

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

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

SECTION A - Please complete all items.

I **Andre van Gils**,  
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 <sup>a</sup>	<b>OMRON DALIAN Co., Ltd.</b>	Address	<b>No. 3, Song Jiang Road, Economic and Technical Development Zone, Dalian 116600, China</b>
Manufacturer <sup>b</sup>	<b>Omron Healthcare Co., Ltd.</b>	Address	<b>53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan</b>
Brand <sup>c</sup>	<b>Omron</b>	Model <sup>d</sup>	<b>HBP-1120</b>

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 <sup>a</sup>	<b>OMRON DALIAN Co., Ltd.</b>	Address	<b>No. 3, Song Jiang Road, Economic and Technical Development Zone, Dalian 116600, China</b>
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Brand <sup>c</sup>	<b>Omron</b>	Model <sup>d</sup>	<b>HBP-1320</b>

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 .4p.Availableform: <http://www.dablededucational.org/Publications/2019/ESH-IP2>  
Validation of the OMRON HBP-1320.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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <input checked="" 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"/>	N/A <sup>f</sup> <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	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 checked="" 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"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>

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.

**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.

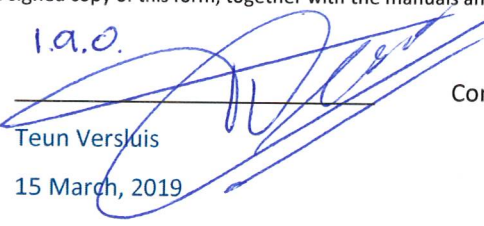
In an attached document. DET9 Form.

**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
  - Completed DET9 Form
  - 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](mailto:info@dableducational.org).

Signature of Director \_\_\_\_\_

*i.a.o.*  


Company Stamp/Seal

Name

Teun Versluis

Date

15 March, 2019

Signature of Witness \_\_\_\_\_

Name

Janet Meijer



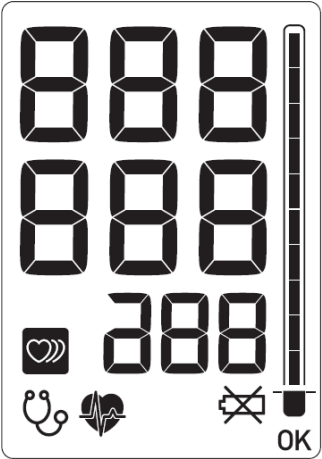
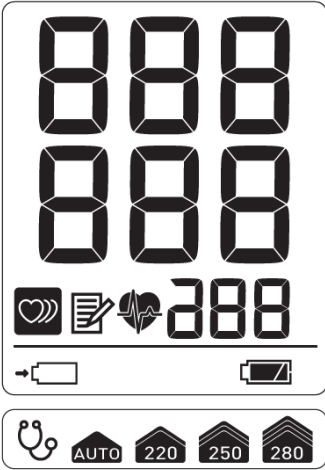
Address

15 March, 2019



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 HBP-1120 with the Omron HBP-1320

Devices – Item 9	Omron HBP-1120 (HBP-1120-E)	Omron HBP-1320 (HBP-1320-E)
Pictures		
Display Image		
Validation	(equivalence)	ESH 2010

Category	Blood Pressure Monitor Device	Blood Pressure Monitor Device
<b>Casing – Item 10</b>	<p><b>Casing</b></p> <p><i>Dimensions</i> Approximately 130 mm (W) × 175 mm (H) × 120 mm (D)</p> <p><i>Display</i> Single screen display</p> <p><b>Buttons</b></p> <p><i>Power</i> [Power On/Off] button</p> <p><i>Measurement</i> [START/STOP] button [Auscultation] button</p>	<p><b>Casing</b></p> <p><i>Dimensions</i> Approximately 123 mm (W) × 201 mm (H) × 99 mm (D)</p> <p><i>Display</i> Dual screen display</p> <p><b>Buttons</b></p> <p><i>Power</i> [START/STOP] button (Power On/Off)</p> <p><i>Measurement</i> [MODE] button [◀] [▶] button</p>
<b>Display – Item 11</b>	<p><b>Display/Symbols/Indicators</b></p> <p><i>Preparation</i> Auscultation mode icon</p> <p>Zero Indicator Icon</p> <p><i>Measurement Procedure</i> Pulse synchronization icon During Measurement: Blood Pressure Level Manual inflation</p> <p><i>Post Measurement</i> SBP, DBP and Pulse Irregular pulse wave icon Measurement error “E1 E2 E3 E9 E40” Technical Alarm Condition error (Flashing measurement) Body movement error ( '''' ↔ == symbol)</p> <p><i>Measurement Mode Indicator</i> Auscultation icon</p> <p><i>Power</i> Battery replacement icon</p>	<p><b>Display/Symbols/Indicators</b></p> <p><i>Preparation</i> Auscultation mode icon Inflation setting icon</p> <p><i>Measurement Procedure</i> Pulse synchronization icon During Measurement: Blood Pressure Level Manual inflation</p> <p><i>Post Measurement</i> SBP, DBP and Pulse Irregular pulse wave icon Measurement error “E1 E2 E3 E9 E40” Technical Alarm Condition error (Flashing measurement) Body movement error ( '''' ↔ == symbol) Alarm lamp</p> <p><i>Measurement Mode Indicator</i> Auscultation icon</p> <p><i>Measurement Records</i> Memory icon</p> <p><i>Power</i> Charge icon Battery charge level icon Battery error “E41, E42” (Battery failed to charge, Battery voltage error)</p>
<b>Carrying/Mounting Facilities – Item 12</b>	<p><i>Carrying/Mounting Facilities</i> No Storage Case</p>	<p><i>Carrying/Mounting Facilities</i> Storage Case</p>

<p><b>Software other than Algorithm – Item 13</b></p>	<p><b>Software other than Algorithm</b>  <i>Diagnostic</i>                  Irregular heartbeat detection                  Body movement error detection</p>	<p><b>Software other than Algorithm</b>  <i>Diagnostic</i>                  Irregular heartbeat detection                  Body movement error detection  <i>Function</i>                  Inflation Pressure Setting: Auto, 220 mmHg, 250 mmHg, 280 mmHg                  Last reading display function                  Auto power off</p>
<p><b>Memory Capacity Item 14</b></p>	<p><i>Number of stored measurements</i>                  No memory</p>	<p><i>Number of stored measurements</i>                  Stores last reading</p>
<p><b>Power Supply Item 17</b></p>	<p><i>Power</i>                  4 “AA” batteries                  AC adapter (HHP-CM01 / HHP-BFH01)</p>	<p><i>Power</i>                  Rechargeable battery pack 3.6 V, 1900 mAh                  AC adapter (AC ADAPTER-E1600 / AC ADAPTER-UK1600)</p>
<p><b>Same Criteria</b></p>	<p><b>Measurement</b>  <i>Accuracy</i>                  Blood Pressure accuracy ± 3 mmHg 1,5                  Pulse accuracy ± 5% 1,5  <i>Method</i>                  Oscillometric measurement method 1,5                  Manually initiated measurements 13                  Press button to note SBP &amp; DBP (Auscultation mode) 13  <i>Ranges</i>                  Cuff Pressure range 0 to 300 mmHg 1,5,7,8                  Blood Pressure measurement SYS 60 to 250 mmHg 1,5,7,8                  Blood Pressure measurement DIA 40 to 200 mmHg 1,5,7,8                  Pulse measurement 40 to 200 beats / min. 1,5,8  <i>Inflation</i>                  Inflation 0 to 300 mmHg 1,5,7                  Automatic Inflation 7                  Manual Inflation option 7                  Zero pressure check before inflation 7  <i>Deflation</i>                  Automatic Deflation 8  <i>Cuffs (Please state sizes and materials used)</i>                  GS CUFF2 XL (42 to 50 cm) (Optional) 6                  GS CUFF2 L (32 to 42 cm) (Optional) 6                  GS CUFF2 M (22 to 32 cm) 6                  GS CUFF2 S (17 to 22 cm) (Optional) 6                  GS CUFF2 SS (12 to 18 cm) (Optional) 6  <i>Measurements other than Blood Pressure</i>                  Pulse 40 to 200 beat / min. 1,5,8  <b>Display/Symbols/Indicators</b>  <i>Preparation</i>                  Auscultation mode icon 11,14  <i>Measurement Procedure</i>                  Pulse synchronization icon 11</p>	<p><b>Measurement</b>  <i>Accuracy</i>                  Blood Pressure accuracy ± 3 mmHg 1,5                  Pulse accuracy ± 5% 1,5  <i>Method</i>                  Oscillometric measurement method 1,5                  Manually initiated measurements 13                  Press button to note SBP &amp; DBP (Auscultation mode) 13  <i>Ranges</i>                  Cuff Pressure range 0 to 300 mmHg 1,5,7,8                  Blood Pressure measurement SYS 60 to 250 mmHg 1,5,7,8                  Blood Pressure measurement DIA 40 to 200 mmHg 1,5,7,8                  Pulse measurement 40 to 200 beats / min. 1,5,8  <i>Inflation</i>                  Inflation 0 to 300 mmHg 1,5,7                  Automatic Inflation 7                  Manual Inflation option 7                  Zero pressure check before inflation 7  <i>Deflation</i>                  Automatic Deflation 8  <i>Cuffs (Please state sizes and materials used)</i>                  GS CUFF2 XL (42 to 50 cm) (Optional) 6                  GS CUFF2 L (32 to 42 cm) (Optional) 6                  GS CUFF2 M (22 to 32 cm) 6                  GS CUFF2 S (17 to 22 cm) (Optional) 6                  GS CUFF2 SS (12 to 18 cm) (Optional) 6  <i>Measurements other than Blood Pressure</i>                  Pulse 40 to 200 beat / min. 1,5,8  <b>Display/Symbols/Indicators</b>  <i>Preparation</i>                  Auscultation mode icon 11,14  <i>Measurement Procedure</i>                  Pulse synchronization icon 11</p>

	During Measurement: Blood Pressure Level	11	During Measurement: Blood Pressure Level	11
	Manual inflation	11	Manual inflation	11
	<i>Post Measurement</i>		<i>Post Measurement</i>	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Irregular pulse wave icon	11	Irregular pulse wave icon	11
	Measurement error “E1 E2 E3 E9 E40”	11	Measurement error “E1 E2 E3 E9 E40”	11
	Technical Alarm Condition error (Flashing measurement)	11	Technical Alarm Condition error (Flashing measurement)	11
	Body movement error ( '""↔"" symbol)	3,11,13	Body movement error ( '""↔"" symbol)	3,11,13
	<i>Measurement Mode Indicator</i>		<i>Measurement Mode Indicator</i>	
	Auscultation icon	11	Auscultation icon	11
	<b>Software other than Algorithm</b>		<b>Software other than Algorithm</b>	
	<i>Diagnostic</i>		<i>Diagnostic</i>	
	Irregular heartbeat detection	13	Irregular heartbeat detection	13
	Body movement error detection	13	Body movement error detection	13

<b>Comments</b>	
<b>Recommendation</b>	<b>Recommended</b>
<b>Date</b>	<b>09 April 2019</b>