

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 Takefumi Nakanishi Director of Omron Healthcare Europe B.V.
Name of a Company Director Company name

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

Omron M6 Comfort (HEM-7000-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

Andrew Coleman, Stephen Steel, Paul Freeman, Annemarie de Greeff and Andrew Shennan
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

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	14	Memory Capacity/Number of stored measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

Brief explanation of differences and further relevant details:

10) includes 1 Start button instead of 2 buttons (Power ON and Start)

11) includes symbol for Irregular Heartbeat detection, includes symbol for the indicator of Hypertension, includes error symbol for the indicator of Body movement, no symbol for the inflation status

13) includes Irregular Heartbeat detection function, includes Hypertension indicator function, includes Body movement error indicator



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 21 Jul. 2008
Signature of Witness Helen Demeny
Name Helen Demeny
Address Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands

Company Stamp/Seal

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Comparison of the Omron M10-IT with the Omron M7

Devices	Omron M6 Comfort (HEM-7000-E)	Omron M7 (HEM-780-E)
Pictures		
Validation		BHS
Device 1 Criteria	Body movement error indicator 3, 11, 13 Hypertension indicator 11, 13 Irregular heartbeat detection 11, 13	
Same Criteria	Accuracy ± 3 mmHg 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Date/Time setting button 10 2 memory buttons (icon symbol) 10, 11 Last 3 measurements averages (icon symbol) 13 Memory: 90 measurements 14	Accuracy ± 3 mmHg 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Date/Time setting button 10 2 memory buttons (M symbol) 10, 11 Last 3 measurements averages (AVG symbol) 13 Memory: 90 measurements 14
Comparable Criteria	Pressure detection by “capacitive” pressure sensor 5 Cuff: 152 mm × 600 mm approx (Arm circ. 22 to 42 cm) 6 O/I Start button 10 Single screen display 10 Deflation symbol 11 Power: 4 “AA” batteries ~ 1500 measurements 17	Pressure detection by “electrostatic” pressure sensor 5 Cuff 150 mm × 582 mm approx (Arm circ. 22 cm to 42 cm) 6 O/I and Start buttons 10 Two screen display 10 Inflation and deflation symbols 11 Power: 4 “AA” batteries ~ 300 measurements 17
Device 2 Criteria		
Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=537	http://www.omron-healthcare.com/sitepreview.php?SiteID=221

Comments	<p>1 The M6 Comfort is already validated according to the ESH protocol¹. This declaration is to for equivalence according to the BHS protocol.</p> <p>2 Pressure sensor: A query was sent to Omron concerning “capacitive” and “electrostatic” sensors when comparing the M10-IT to the M7.</p> <p><i>The pressure sensor in the M10-IT is described as “capacitive” whereas that of the M7 is described as “electrostatic”. No references to these differences are made in the declaration form in which Item 5 (Pressure Transducer) is marked as indicating no differences between the devices.</i></p> <p>Their reply was accepted</p> <p><i>We can say that the sensor is completely same on both M10-IT and M7, though there are a bit different description in the instruction manuals. The sensor is "capacity" type, we normally say "Capacitive pressure sensor". We have put the "Electrostatic capacity pressure sensor" on the instruction manual of M7 accidentally. If this difference can not allow us to say that the pressure sensor is same, we are going to revise our description on M7 instruction manual immediately.</i></p> <p>3 Cuffs: Despite the slightly different descriptions in the manuals, the cuffs are described in the website as the ML ComfortCuff[®]. (ML stands for medium-large). It appears to be the same cuff.</p> <p>4 Batteries: Batteries appear to last 5 times longer in the M6 Comfort than in the M7. This may be due to improvements in battery technology reflected in the newer manual.</p> <p>Reference</p> <p>1 Belghazi J, El Feghali RN, Moussalem T, Rejdych M, Asmar RG. Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension <i>Vascular Health and Risk Management</i> 2007;3(4):389-400</p>
Recommendation	Equivalence is Recommended
Date	26/08/2008