dabl® Educational Trust

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 Omron Healthcare Europe B.V. (Company name)

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Omron R6 (HEM-6000-E7)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron R7 (HEM-637-IT)
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

Topouchian JA, El Assaad MA, Orobinskaia LV, El Feghali RN, Asmar RG
Authors(s)

Validation of two automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension: the Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT)
Title

Blood Pressure Monitoring (Publication) 2006; 11: 165-171 (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:

5) The pressure sensor is replaced to a piezo electric sensor (NPS) from an electrostatic capacitive sensor (CPS), but the accuracy of blood pressure measurement is equivalent between NPS and CPS.

10) No "GRAPH" button, no two of "allow" buttons to select the setting and to view the graph display. No USB data communication port.

11) Segment LCD display instead of dot matrix LCD display, no graph display, no symbol of alarm function, includes the symbol of irregular heartbeat detection.

13) No graph display function, no alarm function, includes irregular heartbeat detection function, includes the memory average function (average of the latest 3 measurements).

16) No communication facilities.

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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 _____ Company Stamp/Seal

Name Takefumi Nakanishi

Date 17 February 2010

Signature of Witness _____

Name Janet Meijer

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Comparison of the Omron R6 (HEM-6000-E7) with the Omron R7 (HEM-637-IT)

Devices	Omron R6 (HEM-6000-E7)	Omron R7 (HEM-637-IT)
Pictures	 Image Omron R6 (HEM-6000-E)	
Validation		ESH
Device 1 Criteria	***Display/Symbols/Indicators*** *Measurement Procedure* Irregular heartbeat 11, 13 Average 11, 13 *Settings* Right wrist 11 ***Algorithms*** *Averages* Last 3 measurements mean 13 *Diagnostic* Atrial fibrillation detection 13	
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 Measurements are from single inflations 13 Manually initiated measurements 13, 14 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7	***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 Measurements are from single inflations 13 Manually initiated measurements 13, 14 *Inflation* Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7

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Devices	Omron R6 (HEM-6000-E7)		Omron R7 (HEM-637-IT)	
Same Criteria (Continued)	***Measurement***		***Measurement***	
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Cuffs		*Cuffs*	
	Wrist circ. 13.5-21.5 cm	6	Wrist circ. 13.5-21.5 cm	6
	Sensors		*Sensors*	
	Wrist positioning sensor	13, 18	Wrist positioning sensor	13, 18
	Measurement Records		*Measurement Records*	
	Memory: 90 measurements	14	Memory: 90 measurements	14
	Buttons/Switches		***Buttons/Switches***	
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	Settings		*Settings*	
	Set	10	Set	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Deflation symbol	11	Deflation symbol	11
	Heartbeat symbol during deflation	11	Heartbeat symbol during deflation	11
	Wrist position – adjust and OK	11, 13, 18	Wrist position – adjust and OK	11, 13, 18
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Date and Time		*Date and Time*	
	Date and Time	11	Date and Time	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		***Algorithms***	
	Parameter Settings		*Parameter Settings*	
	Right or left wrist	1	Right or left wrist	1
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Power		*Power*	
	2 “AAA” batteries ~ 300 measurements	17	2 “AAA” batteries ~ 300 measurements	17
	Automatic switch-off when not used for 2 min	17	Automatic switch-off when not used for 2 min	17

Devices	Omron R6 (HEM-6000-E7)	Omron R7 (HEM-637-IT)
Comparable Criteria	***Measurement*** *Sensors* Pressure sensor: Piezoelectric semiconductor 5 ***Buttons/Switches*** *Power* On/Off with Start/Stop (O/I Start Label) 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error (E ▼, E *height symbol* ▼, E/E ▼, E o*nn*) 11 *Measurement Records* Memory icon 11 ***Case*** *Display* Segment LCD 10	***Measurement*** *Sensors* Pressure sensor: Electrostatic capacitive semiconductor 5 ***Buttons/Switches*** *Power* On/Off with Start/Stop (O/I Label) 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error (E ▼, E HEIGHT ▼, E/E, E 0*nn*) 11 *Measurement Records* Memory "M" symbol 11 ***Case*** *Display* Dot matrix LCD 10
Device 2 Criteria		***Buttons/Switches*** *Settings* Forward 10 Backward 10 *Analysis* Graph 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Inflation symbol 11 Graph 11, 13 *Date and Time* Alarm reminder (2 alarms/day) 18 *Settings* Screen font size adjustment 11 ***Case*** *Ports* USB port, cable and PC software 16, 18
Web link	(HEM-6000-E) http://www.omron-healthcare.com/sitepreview.php?SiteID=234	(HEM-637-E2) http://www.omron-healthcare.com/sitepreview.php?SiteID=235

Comments	The Omron R6 (HEM-6000-E) was approved for equivalence to the Omron R7 on 17/12/2008. The Omron R6 (HEM-6000-E7) is identical to the HEM-600- E device except that the current pressure sensor (CPS), an electrostatic capacitive semiconductor type, is changed to a new pressure sensor (NPS), a piezoelectric semiconductor type. Omron supplied dabl® Educational with full details of tests carried out (in confidence), and a summary of these tests for circulation to the advisory board. Further clarification on a number of queries was requested and provided. Following a review of these documents, it was concluded that the change in sensor would not affect the accuracy of the device and equivalence was recommended and was approved by the board. *Original Comments* The R6 and R7 appear to differ only in the extra features provided. The forward and back control buttons in the R7 are mainly there to move between individual measurements in the graph though they are used when setting the date and time. As the R6 does not have a graph, these buttons are not needed; in the R6 and the Memory (Mem) and Set buttons have arrows beside them and they are used as “forward” and “back” buttons as necessary. The arm positioning and blood pressure measurement instructions are almost identical for both devices. They just differ in the display details. The segment display in the R6 also allows icons to be displayed more readily. The cuffs are the same.
Recommendation	Equivalence is approved.
Date	09/04/2010