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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 (HEM-7001-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron 705IT (HEM-759-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

Andrew Coleman, Paul Freeman, Stephen Steel and Andrew Shennan
Authors(s)
Validation of the Omron 705IT (HEM-759-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol
Title
Blood Pressure Monitoring (Publication) 2006;11:27-32 (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)1 button for both Power ON and START instead of 2 buttons. Adjust button is removed (Memory button for clock adjusting instead of Adjust button.).

11) The symbols for irregular heartbeat detection and body movement detection are added. The symbol for memory average is added.

13) The functions of irregular heartbeat detection and body movement detection are added. Calculates and displays the average based on the last 3 readings.

14) Stores 90 readings instead of 28 readings.

15) No printer connection. (no printer port)

16) USB port is removed.

18) No USB cable and no CD-ROM for data download to PC.

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

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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

Company Stamp/Seal

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

Name Takefumi Nakanishi

Date 4 July. 2008

Signature of Witness J. Meijer-Duel

Name Janet Meijer

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

34 Main Street, Blackrock, Co. Dublin, Ireland.
Tel +353 1 278 0247
Fax +353 1 278 3835

Email info@dableducational.org
Web www.dableducational.org

Comparison of the Omron M6 with the Omron 705IT

Devices	Omron M6 (HEM-7001-E)	Omron 705IT (HEM-759-E)
Pictures		
Validation	BHS	
Device 1 Criteria	Body movement error indicator 3, 11, 13 Irregular heartbeat detection 11, 13 Average of last 3 measurements (including symbol) 11, 13	
Same Criteria	Accuracy ± 3 mmHg 1, 5 Oscillometric measurement method 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Pressure detection by “capacitive” pressure sensor (see Note 3 below) 5 Cuff (Medium): 140 mm × 480 mm (Arm circ. 22 to 32 cm) 6 Optional small (AC 17-22 cm) and large (AC 32-42 cm) cuffs 6 Inflation: Fuzzy Logic, press button if > 220 mmHg 7 Deflation: Automatic release valve 8 Date/Time Display 11 Low battery symbol 11, 17 Power: Optional AC adapter 17	Accuracy ± 3 mmHg 1, 5 Oscillometric measurement method 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Pressure detection by “capacitive” pressure sensor 5 Cuff (Medium): 140 mm × 480 mm (Arm circ. 22 to 32 cm) 6 Optional small (AC 17-22 cm) and large (AC 32-42 cm) cuffs 6 Inflation: Fuzzy Logic, press button if > 220 mmHg 7 Deflation: Automatic release valve 8 Date/Time Display 11 Low battery symbol 11, 17 Power: Optional AC adapter 17
Comparable Criteria	Date/Time Set button (changed with memory buttons) 10 O/I Start button 10 Single screen display 10 2 memory buttons, memory symbol 10, 11 During Measurement: Deflation & Heartbeat Symbols 11 Memory: 90 measurements 11, 14 Power: 4 “AA/LR6” batteries ~ 1500 measurements 17	Date/Time Set (changed with Adjust button) 10 Separate O/I and Start buttons 10 Two screen display 10 Memory button, memory symbol 10, 11 During Measurement: Inflation, Deflation & Heartbeat Symbols 11 Memory: 28 measurements 11, 14 Power: 4 alkaline “AA/LR6” batteries ~ 300 measurements 17
Device 2 Criteria		Optional printer 15 USB/Printer port 15 USB Cable and PC software 16, 18
Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=220	http://www.omron-healthcare.com/sitepreview.php?SiteID=222

Comments	1 The M6 is already validated according to the ESH protocol in four studies[1-3]. This declaration is to for equivalence according to the BHS protocol. 2 Batteries: Batteries appear to last 5 times longer in the M6 than in the 705IT. This may be due to improvements in battery technology reflected in the newer manual. 3 The manual for the M6 does not provide information re the pressure detection sensor. This was queried with Omron who replied with the statement on 09/03/09 “Omron M6 also uses the capacitive pressure sensor, which is same type of sensor as Omron 705IT”. References 1 Topouchian JA, El Assaad MA, Orobinskaia LV, El Feghali RN, Asmar RG. Validation of two automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension: the Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT) *Blood Press Monit* 2006;**11**:165-171 2 Altunkan S, Iliman N, Kayaturk N, Altunkan E. Validation of the Omron M6 (HEM-7001-E) upper-arm blood pressure measuring device according to the International Protocol in adults and obese adults *Blood Press Monit* 2007;**12**:219-225 3 Altunkan S, Iliman N, Altunkan E. Validation of the Omron M6 (HEM-7001-E) upper arm blood pressure measuring device according to the International Protocol in elderly patients *Blood Press Monit* 2008;**13**:117-122
	Equivalence is recommended
Date	10/03/2009