# DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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

I Minoru Yoshimura, (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] | RS1 (HEM-6120-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] | RS3 (HEM-6130-E) |

Existing validated blood pressure measuring device.

which has previously passed the ESH-IP protocol, the results of which were published as follows:

Takahashi H, Yokoi T, Yoshika M. Validation of the OMRON RS3 (HEM-6130-E) wrist blood pressure monitor, in oscillometry mode, for clinic use and self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010 [Internet]. Dublin: dablEducational Trust; 2013 Feb 01 [cited 2013 Feb 14]. 4 p. Available from: http://www.dableducational.org/Publications/2013/ESH-IP 2010 Validation of Omron RS3 (HEM-6130-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.


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**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. Model name RS1 (HEM-6120-E)

10. No Memory button and Date/Time setting button.

11. No Average value symbol, Date/Time display, Blood pressure level indicator, Movement error symbol and Irregular heartbeat symbol.

13. No function of Average value, Date/Time, Movement error and Irregular heartbeat detection.

14. Last measurement only.

**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 _____ Company Stamp/Seal

Name Minoru Yoshimura

Date 14 Feb 2013

Signature of Witness _____

Name Tomohiro Kukita

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# Comparison of the Omron RS1 (HEM-6120-E) with the Omron RS3 (HEM-6130-E)

| Devices | Omron RS1 (HEM-6120-E) | Omron RS3 (HEM-6130-E) |
|---|---|---|
| **Pictures** |  |  |
| **Display** |  |  |
| **Validation** | | ESH 2010 |
| **Device 1 Criteria** | | |
| **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 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 |
| | *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 |


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| Devices | Omron RS1 (HEM-6120-E) | | Omron RS3 (HEM-6130-E) | |
|---|---|---|---|---|
| **Same Criteria** | ***Measurement*** | | ***Measurement*** | |
| | *Deflation* | | *Deflation* | |
| | Automatic Deflation | 8 | Automatic Deflation | 8 |
| | *Cuffs* | | *Cuffs* | |
| | Wrist circ. ~ 13.5 cm to ~ 21.5 cm | 6 | Wrist circ. ~ 13.5 cm to ~ 21.5 cm | 6 |
| | ***Buttons/Switches*** | | ***Buttons/Switches*** | |
| | *Power* | | *Power* | |
| | On/Off with Start/Stop (Start/Stop Label) | 10 | On/Off with Start/Stop (Start/Stop Label) | 10 |
| | ***Display/Symbols/Indicators*** | | ***Display/Symbols/Indicators*** | |
| | *Preparation* | | *Preparation* | |
| | Correct cuff wrapping indicator | 11, 13, 18 | Correct cuff wrapping indicator | 11, 13, 18 |
| | *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 E 1, E3, E4, E5, Er | 11 | Measurement error E 1, E3, E4, E5, Er | 11 |
| | *Measurement Records* | | *Measurement Records* | |
| | Memory icon | 11 | Memory icon | 11 |
| | *Power* | | *Power* | |
| | Low battery | 11, 17 | Low battery | 11, 17 |
| | ***Algorithms*** | | ***Algorithms*** | |
| | *Parameter Settings* | | *Parameter Settings* | |
| | Correct cuff wrapping detection | 13 | Correct cuff wrapping detection | 13 |
| | ***Case*** | | ***Case*** | |
| | *Display* | | *Display* | |
| | Single screen display | 10 | Single screen display | 10 |
| | Segment LCD | 10 | Segment LCD | 10 |
| | *Power* | | *Power* | |
| | 2 “AAA” batteries ~ 300 measurements | 17 | 2 “AAA” batteries ~ 300 measurements | 17 |
| | Automatic switch-off when not used for 2 min | 17 | Automatic switch-off when not used for 2 min | 17 |
| **Comparable Criteria** | ***Measurement*** | | ***Measurement*** | |
| | *Measurement Records* | | *Measurement Records* | |
| | Memory: 1 measurement | 14 | Memory: 60 measurements | 14 |

| Devices | Omron RS1 (HEM-6120-E) | Omron RS3 (HEM-6130-E) |
|---|---|---|
| **Device 2 Criteria** | | ***Buttons/Switches***<br>*Measurement Records*<br>Memory 10<br>*Settings*<br>Set 10<br>***Display/Symbols/Indicators***<br>*Post Measurement*<br>Hypertension (Indicator strip) 11, 13<br>BP classification (Thresholds exceeded) 10, 11, 13<br>Average 11, 13, 14<br>Body movement error 3, 11, 13, 18<br>Irregular heartbeat 11, 13, 18<br>*Measurement Records*<br>Memory recall number (Replaces pulse rate momentarily) 11<br>*Date and Time*<br>Date and Time 11<br>Date and Time (During memory recall) 11<br>***Algorithms***<br>*Averages and Differences*<br>Last 3 measurements (within 10 min of each other) mean 13<br>*Diagnostic*<br>135 / 85 mmHg thresholds 13<br>Irregular heartbeat detection 13<br>Body movement error detection 3, 13 |

| | | | |
|---|---|---|---|
| **Comments** | 1 | Note | These devices are clearly equivalent and from the same family. The RS1 is a basic version with none of the extra features of the RS3 apart from the cuff wrapping indicator. |
| **Recommendation** | Equivalence is Recommended | | |
| **Date** | 15/02/2013 | | |