

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
Company name

Omron Healthcare Europe B.V.

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 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 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 Start button instead of 2 buttons (Power ON and Start), 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 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, 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), includes Irregular Heartbeat detection function, includes Hypertension indicator function, includes Body movement error indicator

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- 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

Company Stamp/Seal

Name Takefumi Nakanishi

OMRON HEALTHCARE EUROPE B.V.

Date 27 Nov. 2008

Kruisweg 577

Signature of Witness J. Meijer

NL-2132 NA Hoofddorp

Name Janet Meijer

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Comparison of the Omron M10-IT with the Omron M7

Devices	Omrone M10-IT (HEM-7080IT-E)	Omrone M7 (HEM-780-E)		
Pictures				
Validation		BHS (and ESH)		
Device 1 Criteria	USB port, cable and PC software Morning/Evening Average buttons and algorithms Weekly averages User ID switch Auto mode (3 continuous measurements) Irregular heartbeat detection Hypertension indicator Body movement error indicator Set button (Auto mode)	16, 18 10, 11, 13 11, 13 10 11 11, 13 11, 13 3, 11, 13 10		
Same Criteria	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm Cuff Accuracy \pm 3 mmHg	1, 5, 7, 8 6 1, 5	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm Cuff Accuracy \pm 4 mmHg	1, 5, 7, 8 6 1, 5
Comparable Criteria	Memory: 84 measurements \times 2 users Single screen display Memory button Start button Pressure detection by “capacitive” pressure sensor	11, 14 10 10 10 5	Memory: 90 measurements Two screen display Two memory buttons (previous/next) On and Start buttons Pressure detection by “electrostatic” pressure sensor	14 10 10 10 5
Device 2 Criteria		Inflation status symbol		11
Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=538		http://www.omron-healthcare.com/sitepreview.php?SiteID=221	

Comments	<p>The M10-IT has averaging and BP/Pulse warning features not available in the Omron M7. As these are calculated on already detected pressures, they have not affect the validation process.</p> <p>Queries sent to Omron.</p> <p>1) The technical data in both manuals were compared to each other. The pressure sensor in the M10-IT is described as "capacitive" whereas that of the M7 is described as "electrostatic". No references to this differences are made in the declaration form in which Item 5 (Pressure Transducer) is marked as indicating no differences between the devices. (Pressure transducer and pressure sensor are the same thing.)</p> <p>Reply</p> <p>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.</p> <p>2) Body movement error detection is noted. This is declared under Item 13 (Software other than Algorithm) rather than Item 3 (Artefact/Error Detection) which is marked as indicating no differences between the devices.</p> <p>Reply</p> <p>Both M10-IT and M7 has completely same function on Item 3 (Artefact/Error Detection). Our "Body movement error" on M10-IT is the additional function on Item 3. M10-IT can show the error same as M7 in case there are some artefact during the measurement and M10-IT can show Body movement mark on its display in case it is estimated there are especially arm movement. This Body movement function can not give any factor to the measurement result. We have thought we should say "Body movement detection function" in the equivalent form.</p>
Recommendation	<p>The issues raised have been adequately addressed. It is accepted that the pressure transducers are the same but given different names and that the "body movement detection" is a display feature on an existing artefact detection.</p> <p>Equivalence is therefore recommended.</p>
Date	21/01/2008