# 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 Comfort (HEM-7221-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M6 Comfort (HEM-7000-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

Belghazi J, El Feghali RN, Moussalem T, Rejdych M, Asmar RG
Authors(s)

Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension
Title

Vascular Health and Risk Management 2007;3(4):389-400
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 ☐ | 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:

10) The memory button and the LED for dual check system* are added.

11) The symbol for cuff wrapping guide** and the indicator for blood pressure level are added.

13) The function to guide cuff wrapping and 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.


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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 T. Nakanishi

Name Takefumi Nakanishi

Date 17 February 2010

Signature of Witness J. Meijer-Dul

Name Janet Meijer

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

Company Stamp/Seal

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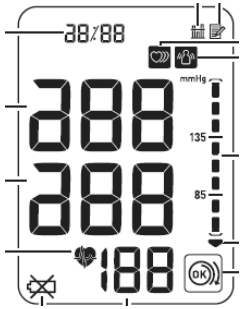
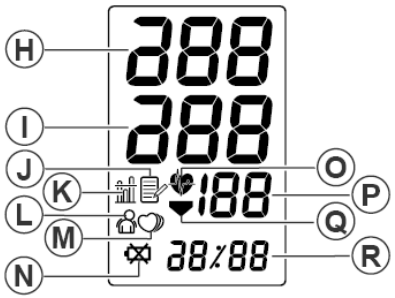
# Comparison of the Omron M6 Comfort (HEM-7221-E) with the Omron M6 Comfort (HEM-7000-E)

| Devices | Omron M6 Comfort (HEM-7221-E) | Omron M6 Comfort (HEM-7000-E) |
|---|---|---|
| **Pictures** |  |  |
| **Display** |  |  |
| **Validation** | | ESH |
| **Device 1 Criteria** | ***Measurement***<br>*Sensors*<br>Pressure sensor: 2nd sensor for dual check 5<br>***Display/Symbols/Indicators***<br>*Preparation*<br>Correct cuff wrapping indicator 11, 13, 18<br>*Measurement Records*<br>Memory recall number (Replaces pulse rate momentarily) 11<br>*Settings*<br>Sensor cross check (LED) 5, 18<br>***Algorithms***<br>*Parameter Settings*<br>Correct cuff wrapping detection 13<br>Sensor cross check 5, 18 | |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| 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, 8 | Pulse 40 bpm -180 bpm 1, 5, 8 |
| | Manually initiated measurements | 13 | Manually initiated measurements 13 |
| | Measurements are from single inflations | 13 | Measurements are from single inflations 13 |
| | *Inflation* | | *Inflation* |
| | Inflation 0 mmHg - 299 mmHg | 1, 5, 7 | Inflation 0 mmHg - 299 mmHg 1, 5, 7 |
| | Automatic Inflation | 7 | Automatic Inflation 7 |
| | Fuzzy Logic | 7 | Fuzzy Logic 7 |
| | Press button if BP > 220 mmHg | 7 | Press button if BP > 220 mmHg 7 |
| | Manually adjustable inflation pressure | 7 | Manually adjustable inflation pressure 7 |
| | *Deflation* | | *Deflation* |
| | Automatic Deflation | 8 | Automatic Deflation 8 |
| | *Cuffs* | | *Cuffs* |
| | Single 152 mm × 600 mm (Arm circ. 22 to 42 cm) | 6 | Single 152 mm × 600 mm (Arm circ. 22 to 42 cm) 6 |
| | *Sensors* | | *Sensors* |
| | Pressure sensor: capacitive | 5 | Pressure sensor: capacitive 5 |
| | *Measurement Records* | | *Measurement Records* |
| | Memory: 90 measurements | 14 | Memory: 90 measurements 14 |
| | ***Buttons/Switches*** | | ***Buttons/Switches*** |
| | *Power* | | *Power* |
| | On/Off with Start/Stop (O/I Start Label) | 10 | On/Off with Start/Stop (O/I Start Label) 10 |
| | *Settings* | | *Settings* |
| | Date/Time set | 10 | Date/Time 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 |
| | *Post Measurement* | | *Post Measurement* |
| | SBP, DBP and Pulse | 11 | SBP, DBP and Pulse 11 |
| | Average icon | 11, 13, 14 | Average icon 11, 13, 14 |
| | Body movement error | 3, 11, 13, 18 | Body movement error 3, 11, 13, 18 |
| | Irregular heartbeat | 11, 13, 18 | Irregular heartbeat 11, 13, 18 |
| | *Measurement Records* | | *Measurement Records* |
| | Memory icon | 11 | Memory icon 11 |

| | | |
|---|---|---|
| | *Date and Time*<br>Date and Time 11<br>Date and Time (During memory recall) 11<br>*Power*<br>Low battery 11, 17<br>***Algorithms***<br>*Averages and Differences*<br>Last 3 measurements (within 10 min of each other) mean 13<br>*Diagnostic*<br>Normotension/Hypertension 13<br>135 / 85 mmHg thresholds 13<br>Irregular heartbeat detection 13<br>Body movement error detection 3, 13<br>***Case***<br>*Display*<br>Single screen display 10<br>Segment LCD 10<br>*Power*<br>4 "AA" batteries ~ 1000 measurements 17<br>AC adapter (Optional) 17 | *Date and Time*<br>Date and Time 11<br>Date and Time (During memory recall) 11<br>*Power*<br>Low battery 11, 17<br>***Algorithms***<br>*Averages and Differences*<br>Last 3 measurements (within 10 min of each other) mean 13<br>*Diagnostic*<br>Normotension/Hypertension 13<br>135 / 85 mmHg thresholds 13<br>Irregular heartbeat detection 13<br>Body movement error detection 3, 13<br>***Case***<br>*Display*<br>Single screen display 10<br>Segment LCD 10<br>*Power*<br>4 "AA" batteries ~ 1500 measurements 17<br>AC adapter (Optional) 17 |
| **Comparable Criteria** | ***Buttons/Switches***<br>*Measurement Records*<br>Memory 10<br>*Settings*<br>Up and down 10<br>***Display/Symbols/Indicators***<br>*Post Measurement*<br>Measurement error E 1, E2, E3, E4, E5 and Er [Query 1] 11<br>Hypertension (Indicator strip) 11, 13<br>***Case***<br>*Power*<br>Automatic switch-off when not used for 2 min 17 | ***Buttons/Switches***<br>*Measurement Records*<br>Memory × 2 10<br><br>***Display/Symbols/Indicators***<br>*Post Measurement*<br>Measurement error EE/0, E and E/E [Query 1] 11<br>Hypertension (Blinking heartbeat) 11, 13<br>***Case***<br>*Power*<br>Automatic switch-off when not used for 5 min 17 |
| **Device 2 Criteria** | | |
| **Web link** | | http://www. |

**Comments**

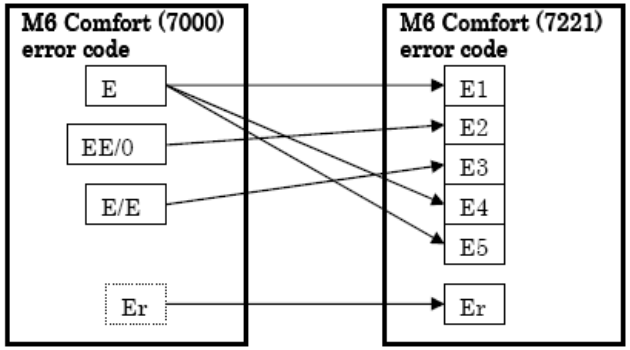
Query 1 There appear to be some differences in the error codes (apart from the extra features) which would not be expected if there were no algorithm changes. In the list, a slash indicates a line break where the error code is on two lines. Please explain.

Response 1 *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**

| Model | Error codes | | | | | |
|---|---|---|---|---|---|---|
| M6 Comfort (7000) | EE/0 | E | E/E | | | |
| M6 Comfort (7221) | E1 | E2 | E3 | E2 | E5 | Er |




**Recommendation** The queries were adequately answered. Equivalence is recommended.

**Date** 26/08/2010