# dabl® Educational Trust

## Declaration of Equivalence Form

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

**SECTION A** - Please complete all items.

I Jacqueline Hart,
Name of a Company Director

a 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

Maker[a] Omron Healthcare Co., Ltd. *Address* 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan

Manufacturer[b] Omron Healthcare Co., Ltd. *Address* 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan

Brand[c] Omron Model[d] M6 Comfort IT (HEM-7322U-E)

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the validated blood pressure measuring device

Maker[a] Omron Healthcare Co., Ltd. *Address* 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan

Manufacturer[b] Omron Healthcare Co., Ltd. *Address* 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan

Brand[c] Omron Model[d] M6 Comfort (HEM-7321-E)

Existing validated blood pressure measuring device.

which has previously passed the ESH2010 protocol, the results of which were published as follows:

dablEducational Trust; 2014 Jan 22. 4 p. Available from: http://www.dableducational.org/Publications/2014/ESH-IP 2010 Validation of Omron M6 Comfort (HEM-7321-E).pdf

Full reference

The only differences between the devices involve the following components:

Tick one box for each item 1–18.

| | | | | | |
|---|---|---|---|---|---|
| Part I | 1 | Algorithm for Oscillometric Measurements | Yes ☐ | No ☒ | N/A[e] ☐ |
| | 2 | Algorithm for Auscultatory Measurements | Yes ☐ | No ☐ | N/A[f] ☒ |
| | 3 | Artefact/Error Detection | Yes ☐ | No ☒ | |
| | 4 | Microphone(s) | Yes ☐ | No ☐ | N/A[f] ☒ |
| | 5 | Pressure Transducer | Yes ☐ | No ☒ | |
| | 6 | Cuffs or Bladders | 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 ☐ | N/A[g] ☒ |
| | 16 | Communication Facilities | Yes ☒ | No ☐ | N/A[g] ☐ |
| | 17 | Power Supply | Yes ☐ | No ☒ | |
| | 18 | Other Facilities | Yes ☒ | No ☐ | N/A[g] ☐ |

**An explanation of each item ticked "Yes" must be included in *Section B* or on a separate sheet.**

Notes:
a Provide the name and address of the actual maker of the device.
b Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
c Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
d Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
e Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
f Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
g Only tick N/A (Not Applicable) if neither device provides printing, communication or other facilities, as appropriate.


Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.
Form DET 130102

(dabl®Educational Trust Limited is a not-for-profit organisation)
Tel +353 1 278 0247
Fax +353 1 278 3835
Email info@dableducational.org
Web www.dableducational.org

**SECTION B** An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

9) The model number is changed to M6 Comfort IT (HEM-7322U-E) from M6 Comfort (HEM-7321-E).

10) The USB port is added to the M6 Comfort IT.

11) The OK symbol, the transfer indicator and the DATA/FULL symbol are added to the M6 Comfort IT.

13) The M6 Comfort IT can manage to blood pressure value by software "BiLink".

16) The USB interface to connect with personal computer are added.

18) The M3 IT can manage to blood pressure value by software "BiLink".

**SECTION C** Please check that the following are included with the application

| | |
|---|---|
| A manual for the validated device | ☒ |
| A manual for the device for which equivalence is being sought | ☒ |
| An image of the validated device | ☒ |
| An image of the device for which equivalence is being sought | ☒ |
| An image of the screen layout of validated device* | ☒ |
| An image of the screen layout of the device for which equivalence is being sought* | ☒ |

* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

**SECTION D** Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dableducational.org.

Signature of Director _____

Name JACQUELINE HART

Date 27/11/14

Signature of Witness _____

Name ANITA KEGSKES

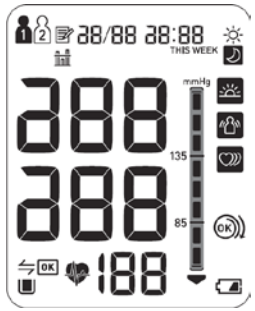
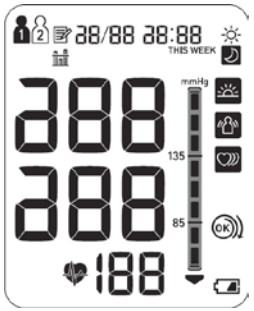
Address Rustenburgerstraat 146 1073GT Amsterdam NL

Company Stamp/Seal

OMRON HEALTHCARE EUROPE BV
Scorpius 33
NL-2132 LR Hoofddorp
P.O.BOX 2050 NL-2130 GL Hoofddorp
TEL +31-23 5544700
FAX +31-23 5544701

OMRON HEALTHCARE EUROPE BV
Scorpius 33
NL-2132 LR Hoofddorp
P.O.BOX 2050 NL-2130 GL Hoofddorp
TEL +31-23 5544700
FAX +31-23 5544701

# Comparison of the Omron M6 Comfort IT (HEM-7322U-E) with the Omron M6 Comfort (HEM-7321-E)

| Devices | Omron M6 Comfort IT (HEM-7322U-E) | Omron M6 Comfort (HEM-7321-E) |
|---|---|---|
| **Pictures** |  |  |
| **Display** |  |  |
| **Validation** | | ESH 2010 |
| **Device 1 Criteria** | ***Display/Symbols/Indicators***<br>*Communication*<br>USB Connection Query 3 — 11, 16<br>Data transmission completed OK Query 3 — 11, 16<br>Data awaiting transmission (Data/Full) Query 3 — 11, 14, 16<br>***Algorithms***<br>*Communication*<br>Data transfer to online database — 13, 16<br>***Casing***<br>*Ports*<br>USB port, cable and downloadable PC software — 16, 18 | |
| **Same Criteria** | ***Measurement***<br>*Accuracy*<br>BP accuracy ± 3 mmHg — 1, 5<br>Pulse accuracy ± 5% — 1, 5 | ***Measurement***<br>*Accuracy*<br>BP accuracy ± 3 mmHg — 1, 5<br>Pulse accuracy ± 5% — 1, 5 |

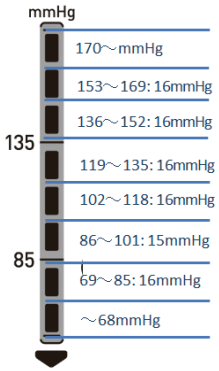

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

| Devices | Omron M6 Comfort IT (HEM-7322U-E) | | Omron M6 Comfort (HEM-7321-E) | |
|---|---|---|---|---|
| **Same Criteria (continued)** | ***Measurement (continued)*** | | ***Measurement (continued)*** | |
| | *Method* | | *Method* | |
| | Oscillometric measurement method | 1, 5 | Oscillometric measurement method | 1, 5 |
| | BP 0 mmHg to 299 mmHg [Query 1] | 1, 5, 7, 8 | BP 0 mmHg to 299 mmHg [Query 1] | 1, 5, 7, 8 |
| | Pulse 40 bpm to 180 bpm | 1, 5, 8 | Pulse 40 bpm to 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 |
| | Prevent storing of result (Guest mode) | 13, 14 | Prevent storing of result (Guest mode) | 13, 14 |
| | *Inflation* | | *Inflation* | |
| | Inflation 0 mmHg to 299 mmHg | 1, 5, 7 | Inflation 0 mmHg to 299 mmHg | 1, 5, 7 |
| | Automatic Inflation | 7 | Automatic Inflation | 7 |
| | Fuzzy Logic | 7 | Fuzzy Logic | 7 |
| | Press button if BP > 210 mmHg | 7 | Press button if BP > 210 mmHg | 7 |
| | *Deflation* | | *Deflation* | |
| | Automatic Deflation | 8 | Automatic Deflation | 8 |
| | *Cuffs* | | *Cuffs* | |
| | Large (Arm circ. 22 cm to 42 cm) No. HEM-FL31 | 6 | Large (Arm circ. 22 cm to 42 cm) No. HEM-FL31 | 6 |
| | *Measurement Records* | | *Measurement Records* | |
| | Memory: 100 measurements × 2 users (Guest not recorded) | 14 | Memory: 100 measurements × 2 users (Guest not recorded) | 14 |
| | ***Buttons/Switches*** | | ***Buttons/Switches*** | |
| | *Power* | | *Power* | |
| | On/Off with Start/Stop (Start/Stop Label) | 10 | On/Off with Start/Stop (Start/Stop Label) | 10 |
| | *Measurement Records* | | *Measurement Records* | |
| | Memory | 10 | Memory | 10 |
| | User ID slider | 10 | User ID slider | 10 |
| | *Function* | | *Function* | |
| | Date/Time set | 10 | Date/Time set | 10 |
| | Up and down | 10 | Up and down | 10 |
| | *Analysis* | | *Analysis* | |
| | Average | 10 | Average | 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 |
| | Measurement error E1 E2 E3 E4 E5 Er | 11 | Measurement error E1 E2 E3 E4 E5 Er | 11 |

| Devices | Omron M6 Comfort IT (HEM-7322U-E) | | Omron M6 Comfort (HEM-7321-E) | |
|---|---|---|---|---|
| **Same Criteria (continued)** | ***Display/Symbols/Indicators (continued)*** | | ***Display/Symbols/Indicators (continued)*** | |
| | *Post Measurement (continued)* | | *Post Measurement (continued)* | |
| | Hypertension (Indicator strip) Query 2 | 11, 13 | Hypertension (Indicator strip) Query 2 | 11, 13 |
| | Hypertension (Indicator LEDs) | 11, 13 | Hypertension (Indicator LEDs) | 11, 13 |
| | Morning hypertension | 11, 13 | Morning hypertension | 11, 13 |
| | Memory zone average | 11, 13, 14 | Memory zone average | 11, 13, 14 |
| | 7-day morning memory zone average | 11, 13, 14 | 7-day morning memory zone average | 11, 13, 14 |
| | 7-day evening memory zone average | 11, 13, 14 | 7-day evening memory zone average | 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 |
| | Correct cuff wrapping indicator (icon + 2 LEDs) | 11, 13, 18 | Correct cuff wrapping indicator (icon + 2 LEDs) | 11, 13, 18 |
| | *Measurement Records* | | *Measurement Records* | |
| | Memory icon | 11 | Memory icon | 11 |
| | Memory recall number (Replaces pulse rate momentarily) | 11 | Memory recall number (Replaces pulse rate momentarily) | 11 |
| | User (1, 2 and Guest) | 11 | User (1, 2 and Guest) | 11 |
| | *Date and Time* | | *Date and Time* | |
| | Date and Time | 11 | Date and Time | 11 |
| | Date and Time (During memory recall) | 11 | Date and Time (During memory recall) | 11 |
| | *Power* | | *Power* | |
| | Low & Exhausted battery | 11, 17 | Low & Exhausted battery | 11, 17 |
| | ***Algorithms*** | | ***Algorithms*** | |
| | *Averages and Differences* | | *Averages and Differences* | |
| | Last 3 measurements (within 10 min) memory zone mean | 13 | Last 3 measurements (within 10 min) memory zone mean | 13 |
| | 7-day morning and evening memory zone means (8 weeks) | 13 | 7-day morning and evening memory zone means (8 weeks) | 13 |
| | *Diagnostic* | | *Diagnostic* | |
| | BP classification Query 2 | 13 | BP classification Query 2 | 13 |
| | 135 / 85 mmHg thresholds | 13 | 135 / 85 mmHg thresholds | 13 |
| | Morning hypertension | 13 | Morning hypertension | 13 |
| | Irregular heartbeat detection | 13 | Irregular heartbeat detection | 13 |
| | Body movement error detection | 3, 13 | Body movement error detection | 3, 13 |
| | *Functions* | | *Functions* | |
| | Correct cuff wrapping detection | 13 | Correct cuff wrapping detection | 13 |
| | ***Casing*** | | ***Casing*** | |
| | *Display* | | *Display* | |
| | Single screen display | 10 | Single screen display | 10 |
| | Segment LCD | 10 | Segment LCD | 10 |

| Devices | Omron M6 Comfort IT (HEM-7322U-E) | Omron M6 Comfort (HEM-7321-E) |
|---|---|---|
| **Same Criteria (continued)** | ***Casing (continued)***<br>*Power*<br>4 “AA” batteries ~ 1000 measurements 17<br>AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17<br>Automatic switch-off when not used for 2 min 17<br>Rechargeable batteries not permitted 17 | ***Casing (continued)***<br>*Power*<br>4 “AA” batteries ~ 1000 measurements 17<br>AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17<br>Automatic switch-off when not used for 2 min 17<br>Rechargeable batteries not permitted 17 |
| **Comparable Criteria** | | |
| **Device 2 Criteria** | | |

| | | | |
|---|---|---|---|
| **Queries** | 1 | Query | Each of the manuals states that the blood pressure measurement range is 0 mmHg to 299 mmHg. They also state that the monitor will not inflate above 299 mmHg. This means that the measurement ranges must be below this.<br><br>According to ISO 80601-2-30 (2009), the device must be capable (in non-neonatal mode) of indicating at least 60 mmHg to 230 mmHg for SBP and 40 mmHg to 130 mmHg for DBP (201.12.1.103), so specifying these separately is necessary. It also requires that the pressure ranges provided are the rated pressures (201.7.9.2.9 h and 201.12.1.101) and that those measurements that are outside of these ranges trigger a technical alarm (201.12.1.106).<br><br>a) What are the SBP and DBP rated ranges for each of the devices?<br><br>b) Are there technical alarm ranges for each of the devices? |
| | | Response | a) There is no SBP and DBP rated ranges because we have not defined the rated range of cuff pressure which is actually limited by measurement range of the pressure (not blood pressure) 0 to 299 mmHg. The capability to measure the required SBP and DBP range (201.12.1.103) are confirmed by technical validation test.<br><br>b) There is no technical alarm because of the reason above. |
| | | Query | The rated ranges for SBP and DBP are simply the ranges, within the inflation range, for which SBP and DBP values are displayed. Where a pulse is detected close to the maximum inflation pressure or the wave envelope suggests SBP as being close to the maximum inflation pressure, it may be rejected an unreliable estimate of SBP. DBP estimates close to zero can be similarly rejected. These are the technical alarm conditions.<br><br>The reply suggests that there are no upper or lower limits to either SBP or DBP i.e. 299 mmHg ≥ SBP > DBP ≥ 0 mmHg. Is this correct? |
| | | Response | Yes, this is correct. |
| | | Comment | The reply answers the query fully. |
| | 2 | Query | Both devices have vertical indicator strips. Each strip contains 8 sections with a 135 mmHg mark between the 3rd and 4th sections and an 85 mmHg mark between the 6th and 7th sections. From the diagrams in the respective manuals, their function appears to be to display the pulse pressure, with a series of sections lit from one indicating a range of SBP values to one indicating a range of DBP values. However, no explanation is provided in either manual. What range of pressure does each section represent and are they the same for both devices? |
| | | Response | Please find the range of the pressure for each section as shown. These are same for both devices. |
| | | Comment | The reply answers the query fully. |



| | | | |
|---|---|---|---|
| | 3 | Query | The M6 Comfort IT (HEM-7322U-E) has Transfer, OK and Data/Full symbols that are not described in the manual. Please outline the functions of these symbols. |
| | | Response | The Transfer indicator ⇋ is displayed when the USB cable is connected.<br>The OK symbol is displayed when the data transfer has finished.<br>The DATA/Full symbol ▣ is not displayed, for the selected user, if there are fewer than 80 measurements not transferred. It will blink if there are between 80 and 99 measurements not transferred. It will be shown as a steady symbol if the memory is full (100 measurements) and none of them are transferred. *(M6 Comfort IT)* |
| | | Comment | The reply answers the query fully. |
| **Note** | 1 | The only difference between these devices is that the M6 Comfort IT (HEM-7322U-E) has additional features to allow measurements to be transferred to an online database. | |
| **Recommendation** | Equivalence is Recommended | | |
| **Date** | 20 March 2014 | | |