

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

### SECTION A - Please complete all items online.

I Tomohiro Kukita 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 M6 Comfort (HEM-7223-E)  
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M6 Comfort (HEM-7221-E8)  
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

Asmar R  
Authors(s)  
Validation of the OMRON M6 COMFORT (HEM-7221-E8) Upper Arm blood pressure monitor, for self/home measurement, according to the revised (2010) European Society of Hypertension International Protocol.

N/A May 27, 2012  
Publication Year Volume Pages

The only differences between the devices involve the following components:

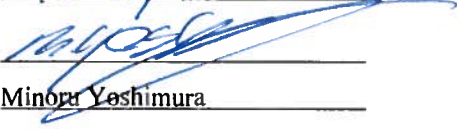
(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences below.)

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 type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>





Brief explanation of differences and further relevant details:

- 10) USER ID Selection Switch (A / B) is added.
- 11) USER ID symbol (A / B) is added.
- 13) The function to select user is added.
- 14) 2 user and 100 memories for each user instead of 90 memories.

**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	<u>Tomohiro Kukita</u>	Company Stamp/Seal
Name	<u>Tomohiro Kukita</u>	<b>OMRON HEALTHCARE EUROPE BV</b>
Date	<u>9 July 2012.</u>	Scorpius 33
Signature of Witness	<u></u>	NL-2132 LR Hoofddorp
Name	<u>Minora Yeshimura</u>	P.O.BOX 2050 NL-2130 GL Hoofddorp
Address	<u>Omron Healthcare Europe B.V., Scorpius 33, 2132 LR Hoofddorp, The Netherlands</u>	TEL +31-23 5544700
		FAX +31-23 5544701

Comparison of the Omron M6 Comfort (HEM-7223-E) with the Omron M6 Comfort (HEM-7221-E8)

Devices	Omron M6 Comfort (HEM-7223-E)	Omron M6 Comfort (HEM-7221-E8)
Pictures		
Display		
Validation		ESH-IP 2010
Device 1 Criteria	<p><b>Buttons/Switches</b></p> <p>Measurement Records</p> <p>User ID (A or B) 10</p> <p><b>Display/Symbols/Indicators</b></p> <p>Measurement Records</p> <p>User (A or B) 11</p>	
Same Criteria	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p>

Devices	Omron M6 Comfort (HEM-7223-E)	Omron M6 Comfort (HEM-7221-E8)
Same Criteria (continued)	<b>Measurement (continued)</b>	<b>Measurement (continued)</b>
	<i>Inflation</i>	<i>Inflation</i>
	Inflation 0 mmHg - 299 mmHg	Inflation 0 mmHg - 299 mmHg
	Automatic Inflation	Automatic Inflation
	Fuzzy Logic	Fuzzy Logic
	Press button if BP > 220 mmHg	Press button if BP > 220 mmHg
	Manually adjustable inflation pressure	Manually adjustable inflation pressure
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation	Automatic Deflation
	<i>Cuffs</i>	<i>Cuffs</i>
	Single 152 mm × 600 mm (Arm circ. 22 to 42 cm)	Single 152 mm × 600 mm (Arm circ. 22 to 42 cm)
	<i>Sensors</i>	<i>Sensors</i>
	Pressure sensor: piezo-resistive	Pressure sensor: piezo-resistive
	Pressure sensor: 2 <sup>nd</sup> sensor for dual check	Pressure sensor: 2 <sup>nd</sup> sensor for dual check
	<b>Buttons/Switches</b>	<b>Buttons/Switches</b>
	<i>Power</i>	<i>Power</i>
	On/Off with Start/Stop (O/I Start Label)	On/Off with Start/Stop (O/I Start Label)
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory	Memory
	<i>Settings</i>	<i>Settings</i>
	Date/Time set	Date/Time set
	Up and down	Up and down
	<b>Display/Symbols/Indicators</b>	<b>Display/Symbols/Indicators</b>
	<i>Preparation</i>	<i>Preparation</i>
	Correct cuff wrapping indicator	Correct cuff wrapping indicator
	<i>Settings</i>	<i>Settings</i>
	Sensor cross check (LED)	Sensor cross check (LED)
<i>Measurement Procedure</i>	<i>Measurement Procedure</i>	
Deflation symbol	Deflation symbol	
During Measurement: BP Level & Heartbeat	During Measurement: BP Level & Heartbeat	
<i>Post Measurement</i>	<i>Post Measurement</i>	
SBP, DBP and Pulse	SBP, DBP and Pulse	
Measurement error E1, E2, E3, E4, E5 and Er	Measurement error E1, E2, E3, E4, E5 and Er	
Hypertension (Indicator strip)	Hypertension (Indicator strip)	
Average icon	Average icon	
Body movement error	Body movement error	
Irregular heartbeat	Irregular heartbeat	

Devices	Omron M6 Comfort (HEM-7223-E)	Omron M6 Comfort (HEM-7221-E8)
<b>Same Criteria (continued)</b>	<p><b>Display/Symbols/Indicators (continued)</b></p> <p><i>Measurement Records</i></p> <p>Memory icon 11</p> <p>Memory recall number (Replaces pulse rate momentarily) 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements (within 10 min of each other) mean 13</p> <p><i>Diagnostic</i></p> <p>Normotension/Hypertension 13</p> <p>135 / 85 mmHg thresholds 13</p> <p>Irregular heartbeat detection 13</p> <p>Body movement error detection 3, 13</p> <p><i>Parameter Settings</i></p> <p>Correct cuff wrapping detection 13</p> <p>Sensor cross check 5, 18</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 "AA" batteries ~ 1000 measurements 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 2 min 17</p>	<p><b>Display/Symbols/Indicators (continued)</b></p> <p><i>Measurement Records</i></p> <p>Memory icon 11</p> <p>Memory recall number (Replaces pulse rate momentarily) 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements (within 10 min of each other) mean 13</p> <p><i>Diagnostic</i></p> <p>Normotension/Hypertension 13</p> <p>135 / 85 mmHg thresholds 13</p> <p>Irregular heartbeat detection 13</p> <p>Body movement error detection 3, 13</p> <p><i>Parameter Settings</i></p> <p>Correct cuff wrapping detection 13</p> <p>Sensor cross check 5, 18</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 "AA" batteries ~ 1000 measurements 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 2 min 17</p>
<b>Comparable Criteria</b>	<p><b>Measurement</b></p> <p><i>Measurement Records</i></p> <p>Memory: 100 measurements × 2 14</p>	<p><b>Measurement</b></p> <p><i>Measurement Records</i></p> <p>Memory: 90 measurements 14</p>
<b>Device 2 Criteria</b>		
<b>Comments</b>	The HEM-7223-E is a two-user version of the HEM-7221-E8	
<b>Recommendation</b>	Equivalence is recommended.	
<b>Date</b>	11/07/2012	