dabl® Educational Trust

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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SECTION A - Please complete all items online.

I Tomohiro Kukita (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-6052-E7)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron R7
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 “left arrow” button to select the setting and to view the graph display. No USB data communication port. The “user ID selection” switch is added.
11) Segment LCD display instead of dot matrix LCD display, no graph display, no symbol of alarm function, includes the symbols of irregular heartbeat detection, movement error, memory average, user ID and buzzer, includes the blood pressure level indicator.
13) No graph display function, no alarm function, includes the functions of irregular heartbeat detection, body movement detection, memory average function (average of the latest 3 measurements).
14) Stores 90 readings each for two users instead of 90 readings for one user.
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 Tomohiro Kukita

Date 6 September, 2010

Signature of Witness _____

Name Janet Meijer

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

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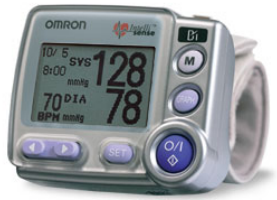
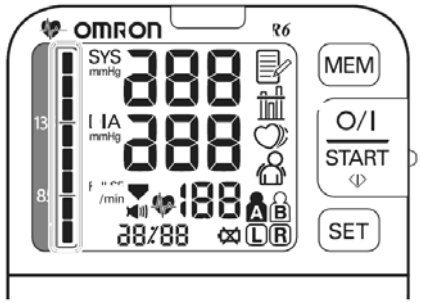
Comparison of the Omron R6 (HEM-6052-E7) with the Omron R7 (HEM-637-IT)

Devices	Omron R6 (HEM-6052-E7)	Omron R7 (HEM-637-IT)
Picture		
Display		
Validation		ESH
Device 1 Criteria	***Buttons/Switches***	
	Settings	
	User ID switch (A, B and Guest) 10	
	Two date/time setting buttons 10	
	Display/Symbols/Indicators	
	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	
	User A or B 11	
	Selected wrist 11	
	Audible pulse indicator mode active 11, 18	

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Devices	Omron R6 (HEM-6052-E7)		Omron R7 (HEM-637-IT)	
Device 1 Criteria	***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		
Same Criteria	***Measurement***		***Measurement***	
	Accuracy		*Accuracy*	
	BP accuracy ± 3 mmHg	1, 5	BP accuracy ± 3 mmHg	1, 5
	Pulse accuracy ± 5%	1, 5	Pulse accuracy ± 5%	1, 5
	Method		*Method*	
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	Pulse 40 bpm -180 bpm	1, 5	Pulse 40 bpm -180 bpm	1, 5
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Manually initiated measurements	13, 14	Manually initiated measurements	13, 14
	Inflation		*Inflation*	
	Inflation 0 mmHg - 299 mmHg	1, 5, 7	Inflation 0 mmHg - 299 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	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 (disabled/enabled options)	13, 18	Wrist positioning sensor (disabled/enabled options)	13, 18
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (O/I Start Label)	10	On/Off with Start/Stop (O/I or Start/Stop Label)	10
	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
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11

Devices	Omron R6 (HEM-6052-E7)	Omron R7 (HEM-637-IT)
Same Criteria (Continued)	***Display/Symbols/Indicators (continued)*** *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 ***Algorithms*** *Parameter Settings* Right or left wrist 1 ***Case*** *Display* Single screen display 10 *Power* 2 "AAA" batteries ~ 300 measurements 17 Automatic switch-off when not used for 2 min 17	***Display/Symbols/Indicators (continued)*** *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 ***Algorithms*** *Parameter Settings* Right or left wrist 1 ***Case*** *Display* Single screen display 10 *Power* 2 "AAA" batteries ~ 300 measurements 17 Automatic switch-off when not used for 2 min 17
Comparable Criteria	***Measurement*** *Sensors* Pressure sensor: Piezoelectric semiconductor 5 *Measurement Records* Memory: 90 measurements each A & B (None for Guest) 14 ***Display/Symbols/Indicators*** *Measurement Procedure* Wrist position – adjust with lights and beep when OK 11, 13, 18 Orange light to blue lights and beeps when OK *Post Measurement* Measurement error (E, E + flashing light, E/E, Er *nnn*) 11 *Measurement Records* Memory icon 11 ***Case*** *Display* Segment LCD 10	***Measurement*** *Sensors* Pressure sensor: Electrostatic capacitive semiconductor 5 *Measurement Records* Memory: 90 measurements (Can be disabled/enabled) 14 ***Display/Symbols/Indicators*** *Measurement Procedure* Wrist position – adjust with symbol and beep when OK 11, 13, 18 Arrows to symbol and beep when OK *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 (for date/time setting and graph details) 10 Backward (for date/time setting and graph details) 10

Devices	Omron R6 (HEM-6052-E7)	Omron R7 (HEM-637-IT)
Device 2 Criteria		***Buttons/Switches (continued)*** *Analysis* Graph 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Inflation symbol 11 *Post Measurement* Graphs (Morning/Evening/All measurements) 11, 13 *Date and Time* Alarm reminder (2 alarms/day) 18 *Settings* Screen font size adjustment 11 ***Case*** *Ports* Data port (Optional USB cable and PC software) 16, 18
Web link		

Comments	
	The R6 (HEM-6052-E7) (not to be confused with the R6 (HEM-6000-E7)), provides very different extra features to the R7 (HEM-637-IT). The R6 provides blood pressure diagnostic information, irregular heartbeat and body movement errors whereas the R7 provides graphs and PC linking features. The R6 provides records to be kept on two users with both devices providing a facility for not recording measurements. The R7 provides an alarm facility. Buttons and switches are provided accordingly. The arm positioning and blood pressure measurement instructions are similar in outcome though they differ in presentation with the R6 providing a light that changes from orange to blue while the R7 provides arrows that change to a heart symbol. The light is also used in the R6 to indicate an error where the wrist moves out of position during the measurement whereas the R7 indicates this by displaying the word “height” with the error. The segment display in the R6 also allows icons to be displayed more readily. The cuffs are the same. The fundamental measurement aspects of both devices, however, appear to be the same. The pressure sensor for the Omron R6 (HEM-6052-E7) uses a new pressure sensor (NPS), a piezoelectric semiconductor type, as distinct from the current pressure sensor (CPS), an electrostatic capacitive semiconductor type, used in the R7 (HEM-637-IT). This change is sensor was approved for the R6 (HEM-6000-E7) by the advisory board on 09/04/2010. At that time, Omron supplied dabl®Educational with full details of tests carried out (in confidence), and a summary of these tests was provided 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.
Recommendation	Equivalence is recommended.
Date	16/09/2010