dabl® Educational Trust

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items online.

I Tomohiro Kukita (Name of a Company Director) Director of (Company name) Omron Healthcare Europe B.V.

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Omron M6 Comfort (HEM-7221-E8)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M6 Comfort (HEM-7000-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

Belghazi J, El Feghali RN, Moussalem T, Rejdych M, Asmar RG
Authors(s)
Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension
Title
Vascular Health and Risk Management 2007;3(4):389-400
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:

5) The pressure sensor is replaced to a piezo electric sensor (NPS) from a capacitive sensor (CPSU), but the accuracy of blood pressure measurement is equivalent between NPS and CPSU.

10) The memory button is added.

11) The symbol for cuff wrapping guide and the indicator for blood pressure level are added. The dual check system indicator (LED) is added.

13) The function to guide cuff wrapping and the function to check the pressure sensor ("the dual check system") included.

34 Main Street, Blackrock, Co. Dublin, Ireland.
Tel + 353 1 278 0247
Fax + 353 1 278 3835
(dabl® Educational Trust Limited is a not-for-profit organisation)
Email info@dableducational.org
Web www.dableducational.org

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

Company Stamp/Seal

Name Tomohiro Kukita

Date 29 June 2011.

Signature of Witness J. Meijer

Name Janet Meijer

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

OMRON HEALTHCARE EUROPE B.V.
Kruisweg 577
NL-2132 NA Hoofddorp
P.O. Box 2150 NL- 2130 GL Hoofddorp
Tel. +31 - 20 354 82 00
Fax +31 - 20 354 82 01

Comparison of the Omron M6 Comfort (HEM-7221-E8) with the Omron M6 Comfort (HEM-7000-E)

Devices	Omron M6 Comfort (HEM-7221-E8)	Omron M6 Comfort (HEM-7000-E)
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	***Measurement*** *Sensors* Pressure sensor: 2nd sensor for dual check 5 ***Display/Symbols/Indicators*** *Preparation* Correct cuff wrapping indicator 11, 13, 18 *Measurement Records* Memory recall number (Replaces pulse rate momentarily) 11 *Settings* Sensor cross check (LED) 5, 18 ***Algorithms*** *Parameter Settings* Correct cuff wrapping detection 13 Sensor cross check 5, 18	

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

Devices	Omron M6 Comfort (HEM-7221-E8)		Omron M6 Comfort (HEM-7000-E)	
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
	Cuffs		*Cuffs*	
	Single 152 mm × 600 mm (Arm circ. 22 to 42 cm)	6	Single 152 mm × 600 mm (Arm circ. 22 to 42 cm)	6
	Measurement Records		*Measurement Records*	
	Memory: 90 measurements	14	Memory: 90 measurements	14
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (O/I Start Label)	10	On/Off with Start/Stop (O/I Start Label)	10
	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	SBP, DBP and Pulse	11
	Average icon	11, 13, 14	Average icon	11, 13, 14
	Body movement error	3, 11, 13, 18	Body movement error	3, 11, 13, 18
	Irregular heartbeat	11, 13, 18	Irregular heartbeat	11, 13, 18
	Measurement Records		*Measurement Records*	
	Memory icon	11	Memory icon	11

Devices	Omron M6 Comfort (HEM-7221-E8)		Omron M6 Comfort (HEM-7000-E)	
Same Criteria (continued)	***Display/Symbols/Indicators (continued)***		***Display/Symbols/Indicators (continued)***	
	Date and Time		*Date and Time*	
	Date and Time	11	Date and Time	11
	Date and Time (During memory recall)	11	Date and Time (During memory recall)	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		***Algorithms***	
	Averages and Differences		*Averages and Differences*	
	Last 3 measurements (within 10 min of each other) mean	13	Last 3 measurements (within 10 min of each other) mean	13
	Diagnostic		*Diagnostic*	
	Normotension/Hypertension	13	Normotension/Hypertension	13
	135 / 85 mmHg thresholds	13	135 / 85 mmHg thresholds	13
	Irregular heartbeat detection	13	Irregular heartbeat detection	13
	Body movement error detection	3, 13	Body movement error detection	3, 13
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Segment LCD	10	Segment LCD	10
	Power		*Power*	
	4 “AA” batteries ~ 1000 measurements	17	4 “AA” batteries ~ 1500 measurements	17
	AC adapter (Optional)	17	AC adapter (Optional)	17
Comparable Criteria	***Measurement***		***Measurement***	
	Sensors		*Sensors*	
	Pressure sensor: piezo-resistive Note 1	5	Pressure sensor: capacitive Note 1	5
	Buttons/Switches		***Buttons/Switches***	
	Measurement Records		*Measurement Records*	
	Memory	10	Memory × 2	10
	Settings			
	Up and down	10		
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Post Measurement		*Post Measurement*	
	Measurement error E 1, E2, E3, E4, E5 and Er Note 2	11	Measurement error EE/0, E and E/E Note 2	11
	Hypertension (Indicator strip)	11, 13	Hypertension (Blinking heartbeat)	11, 13
	Case		***Case***	
	Power		*Power*	
	Automatic switch-off when not used for 2 min	17	Automatic switch-off when not used for 5 min	17
Device 2 Criteria				

<table>
<tr><td>Query</td><td>1</td><td>Query The dual check system (function and LED) is not included in the declaration.
Response This was mistake. Please confirm the revised application.
Comment The revised application is OK.</td></tr>
<tr><td rowspan="2">Notes</td><td>1</td><td>The Omron M6 Comfort (HEM-7221-E) was approved as equivalent to the Omron M6 Comfort (HEM-7000-E) on 26/08/2010. The Omron M6 Comfort (HEM-7221-E8) is identical to the M6 Comfort (HEM-7221-E) device except that the current pressure sensor (CPSU), a capacitive type, is changed to a new pressure sensor (NPS), a piezoelectric semiconductor type. Details of comparatives tests have been reviewed by dabl®Educational. Furthermore, the Omron M6 Comfort (HEM-7221-E8) has itself been validated using the ESH-IP 2010 protocol and is recommended for use. Following a review of these documents, it was concluded that the change in sensor would not have a detrimental effect on the accuracy of the device.

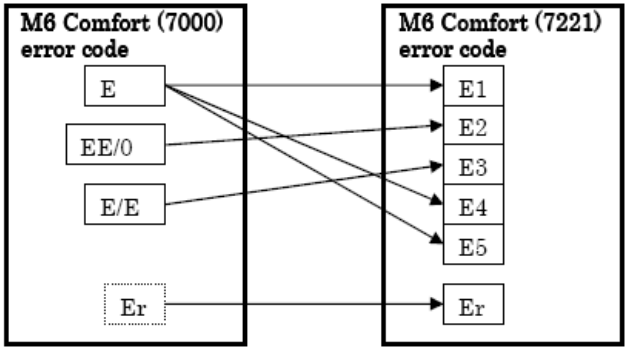
The manual for the HEM-7221-E was updated to refer to the HEM-7221-E and HEM-7221-E8. The main difference was the removal of the pressure detection item in the technical data section. The optional AC adapter has also changed.</td></tr>
<tr><td>2</td><td>This query from the equivalence application for the HEM-7221-E is also applicable to the HEM-7221-E8.

Query 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 Regarding to Group 4, 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).

Group 4 Error Codes
<table>
<tr><th>Model</th><th colspan="6">Error codes</th></tr>
<tr><td>M6 Comfort (7000)</td><td>EE/0</td><td>E</td><td>E/E</td><td></td><td></td><td></td></tr>
<tr><td>M6 Comfort (7221)</td><td>E1</td><td>E2</td><td>E3</td><td>E2</td><td>E5</td><td>Er</td></tr>
</table>
</td></tr>
</table>

		 Comment The explanation is accepted
Recommendation	Equivalence is recommended.	
Date	02/07/2012	