dabl® Educational Trust

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 (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 M4-I (HEM-752A-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 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 ☐	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) No SET and ADJUST buttons.

11) The symbols for Date and Time, single screen display instead of two screen display.

13) No Date and Time function.

14) Stores 14 memories instead of 28 memories.

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

Name Takefumi Nakanishi

Date 7 May. 2008

Signature of Witness J. Meijer

Name Janet Meijer

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

Tel +353 1 278 0247
Fax +353 1 278 3835

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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 — 2006;11:27-32
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 ☐	No ☒
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Comparison of the Omron M4-I with the Omron 705IT

Devices	Omron M4-I (HEM-752-E)	Omron 705IT (HEM-759-E)
Pictures		
Validation		ESH and BHS
Device 1 Criteria		
Same Criteria	Accuracy ± 3 mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Cuff (140 mm × 480 mm – Arm Circ. 22 cm to 32 cm) 6 “Intellisense” technology (Fuzzy logic on inflation) 7 Memory button 10 On/Off (inc Stop) and Start buttons 10, 13 4 × 1.5 V “LR6” Batteries (alkaline “AA”) (300 measurements) 17 AC adapter jack (Adapter available as accessory) 17	Accuracy ± 3 mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Cuff (140 mm × 480 mm – Arm Circ. 22 cm to 32 cm) 6 “Intellisense” technology (Fuzzy logic on inflation) 7 Memory button 10 On/Off (inc Stop) and Start buttons 10, 13 4 × 1.5 V “LR6” Batteries (alkaline “AA”) (300 measurements) 17 AC adapter jack (Adapter available as accessory) 17
Comparable Criteria	BP 0 mmHg to 280 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Single screen display 10 Memory: 14 measurements 14	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Two screen display 10 Memory: 28 measurements 14
Device 2 Criteria		Date/Time Set and Adjust buttons 10, 13 24-hour Clock, Date/Time display 11, 13 USB/Printer Port 15 USB Cable and PC Software 16, 18
Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=596	http://www.omron-healthcare.com/sitepreview.php?SiteID=222

Comments	The M4-I is, essentially, a trimmed down version of the 705IT. All of the blood pressure detection mechanisms appear to be identical. The main differences are 1) There are no date or time facilities whatsoever available on the M4-I; these have a special button and screen on the 705-IT 2) There is no facility for keeping a permanent record available on the M4-I; both printing and PC link facilities are available on the 705-IT Query from Advisory Board … there are 2 points I would like to make. First, I think (not entirely sure) that the M4-I is an older device than the 705-IT and is not on the market anymore. Second, having experience with both these devices it is easy to see that the pump function is different. The inflation function of the 705IT pump is better (a lot more quiet and smooth - probably technologically more advanced and possibly more expensive). So, my main question is whether the inflation mechanism (part 1, no 7) is unchanged. I think not. Response from Omron We hope the following explanation is sufficient for your Advisory Board members. First of all, M4-I is still available on the market, however based on our product range strategy in each country and are, M4-I might not be on the market for some of market. But generally speaking, M4-I is still on the market. As you said, M4-I has been sold a bit earlier than 705IT. However, in our clinically validation strategy, we forecast the product life time of 705IT will be longer than M4-I, then we have decided to use 705IT as the important base model. Regarding the pump, we always try to improve the products until the product will be discontinued. We can say that the inflation mechanism on M4-I has not been changed from the first production. What we improved is that the pump has been more silent without any changes of technical specifications (e.g. inflation speed, mechanism) and without any retail price increasing. We do believe the more silent pump can provide more comfort to the end user.
Recommendation	Equivalence is Recommended
Date	27/08/2008