

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 Director of Omron Healthcare Europe B.V.
Name of a Company Director Company name

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

Omron R3 Intellisense (HEM-6021-E)

Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron R3-I Plus (HEM-6022-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

Asmar R, Khabouth J, Topouchian J, El Feghali R, Mattar J

Authors(s)

Validation of three automatic devices for self-measurement of blood pressure according

to the International Protocol: The Omron M3 Intellisense (HEM-7051-E), the Omron M2

Compact (HEM 7102-E), and the Omron R3-I Plus (HEM 6022-E)

Title

Blood Pressure Monitoring

Publication

2010; 15:49-54

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input 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"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	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 type="checkbox"/>	No <input checked="" type="checkbox"/>
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input 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"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

Brief explanation of differences and further relevant details:

11) No symbol for irregular heart beat.

13) No function to detect irregular heart beat and no function to detect hypertension.



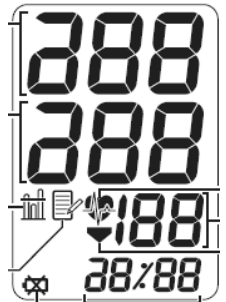
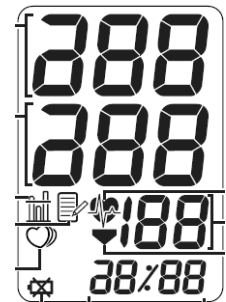
14) Stores 42 readings instead of 60.



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	<u>T. Nakanishi</u>	Company Stamp/Seal
Name	<u>Takefumi Nakanishi</u>	OMRON HEALTHCARE EUROPE B.V.
Date	<u>04 February 2010</u>	Kruisweg 577
Signature of Witness	<u>J. Meijer</u>	NL-2132 NA Hoofddorp
Name	<u>Janet Meijer</u>	P.O. Box 2150 NL- 2130 GL Hoofddorp
Address	<u>Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands</u>	Tel. +31 - 20 354 82 00
		Fax +31 - 20 354 82 01

Comparison of the Omron R3 Intellisense (HEM-6021-E) with the Omron R3-I Plus (HEM-6022-E)

Devices	R3 Intellisense (HEM-6021-E)	R3-I Plus (HEM-6022-E)
Pictures		
Display		
Validation		ESH
Device 1 Criteria		
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Automatic Inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Automatic Inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p>

	Single (Wrist circ. 13.5 to 21.5 cm) <i>Sensors</i>	6	Single (Wrist circ. 13.5 to 21.5 cm) <i>Sensors</i>	6
	Pressure sensor: capacitive	5	Pressure sensor: capacitive	5
	Buttons/Switches		Buttons/Switches	
	<i>Power</i>		<i>Power</i>	
	On/Off with Start/Stop (O/I Start Label)	10	On/Off with Start/Stop (O/I Start Label)	10
	<i>Measurement Records</i>		<i>Measurement Records</i>	
	Memory	10	Memory	10
	<i>Settings</i>		<i>Settings</i>	
	Set	10	Set	10
	Display/Symbols/Indicators		Display/Symbols/Indicators	
	<i>Measurement Procedure</i>		<i>Measurement Procedure</i>	
	Deflation symbol	11	Deflation symbol	11
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
	<i>Post Measurement</i>		<i>Post Measurement</i>	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Measurement error E/E , E and $E_{0.25}$	11	Measurement error E/E , E and $E_{0.25}$	11
	Average icon	11, 13, 14	Average icon	11, 13, 14
	<i>Measurement Records</i>		<i>Measurement Records</i>	
	Memory icon	11	Memory icon	11
	<i>Date and Time</i>		<i>Date and Time</i>	
	Date and Time	11	Date and Time	11
	Date and Time (During memory recall)	11	Date and Time (During memory recall)	11
	<i>Power</i>		<i>Power</i>	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		Algorithms	
	<i>Averages and Differences</i>		<i>Averages and Differences</i>	
	Last 3 measurements (within 10 min of each other) mean	13	Last 3 measurements (within 10 min of each other) mean	13
	Case		Case	
	<i>Display</i>		<i>Display</i>	
	Single screen display	10	Single screen display	10
	Segment LCD	10	Segment LCD	10
	<i>Power</i>		<i>Power</i>	
	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 <i>Measurement Records</i> Memory: 42 measurements	14	Measurement <i>Measurement Records</i> Memory: 60 measurements	14

Device 2 Criteria		<p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>Hypertension (Blinking heartbeat) 11, 13</p> <p>Irregular heartbeat 11, 13, 18</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Normotension/Hypertension 13</p> <p>135 / 85 mmHg thresholds 13</p> <p>Irregular heartbeat detection 13</p>
Web link		http://www.

Comments	The devices are the same except for the diagnostic features and memory capacity.
Recommendation	Equivalence is recommended.
Date	26/08/2010