

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 M10-IT (HEM-7080IT-E)
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

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Authors(s)

Validation of four automatic devices for self-measurement of blood pressure

according to the International Protocol of the European Society of Hypertension

Vascular Health and Risk Management 2007:3(4) 1-12
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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

Brief explanation of differences and further relevant details:

10) includes 1 memory button (to see the individual readings) instead of 2 memory button, includes memory button for Morning time and Evening time, includes 2 user button

11) includes symbol for 2 user, includes symbol for the high blood pressure in morning, includes symbol for the weekly average readings in Morning and Evening, includes symbol for Auto-mode (3 continuous measurements)

13) includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements)

14) 84 x 2 user readings in memory instead of 90 readings

16) includes USB port

18) includes USB cable and PC software with CD-ROM for data download to PC



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 M10-IT (HEM-7080IT-E)	Omron M6 Comfort (HEM-7000-E)
Pictures		
Validation		ESH
Device 1 Criteria	User ID switch, symbol 10, 11 Auto mode (3 continuous measurements - button, symbol) 10, 11, 13 Morning/Evening Average buttons and algorithms 10, 11, 13 Weekly averages 11, 13 Morning hypertension symbol 11, 13 USB port, cable and PC software 16, 18	
Same Criteria	Accuracy ± 3 mmHg 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Body movement error indicator 3, 11, 13 Pressure detection by “capacitive” pressure sensor 5 Cuff: 152 mm × 600 mm (Arm circ. 22 to 42 cm) 6 O/I Start button 10 Single screen display 10 Hypertension indicator 11, 13 Irregular heartbeat detection 11, 13 Last 3 measurements averages 13	Accuracy ± 3 mmHg 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Body movement error indicator 3, 11, 13 Pressure detection by “capacitive” pressure sensor 5 Cuff: 152 mm × 600 mm (Arm circ. 22 to 42 cm) 6 O/I Start button 10 Single screen display 10 Hypertension indicator 11, 13 Irregular heartbeat detection 11, 13 Last 3 measurements averages 13
Comparable Criteria	Memory button, memory symbol 10, 11 Memory: 84 measurements × 2 users 11, 14 Power: 4 “AA” batteries ~ 1400 measurements 17	2 memory buttons, memory symbol 10, 11 Memory: 90 measurements 11, 14 Power: 4 “AA” batteries ~ 1500 measurements 17
Device 2 Criteria		Date/Time setting button 10
Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=538	http://www.omron-healthcare.com/sitepreview.php?SiteID=537

Comments	<p>BHS/AAMI equivalence of the M10-IT with the M7 is previously approved. This application seeks equivalence with the ESH validated M6 Comfort.</p> <p>The M10-IT essentially has extra averaging facilities not available on the M6 Comfort. Weekly morning and evening averages are included with a special symbol if the morning average is elevated. While both devices provide averages for the last three readings, the M10-IT has a facility for automatically taking three readings in sequence. Readings can be stored separately for 2 people with the M10-IT and results can be transferred to a PC. Date and time settings on the M10-IT are provided using the set (auto mode) and memory buttons.</p> <p>All of the additions are calculated extras There appears to be no differences in any aspects concerned with BP detection.</p>
Recommendation	Equivalence is recommended.
Date	20/08/2008