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 M6 (HEM-7211-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

El Assaad, Mohamed A.; Topouchian, Jirar A.; Asmar, Roland G
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 (Publication) 2003;8(3):127-133 (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:

6) Outer cloth is changed, no change on the size, shape and material on bladder.

10) No power button (the start button is used for power on and measurement start.). No adjust button. No USB port. The up button and down button and the LED for dual check system* are added.

11) No symbol for inflation. The symbol for average of 3 readings in memory, the symbol for irregular heart beat, the symbol for body movement, the symbol for cuff wrapping guide** and the indicator for blood pressure level are added.

13) The function to detect irregular heart beat, the function to detect body movement, the function to average of memories (average of the latest 3 measurements), the function to guide cuff wrapping, the function of hypertension indicator, the function to check sensor (dual check system) are added.

14) 90 memories instead of 28 memories.

15) No printing facility.

16) No communication facility.

*Main sensor takes the measurement, sub sensor checks if the device works.

**Informs to user if the cuff was incorrectly wrapped.

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

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

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

Name Takefumi Nakanishi

Date 17 February 2010

Signature of Witness M. Meijer-Dul

Name Janet Meijer

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

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

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 M6 (HEM-7211-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 BHS protocol, the results of which were published as follows

Coleman A, Freeman P, Steel S, Shennan A
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)

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:

6) Outer cloth is changed, no change on the size, shape and material on bladder.

10) No power button (the start button is used for power on and measurement start.). No adjust button. No USB port. The up button and down button and the LED for dual check system* are added.

11) No symbol for inflation. The symbol for average of 3 readings in memory, the symbol for irregular heart beat, the symbol for body movement, the symbol for cuff wrapping guide** and the indicator for blood pressure level are added.

13) The function to detect irregular heart beat, the function to detect body movement, the function to average of memories (average of the latest 3 measurements), the function to guide cuff wrapping, the function of hypertension indicator, the function to check sensor (dual check system) are added.

14) 90 memories instead of 28 memories.

15) No printing facility.

16) No communication facility.

*Main sensor takes the measurement, sub sensor checks if the device works.

**Informs to user if the cuff was incorrectly wrapped.

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

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

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

Name Takefumi Nakanishi

Date 17 February 2010

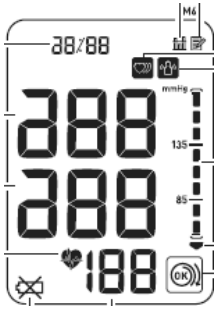
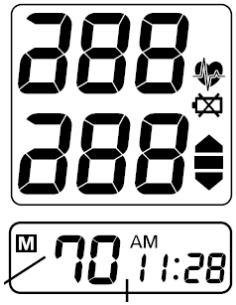
Signature of Witness M. Meijer

Name Janet Meijer

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

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

Comparison of the Omron M6 (HEM-7211-E) with the Omron 705IT (HEM-759-E)

Devices	Omron M6 (HEM-7211-E)	Omron 705IT (HEM-759-E)
Pictures		
Display		
Validation		ESH BHS AAMI
Device 1 Criteria	***Measurement*** *Sensors* Pressure sensor: 2nd sensor for dual check 5 ***Buttons/Switches*** *Settings* Up and down 10 ***Display/Symbols/Indicators*** *Preparation* Correct cuff wrapping indicator 11, 13, 18 *Post Measurement* Hypertension (Indicator strip) 11, 13 Average icon 11, 13, 14 Body movement error 3, 11, 13, 18 Irregular heartbeat 11, 13, 18 *Settings*	

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

	Sensor cross check (LED) 5, 18 ***Algorithms*** *Averages and Differences* Last 3 measurements (within 10 min of each other) mean 13 *Diagnostic* Normotension/Hypertension 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13 Body movement error detection 3, 13 *Parameter Settings* Correct cuff wrapping detection 13 Sensor cross check 5, 18	
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Fuzzy Logic 7 Press button if BP > 220 mmHg 7 Manually adjustable inflation pressure 7 *Deflation* Automatic Deflation 8 *Cuffs* Large (Arm circ. 32-42 cm) (Optional) Query 1 6 Small (Arm circ. 17-22 cm) (Optional) Query 1 6 *Sensors* Pressure sensor: capacitive 5 ***Buttons/Switches*** *Measurement Records* Memory 10 ***Display/Symbols/Indicators***	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 Fuzzy Logic 7 Press button if BP > 220 mmHg 7 Manually adjustable inflation pressure 7 *Deflation* Automatic Deflation 8 *Cuffs* Large (Arm circ. 32-42 cm) (Optional) Query 1 6 Small (Arm circ. 17-22 cm) (Optional) Query 1 6 *Sensors* Pressure sensor: capacitive 5 ***Buttons/Switches*** *Measurement Records* Memory 10 ***Display/Symbols/Indicators***

	Measurement Procedure	
	Deflation symbol	11
	During Measurement: BP Level & Heartbeat	11
	Post Measurement	
	SBP, DBP and Pulse	11
	Date and Time	
	Date and Time	11
	Date and Time (During memory recall)	11
	Power	
	Low battery	11, 17
	Case	
	Display	
	Segment LCD	10
	Power	
	AC adapter (Optional)	17
Comparable Criteria	***Measurement***	
	Cuffs	
	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Query 1	6
	Measurement Records	
	Memory: 90 measurements	14
	Buttons/Switches	
	Power	
	On/Off with Start/Stop (O/I Label)	10
	Settings	
	Date/Time set	10
	Display/Symbols/Indicators	
	Post Measurement	
	Measurement error E 1, E2, E3, E4, E5 and Er Query 2	11
	Measurement Records	
	Memory icon	11
	Case	
	Display	
	Single screen display	10
	Power	
	4 “AA” batteries ~ 1500 measurements	17
	Automatic switch-off when not used for 2 min	17
	Measurement Procedure	
	Deflation symbol	11
	During Measurement: BP Level & Heartbeat	11
	Post Measurement	
	SBP, DBP and Pulse	11
	Date and Time	
	Date and Time	11
	Date and Time (During memory recall)	11
	Power	
	Low battery	11, 17
	Case	
	Display	
	Segment LCD	10
	Power	
	AC adapter (Optional)	17
	Measurement	
	Cuffs	
	Medium 140 mm × 480 mm (Arm circ. 22 to 32 cm) Query 1	6
	Measurement Records	
	Memory: 28 measurements	14
	Buttons/Switches	
	Power	
	On/Off with Stop (O/I Label)	10
	Start	10
	Settings	
	Adjust	10
	Set	10
	Display/Symbols/Indicators	
	Post Measurement	
	Measurement error E and Er Query 2	11
	Measurement Records	
	Memory “M” symbol	11
	Case	
	Display	
	Dual screen display	10
	Power	
	4 “AA” (LR6) batteries ~ 300 measurements	17
	Automatic switch-off when not used for 5 min	17

Device 2 Criteria		***Display/Symbols/Indicators*** *Measurement Procedure* Inflation symbol 11 ***Case*** *Ports* USB/Printer port 15 USB port, cable and PC software 16, 18 *Features* Optional printer 15
Web link		http://www.

Comments

Query 1 There appear to be some differences in the cuffs supplied with the monitors.

a) There are different part numbers between those listed for the devices. These match the declaration of the different cloth covers. No difference is made in the declaration. It is taken that there are no changes.

b) It is understood that the cloth changes apply to the large cuffs also.

c) The dimensions of the cuff supplied with the M6 differ from that supplied with the 705-IT, with which it is being compared. However, the declaration declares only a change in the outer cloth and that there is no change in size. Please explain.

Response 1 a) *These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.*

b) *These cuffs have no differences except cloth covers.*

c) *Please confirm chart1 which explains the relation between the models and dimensions.*

Chart1 Models and cuff dimensions

Models	Dimensions (in manual)
705IT	140 mm x 480 mm
M6	146 mm x 446 mm

The actual size of these cuffs is same (Fig1).

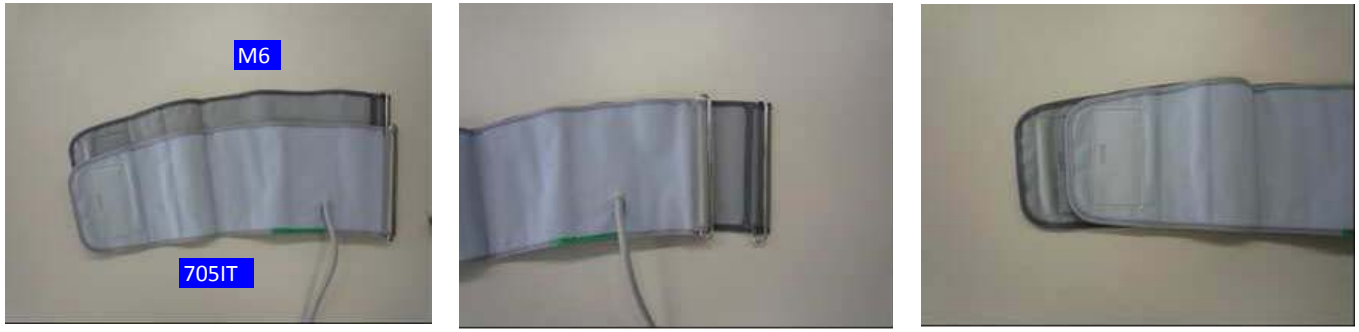


Fig1 Size comparison

The dimensions in manual were different because the measurement point was different. (Fig4)

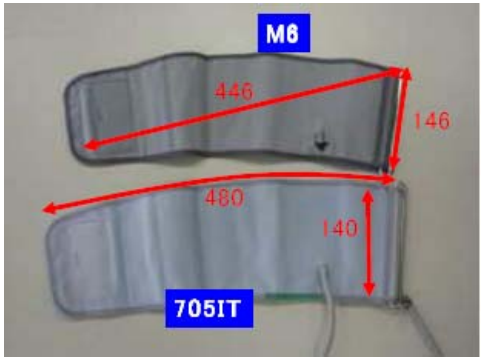


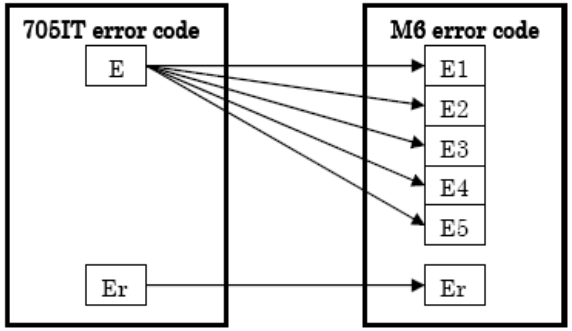
Fig2 Measurement point

However, this does not make any difference to measurement accuracy because the dimensions of bladder are all the same. In order not to confuse users, we will standardize the measurement point of cuff and describe the standardize dimensions in the manual.

Query 2	There appear to be some differences in the error codes (apart from the extra features) which would not be expected if there were no algorithm changes. In the list, a slash indicates a line break where the error code is on two lines. Please explain.
Response 2	*Regarding to Chart 2, the 705IT error code E had subdivide to E1, E2, E3, E4 and E5. For our software, error codes consist of several error judgment conditions. We had a limitation to show enough information on the display in the past due to technical restriction on hardware. For now, the hardware performance has advanced to display more error code. Therefore, we reconsidered the constitution of the error judgment conditions and changed the expression to make it more easy to understand for users, starting from M6 (HEM-7211-E) and M6 Comfort (HEM-7221-E).*

Chart 2 Error Codes

Model	Error codes					
705IT	E					Er
M6	E1	E2	E3	E2	E5	Er



Recommendation	The queries were adequately answered. Equivalence is recommended.
Date	26/08/2010