

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 IA2 (HEM-7011-C1)
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 International protocol, the results of which were published as follows

Mohamed A. El Assaad, Jirar A. Topouchian and Roland G. Asmar
Authors(s)

Evaluation of two devices for self-measurement of blood pressure

according to the international protocol: the Omron M5-I and the Omron 705IT
Title

Blood Pressure Monitoring 2003, 8:127-133
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 checked="" 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) 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, hypertension indicator and body movement detection are added. Clock displays AM/PM instead of 24 hours. The symbol for memory average is added.

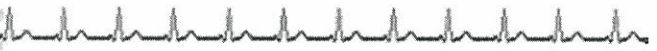
13) The functions of irregular heartbeat detection, hypertension indicator and body movement detection are added. Calculates and displays the average based on the last 3 readings.

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.



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. Natanuslew

Name Takefumi Nakanishi

Date 29 Jan. 2008

Signature of Witness Helen Demeny

Name Helen Demeny

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

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

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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

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Company Stamp/Seal

Name Takefumi Nakanishi

OMRON HEALTHCARE EUROPE B.V.

Date 29 Jan. 2008

Kruisweg 577

Signature of Witness Helen Demeny

NL-2132 NA Hoofddorp

Name Helen Demeny



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Comparison of the Omron IA2 with the Omron 705IT

Devices	Omron IA2 (HEM-7011-C1)	Omron 705IT (HEM-759-E)
Pictures		
Validation		ESH and BHS
Device 1 Criteria	Body movement error indicator 3, 11, 13 Average algorithm (3 most recent measurements) 11, 13 Irregular heartbeat detection 11, 13 Hypertension indicator 11, 13	
Same Criteria	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Accuracy ± 3 mmHg 1, 5 Pressure detection by “capacitance” pressure sensor 5 Cuff (140 mm \times 480 mm – Arm Circ. 22 cm to 32 cm) 6 Automatic Inflation (Fuzzy Logic) 7 Memory button 10 AC adapter jack (Adapter available as accessory) 17	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Accuracy ± 3 mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Cuff (140 mm \times 480 mm – Arm Circ. 22 cm to 32 cm) 6 Fuzzy Logic Inflation 7 Memory button 10 AC adapter jack (Adapter available as accessory) 17
Comparable Criteria	Single screen display 10 Start/Stop (inc On/Off) button 10, 13 Date/Time Setting button + use of memory button 10, 13 12-hour Clock 11 Memory: 90 measurements 14 4 \times 1.5 V “AA” Batteries (300 measurements) 17	Two screen display 10 On/Off (inc Stop) and Start buttons 10, 13 Date/Time Set and Adjust buttons 10, 13 24-hour Clock 11 Memory: 28 measurements 14 4 \times 1.5 V “LR6” Batteries (alkaline “AA”) (300 measurements) 17
Device 2 Criteria		USB/Printer Port, USB Cable and PC Software 15, 16, 18
Web link	<i>Not available on Omron websites</i>	http://www.omron-healthcare.com/sitepreview.php?SiteID=222
Comments	The Omron IA2 appears to be very similar to the 705IT. It does not provide the ability to print or export results but it includes some extra functions similar to other Omron devices. The basic functions are the same except requiring fewer buttons.	
Recommendation	Equivalence is recommended.	
Date	09/04/2008	