

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

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

SECTION A - Please complete all items.

I **LiXiong Cheng,** a Director of **Omron Healthcare (China) Co.,Ltd,**
 Name of a Company Director Company name

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

Maker^a **Omron (Dalian) Co.,Ltd** Address **No.28 Dong Bei 2 street Economi&Technical,DALIAN,China**
 Manufacturer^b **Omron Healthcare Co.,Ltd** Address **53, Kunotsubo, Terado-cho, Muko, KYOTO, Japan**
 Brand^c **OMRON** Model^d **HBP-9030**

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 (Dalian) Co.,Ltd** Address **No.28 Dong Bei 2 street Economi&Technical,DALIAN,China**
 Manufacturer^b **Omron Healthcare Co.,Ltd** Address **53, Kunotsubo, Terado-cho, Muko, KYOTO, Japan**
 Brand^c **OMRON** Model^d **HBP-9031C**

Existing validated blood pressure measuring device.

which has previously passed the **ANSI/AAMI/ISO 81060-2:2013** protocol, the results of which were published as follows:

Journal of human Hypertension <https://doi.org/10.1038/s41371-020-0301-0>(Published online:22 Jan,2020)

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 ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <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 ^f <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 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 checked="" type="checkbox"/>	
	13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^g <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^g <input type="checkbox"/>

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

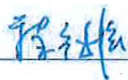
- Notes:
- a Provide the name and address of the actual maker of the device.
 - b Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
 - c Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer 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.

Signature of Director _____ 

Name _____

Date _____



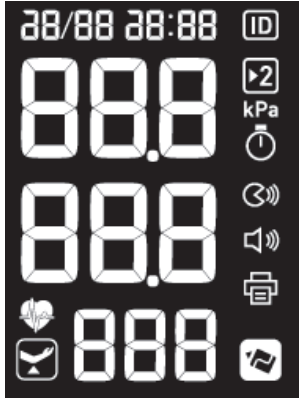
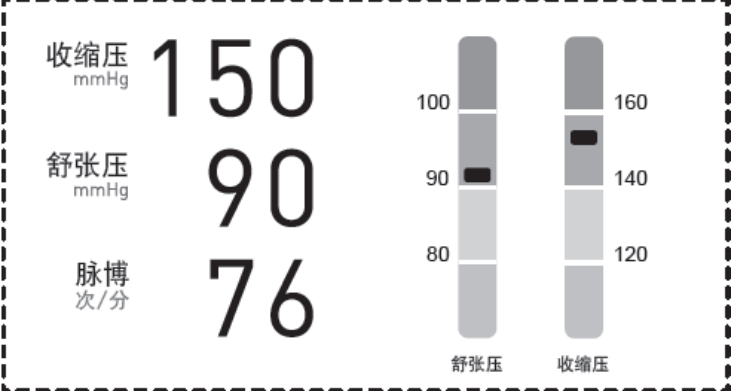
Signature of Witness _____ 

Name _____

Address _____



Comparison of the OMRON HBP-9030 with the OMRON HBP-9031C

Devices – Item 9	OMRON HBP-9030	OMRON HBP-9031C
Pictures		
Display Image		 <p>The screen display within the dotted frame varies before,during,after measurement.</p>
Validation	(equivalence)	AAMI
Category	Upper Arm Devices for self0measurement of Blood pressure	Upper Arm Devices for self0measurement of Blood pressure
Casing – Item 10	<p>Casing Dimensions 460mm(L)*420mm(W)*270mm(H) (Not include Arm rest)</p> <p>Buttons/Switches Power on/off Begin to measure Start /Stop Emergency to stop all measure Clear</p>	<p>Casing Dimensions 460mm(L)*420mm(W)*270mm(H) (Not include Arm rest)</p> <p>Buttons/Switches Power on/off Begin to measure Start /Stop Emergency to stop all measure Clear</p>

	<p>Features <i>Accurate Measurement Support</i> Elbow detection sensor Movable arm Voice guidance <i>Printing</i> 3 Mode 2-3 times continuously measurement and display the average value Communication USB</p>	<p>Features <i>Accurate Measurement Support</i> Elbow detection sensor Movable arm Voice guidance <i>Printing</i> 3 Mode 2-3 times continuously measurement and display the average value Communication USB/LAN/WIFI/BLUETOOTH</p>
Display – Item 11	<p>Display/Symbols/Icons SBP,DBPand Pulse Date and Time Error code Pulse Icon Elbow detection Icon Average measurement Icon Voice reading Icon Printer Icon Display Time Icon Speaker Icon Arm cuff replacement Icon</p> <p>Lamp <i>Alert Lamp</i> Body motion Remeasure Please relax Try not to move and talk <i>Posture guidance Lamp</i></p>	<p>Display/Symbols/Icons SBP,DBPand Pulse Date and Time Error code Pulse symbol Arm cuff replacement symbol Elbow detection Symbol Average measurement Icon Voice reading Icon Printer Icon Speaker Icon Wired LAN Icon Wireless LAN Icon <i>User measurement process is guided by picture displayed in LCD</i></p>
Carrying/Mounting Facilities – Item 12	<p>Carrying/Mounting Facilities N/A</p>	<p>Carrying/Mounting Facilities N/A</p>
Software other than Algorithm – Item 13	<p>Software other than Algorithm <i>Average 2-3 times measurement</i> Two BP measurements should be taken 1–2 min apart and averaged for records. An additional measurement is required if the first two readings differ by > 5 mmHg, and the mean value of the three readings should be recorded.</p> <p><i>Irregular heartbeat detection</i> <i>Body Movement error detection</i></p> <p>Communication <i>Data transfer via USB</i></p>	<p>Software other than Algorithm <i>Average 2-3 times measurement</i> Two BP measurements should be taken 1–2 min apart and averaged for records. An additional measurement is required if the first two readings differ by > 5 mmHg, and the mean value of the three readings should be recorded.</p> <p><i>Irregular heartbeat detection</i> <i>Body Movement error detection</i></p> <p>Communication <i>Data transfer via USB/LAN/WIFI/BLUETOOTH</i></p>

Memory Capacity Item 14	Memory Capacity 0	Memory Capacity 0
Printing Facilities Item 15	Printing Facilities Built-in thermal printing module	Printing Facilities Built-in thermal printing module
Communication Facilities – Item 16	Communication Facilities USB	Communication Facilities USB/LAN/WIFI/BLUETOOTH
Power Supply Item 17	Power Supply AC adaptor 12V 3.5A	Power Supply AC adaptor 12V 3.5A
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i> N/A	<i>Other Details on Validated device that are different to Equivalent device</i> N/A
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>Pressure display accuracy: ± 3mmhg Blood pressure accuracy: Average within ± 5mmhg, Standard deviation within 8mmHg Pulse rate accuracy: $\pm 5\%$ of reading</p> <p><i>Method</i></p> <p><i>Oscillometric measurement method</i></p> <p><i>Ranges</i></p> <p><i>Blood pressure range</i> SYS 60-260mmHg DIA 30-215mmHg</p> <p><i>Pulse measurement range</i> 40-180 beats/min</p> <p><i>Inflation</i></p> <p>Automatic inflation 0-299 mmHg</p> <p><i>Deflation</i></p> <p>Automatic deflation</p> <p><i>Cuffs (Please state sizes and materials used)</i> Arm cuff unit 17-42cm</p> <p><i>Sensors</i></p> <p>The electric pressure sensor</p> <p><i>Measurement Records</i> N/A</p> <p><i>Measurements other than Blood Pressure</i> 40-180 beats/min</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>Pressure display accuracy: ± 3mmhg Blood pressure accuracy: Average within ± 5mmhg, Standard deviation within 8mmHg Pulse rate accuracy: $\pm 5\%$ of reading</p> <p><i>Method</i></p> <p><i>Oscillometric measurement method</i></p> <p><i>Ranges</i></p> <p><i>Blood pressure range</i> SYS 60-260mmHg DIA 30-215mmHg</p> <p><i>Pulse measurement range</i> 40-180 beats/min</p> <p><i>Inflation</i></p> <p>Automatic inflation 0-299 mmHg</p> <p><i>Deflation</i></p> <p>Automatic deflation</p> <p><i>Cuffs (Please state sizes and materials used)</i> Arm cuff unit 17-42cm</p> <p><i>Sensors</i></p> <p>The electric pressure sensor</p> <p><i>Measurement Records</i> N/A</p> <p><i>Measurements other than Blood Pressure</i> 40-180 beats/min</p>

	<p>Buttons/Switches</p> <p><i>Power</i> On/off</p> <p><i>Measurement Records</i> N/A</p> <p><i>Function</i> Begin to measure Start /Stop Emergency to stop all measure Clear</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> Menu setting</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> Elbow location detection</p> <p><i>Measurement Procedure</i> Heartbeat symbol</p> <p><i>Post Measurement</i> SBP,DBP and Pulse rate Error code</p> <p><i>Measurement Records</i> N/A</p> <p><i>Date and Time</i> Display</p> <p><i>Power</i> N/A</p> <p><i>Function</i> SBP,DBP and Pulse Date and Time Error code Pulse Icon Elbow detection Icon Average measurement Icon</p>	<p>Buttons/Switches</p> <p><i>Power</i> On/off</p> <p><i>Measurement Records</i> N/A</p> <p><i>Function</i> Begin to measure Start /Stop Emergency to stop all measure Clear</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> Menu setting</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> User measurement process is guided by picture displayed in LCD</p> <p><i>Measurement Procedure</i> Heartbeat symbol</p> <p><i>Post Measurement</i> SBP,DBP and Pulse rate Error code</p> <p><i>Measurement Records</i> N/A</p> <p><i>Date and Time</i> Display</p> <p><i>Power</i> N/A</p> <p><i>Function</i> SBP,DBP and Pulse Date and Time Error code Pulse symbol Arm cuff replacement symbol Elbow detection Symbol</p>
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	<p>Voice reading Icon Printer Icon Display Time Icon Speaker Icon Arm cuff replacement Icon</p> <p><i>Communication</i> No display</p> <p><i>Features</i> Alert Lamp Body motion Remeasure Please relax Try not to move and talk Posture guidance Lamp</p> <p><i>Not described</i> N/A</p> <p>Algorithms <i>Averages and Differences</i> Average 2-3 times measurement Two BP measurements should be taken 1–2 min apart and averaged for records. An additional measurement is required if the first two readings differ by > 5 mmHg, and the mean value of the three readings should be recorded.</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>	<p>Average measurement Icon Voice reading Icon Printer Icon Speaker Icon Wired LAN Icon Wireless LAN Icon <i>User measurement process is guided by picture displayed in LCD</i></p> <p><i>Communication</i> Wired/wireless communication symbol display</p> <p><i>Features</i> Body motion Remeasure Please relax Try not to move and talk Posture guidance via picture in LCD</p> <p><i>Not described</i> N/A</p> <p>Algorithms <i>Averages and Differences</i> Average 2-3 times measurement Two BP measurements should be taken 1–2 min apart and averaged for records. An additional measurement is required if the first two readings differ by > 5 mmHg, and the mean value of the three readings should be recorded.</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>
<p>Comparable Criteria</p>	<p><i>Communication</i> Only USB <i>Display</i> Fixed format LCD display, display content fixed</p>	<p><i>Communication</i> USB/LAN/WIFI/BLUETOOTH <i>Display</i> <i>Customizable FORMAT LCD, The screen display within the dotted frame varies before, during, after measurement.</i></p>

Comments		
Recommendation		Recommended
Date		October 2020