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.

<table>
<thead>
<tr>
<th>I</th>
<th>Takefumi Nakanishi</th>
<th>Director of</th>
<th>Omron Healthcare Europe B.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name of a Company Director</td>
<td>Company name</td>
<td></td>
</tr>
</tbody>
</table>

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

**Omron M6 Comfort (HEM-7221-E)**

Blood pressure measuring device for which validation is claimed

**Omron M7 (HEM-780-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, Steel S, Freeman P, de Greeff A, Shennan A**

**Authors**

**Validation of the Omron M7 (HEM-780-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol**

**Title**

Blood pressure monitoring 2008:13(1):49-54

**Publication**

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.)

<table>
<thead>
<tr>
<th>Part I</th>
<th>1 Algorithm for Oscillometric Measurements</th>
<th>Yes ☐</th>
<th>No ☑</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 Algorithm for Auscultatory Measurements</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td></td>
<td>3 Artefact/ Error Detection</td>
<td>Yes ☐</td>
<td>No ☑</td>
</tr>
<tr>
<td></td>
<td>4 Microphone(s)</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td></td>
<td>5 Pressure Transducer</td>
<td>Yes ☒</td>
<td>No ☒</td>
</tr>
<tr>
<td></td>
<td>6 Cuff or Bladder</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td></td>
<td>7 Inflation Mechanism</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td></td>
<td>8 Deflation Mechanism</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
</tbody>
</table>

| 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 power button (the start button is used for power on and measurement start.). The memory button and the LED for dual check system* are added.

11) No symbol for inflation. 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 of hypertension indicator, the function to guide cuff wrapping, the function to check sensor (dual check system) are added.

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

**Informs to user if the cuff was incorrectly wrapped.
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  
Name: Takefumi Nakanishi  
Date: 17 February 2010

Signature of Witness  
Name: Janet Meijer

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

Address: Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands
# Device Equivalence Evaluation Form

## Comparison of the Omron M6 Comfort (HEM-7221-E) with the Omron M7 (HEM-7221-E)

<table>
<thead>
<tr>
<th>Devices</th>
<th>Omron M6 Comfort (HEM-7221-E)</th>
<th>Omron M7 (HEM-7221-E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pictures</td>
<td><img src="image1" alt="Image of Omron M6 Comfort" /></td>
<td><img src="image2" alt="Image of Omron M7" /></td>
</tr>
<tr>
<td>Display</td>
<td><img src="image3" alt="Display of Omron M6 Comfort" /></td>
<td><img src="image4" alt="Display of Omron M7" /></td>
</tr>
<tr>
<td>Validation</td>
<td>BHS AAMI</td>
<td></td>
</tr>
</tbody>
</table>

## Device 1 Criteria

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Sensors</th>
<th>Pressure sensor: 2(^{nd}) sensor for dual check</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Display/Symbols/Indicators</td>
<td>Preparation</td>
<td>Correct cuff wrapping indicator</td>
<td>11, 13, 18</td>
</tr>
<tr>
<td>Post Measurement</td>
<td>Hypertension (Indicator strip)</td>
<td>11, 13</td>
<td></td>
</tr>
<tr>
<td>Body movement error</td>
<td>3, 11, 13, 18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irregular heartbeat</td>
<td>11, 13, 18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Memory recall number (Replaces pulse rate momentarily)</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Settings</td>
<td>Sensor cross check (LED)</td>
<td>5, 18</td>
<td></td>
</tr>
</tbody>
</table>

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### Algorithms

#### 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

### 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
- Sensors
- Pressure sensor: capacitive 5

#### Measurement Records
- Memory: 90 measurements 14

#### Buttons/Switches
- Settings
- Date/Time set 10

#### Display/Symbols/Indicators
- Measurement Procedure
- Deflation symbol 11
- During Measurement: BP Level & Heartbeat 11

#### Measurement

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- BP accuracy ± 3 mmHg 1, 5
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- Inflation 0 mmHg - 299 mmHg 1, 5, 7
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- Deflation symbol 11
- During Measurement: BP Level & Heartbeat 11

Post Measurement
### Measurement Cuffs
- Single 152 mm × 600 mm (Arm circ. 22 to 42 cm) \textsuperscript{Query 1} (Arm)

### Buttons/Switches
- Power
- On/Off with Start/Stop (O/I Start Label)

### Measurement Records
- Memory
- Settings

### Display/Symbols/Indicators
- Post Measurement
- Memory icon
- Alphanumerics

### Algorithms
- Averages and Differences
- Last 3 measurements (within 10 min of each other) mean

### Case
- Single screen display
- Automatic switch-off when not used for 2 min

---

### Measurement Cuffs
- Single 150 mm × 582 mm (Arm circ. 22 to 42 cm) \textsuperscript{Query 1} (Arm)

### Buttons/Switches
- Power
- On/Off with Stop (O/I Label)

### Measurement Records
- Memory × 2

### Display/Symbols/Indicators
- Post Measurement
- Memory “M” symbol
- Alphanumerics

### Algorithms
- Averages and Differences
- Last 3 measurements mean

### Case
- Dual screen display
- Automatic switch-off when not used for 5 min

---
The dimensions of the cuff supplied with the M6 Comfort (HEM-7221-E) differ from that supplied with the M7, one of the devices with which it is being compared, but no differences are declared. Please explain.

**Response 1**

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

**Chart1 Models and cuff dimensions**

<table>
<thead>
<tr>
<th>Models</th>
<th>Dimensions (in manual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M6 Comfort (HEM-7221-E)</td>
<td>152 mm x 600 mm</td>
</tr>
<tr>
<td>M7</td>
<td>150 mm x 582 mm</td>
</tr>
</tbody>
</table>

Regarding to longer dimension, the measurement point was different. For shorter dimension, 2mm difference is caused by treatment of edge of cuff. We consider this as cloth cover change. (Fig1)

![Fig1 Measurement point](image)

However, these do 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
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 Chart 2, M6 Comfort (7000) error code E had subdivide to M6 Comfort (7221) error code E1, E4 and E5. EE/0 is as same as E2. E/E is as same as E3. The background is explained below. For M6 Comfort (7000), EE/0 is as same as EE, 0 means 0mmHg, and this has the error code Er, but not described in manual. We consider there is no change in the error codes and algorithms among these devices.

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*

<table>
<thead>
<tr>
<th>Model</th>
<th>Error codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>M7</td>
<td>EE E E/E Er</td>
</tr>
<tr>
<td>M6 Comfort (7221)</td>
<td>E1 E2 E3 E2 E5 Er</td>
</tr>
<tr>
<td>M6 Comfort (7000)</td>
<td>EE/0 E E/E</td>
</tr>
</tbody>
</table>

Comment 2

In the response, there appears to be some confusion in the explanation. It is taken to read

The M7 error codes E are subdivide in the M6 Comfort (7221) to error codes E1, E4 and E5. EE is the same as E2 and E/E is the same as E3. For the M6 Comfort (7000), EE/0 is as same as EE, 0 means 0mmHg, and it has the error code Er, but it is not described in manual.
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>The queries were adequately answered. Equivalence is recommended.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>26/08/2010</td>
</tr>
</tbody>
</table>