heartbeat 11, 13, 18 *Measurement Records* Memory recall number (Replaces pulse rate momentarily) 11 *Settings* Sensor cross check (LED) 5, 18	

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	Algorithms	
	Diagnostic	
	Normotension/Hypertension 13	
	135 / 85 mmHg thresholds 13	
	Irregular heartbeat detection 13	
	Body movement error detection 3, 13	
	Parameter Settings	
	Correct cuff wrapping detection 13	
	Sensor cross check 5, 18	
Same Criteria	***Measurement***	***Measurement***
	Accuracy	*Accuracy*
	BP accuracy ± 3 mmHg 1, 5	BP accuracy ± 3 mmHg 1, 5
	Pulse accuracy ± 5% 1, 5	Pulse accuracy ± 5% 1, 5
	Method	*Method*
	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
	Fuzzy Logic 7	Fuzzy Logic 7
	Press button if BP > 220 mmHg 7	Press button if BP > 220 mmHg 7
	Manually adjustable inflation pressure 7	Manually adjustable inflation pressure 7
	Deflation	*Deflation*
	Automatic Deflation 8	Automatic Deflation 8
	Sensors	*Sensors*
	Pressure sensor: capacitive 5	Pressure sensor: capacitive 5
	Measurement Records	*Measurement Records*
	Memory: 90 measurements 14	Memory: 90 measurements 14
	Buttons/Switches	***Buttons/Switches***
	Settings	*Settings*
	Date/Time set 10	Date/Time set 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 *Date and Time* Date and Time 11 Date and Time (During memory recall) 11 *Power* Low battery 11, 17 ***Case*** *Display* Segment LCD 10 *Power* AC adapter (Optional) 17	SBP, DBP and Pulse 11 *Date and Time* Date and Time 11 Date and Time (During memory recall) 11 *Power* Low battery 11, 17 ***Case*** *Display* Segment LCD 10 *Power* AC adapter (Optional) 17
Comparable Criteria	***Measurement*** *Cuffs* Single 152 mm × 600 mm (Arm circ. 22 to 42 cm) Query 1 6 ***Buttons/Switches*** *Power* On/Off with Start/Stop (O/I Start Label) 10 *Measurement Records* Memory 10 *Settings* Up and down 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error E 1, E2, E3, E4, E5 and Er Query 2 11 Average icon 11, 13, 14 *Measurement Records* Memory icon 11 ***Algorithms*** *Averages and Differences* Last 3 measurements (within 10 min of each other) mean 13 ***Case*** *Display* Single screen display 10 *Power* 4 “AA” batteries ~ 1000 measurements 17 Automatic switch-off when not used for 2 min 17	***Measurement*** *Cuffs* Single 150 mm × 582 mm (Arm circ. 22 to 42 cm) Query 1 6 ***Buttons/Switches*** *Power* On/Off with Stop (O/I Label) 10 Start 10 *Measurement Records* Memory × 2 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error EE, E, E/E and Er Query 2 11 Average “AVG” symbol 11, 13, 14 *Measurement Records* Memory “M” symbol 11 ***Algorithms*** *Averages and Differences* Last 3 measurements mean 13 ***Case*** *Display* Dual screen display 10 *Power* 4 “AA” batteries ~ 300 measurements 17 Automatic switch-off when not used for 5 min 17

Device 2 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
Web link		http://www.

Comments

Query 1 The dimensions of the cuff supplied with the M6 Comfort (HEM-7221-E) differ from that supplied with the M7, one of the devices with which it is being compared, but no differences are declared. Please explain.

Response 1 *Please confirm chart1 which explains the relation between the models and dimensions.*

Chart1 Models and cuff dimensions

Models	Dimensions (in manual)
M6 Comfort (HEM-7221-E)	152 mm x 600 mm
M7	150 mm x 582 mm

Regarding to longer dimension, the measurement point was different. For shorter dimension, 2mm difference is caused by treatment of edge of cuff. We consider this as cloth cover change.(Fig1)

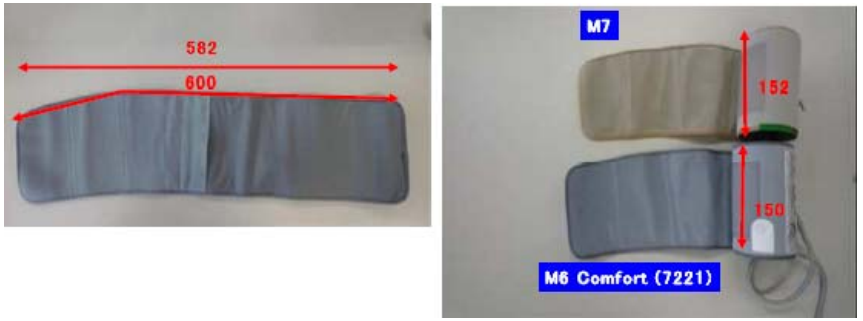


Fig1 Measurement point

However, these do 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.

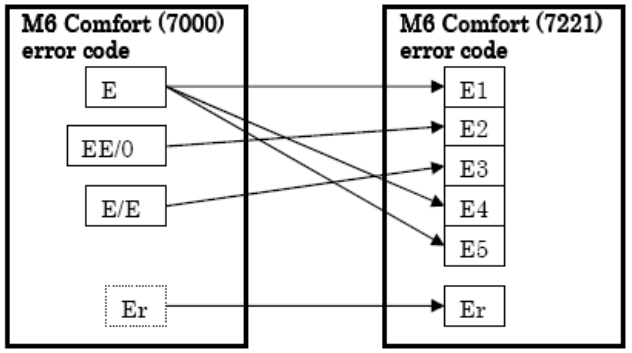
Query 2 There appear to be some differences in the error codes (apart from the extra features) which would not be expected if there were no algorithm changes. In the list, a slash indicates a line break where the error code is on two lines. Please explain.

Response 2 *Regarding Chart 2, M6 Comfort (7000) error code E had subdivide to M6 Comfort (7221) error code E1, E4 and E5. EE/0 is as same as E2. E/E is as same as E3. The background is explained below. For M6 Comfort (7000), EE/0 is as same as EE, 0 means 0mmHg, and this has the error code Er, but not described in manual. We consider there is no change in the error codes and algorithms among these devices.*

For our software, error codes consist of several error judgment conditions. We had a limitation to show enough information on the display in the past due to technical restriction on hardware. For now, the hardware performance has advanced to display more error code. Therefore, we reconsidered the constitution of the error judgment conditions and changed the expression to make it more easy to understand for users, starting from M6 (HEM-7211-E) and M6 Comfort (HEM-7221-E).

Chart 2 Error Codes

Model	Error codes					
M7	EE	E	E/E	Er		
M6 Comfort (7221)	E1	E2	E3	E2	E5	Er
M6 Comfort (7000)	EE/0	E	E/E			



Comment 2 In the response, there appears to be some confusion in the explanation. It is taken to read

The *M7 error codes E are subdivided in the M6 Comfort (7221) to error codes E1, E4 and E5. EE is the same as E2 and E/E is the same as E3. For the M6 Comfort (7000), EE/0 is as same as EE, 0 means 0mmHg, and it has the error code Er, but it is not described in manual.*

Recommendation	The queries were adequately answered. Equivalence is recommended.
Date	26/08/2010