

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2011

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

### SECTION A - Please complete all items.

I **Mark Beaton**, a Director of **Thermor Limited**,  
Name of a Company Director Company name

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

**Manufacturer** Honsun **Brand** BIOS Diagnostics **Model** BD204

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

blood pressure measuring device and the

**Manufacturer** Honsun **Brand** Honsun **Model** LD-578

Existing validated blood pressure measuring device. If alternative model names are used, include all.

blood pressure measuring device, which has previously passed the Internatio protocol, the results of which were published as follows:

Yi Zhang, Jie Wang, Qi-Fang Huang, Chang-Sheng, Yan Li and Ji-Guang Wang

Authors(s)

Validation of Honsun LD-578 blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol

Title

Blood Pressure Monitoring

Publication

June 2009-Volume 14-Issue 3-pp 128-131.

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. It is necessary to provide details on each item ticked "Yes" in Section C or on a separate sheet.

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 checked="" type="checkbox"/>	No <input 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 type="checkbox"/>	No <input checked="" 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 checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section C on the next page

**SECTION B** 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 manuals and images for both devices to [info@dableducational.org](mailto:info@dableducational.org).

Signature of Director  Company Stamp/Seal

Name Mark Beaton

Date October 25, 2011

Signature of Witness 



Name Joanna Biniek

Address 16975 Leslie Street, Newmarket, ON, Canada.

**SECTION C** 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.





See Appendix A - Comparison of BIOS BD204 with Honsun LD-578

## Appendix A

Devices	BIOS BD204	Honsun LD-578
Pictures		
<b>Validation</b>		ESH
<b>Device 1 Criteria</b>	<p><b>Display/Symbols/Indicators</b></p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><b>Buttons/Switches</b></p> <p><i>Measurement Records</i></p> <p>Memory (includes Date/Time set) 10</p>	<p><b>Buttons/Switches</b></p> <p><i>Measurement Records</i></p> <p>Memory 10</p>
<b>Same Criteria</b>	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>BP accuracy <math>\pm 3</math> mmHg 1, 5</p> <p>Pulse accuracy <math>\pm 5\%</math> 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>BP 40 mmHg – 260 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm – 160 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>Fuzzy Logic 7</p> <p>Four preset inflation pressures 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Large (Arm circ. 32-43 cm) (Optional) 6</p> <p>Medium (Arm circ. 22-32 cm) 6</p> <p><i>Measurement Records</i></p> <p>Memory: 90 measurements 14</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>BP accuracy <math>\pm 3</math> mmHg 1, 5</p> <p>Pulse accuracy <math>\pm 5\%</math> 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>BP 40 mmHg – 260 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm – 160 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>Fuzzy Logic 7</p> <p>Four preset inflation pressures 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Large (Arm circ. 32-43 cm) (Optional) 6</p> <p>Medium (Arm circ. 22-32 cm) 6</p> <p><i>Measurement Records</i></p> <p>Memory: 90 measurements 14</p>

	<p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurement 18</p> <p>During Measurement: BP Level &amp; Heartbeat 11</p> <p>Beeps after measurement 18</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error (no error numbers) 11</p> <p><i>Measurement Records</i></p> <p>Average “A” symbol 11</p> <p>Memory recall number (replaces pulse rate momentarily) 11</p> <p>Delete memory (Clr) 11</p> <p>Last 3 measurements mean 11</p> <p>Memory “M” symbol 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries (Optional) 17</p> <p>AC adapter 17</p> <p>Automatic switch-off when not used for 3 min 17</p> <p>Rechargeable batteries not permitted 17</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p>	<p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurement 18</p> <p>During Measurement: BP Level &amp; Heartbeat 11</p> <p>Beeps after measurement 18</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error (no error numbers) 11</p> <p><i>Measurement Records</i></p> <p>Average “A” symbol 11</p> <p>Memory recall number (replaces pulse rate momentarily) 11</p> <p>Delete memory (Clr) 11</p> <p>Last 3 measurements mean 11</p> <p>Memory “M” symbol 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 3 min 17</p> <p>Rechargeable batteries not permitted 17</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p>
<b>Comments</b>	<p>In addition to the above, both manuals provide detailed electromagnetic information which is the same in each case. The BD204 appears identical from a measurement perspective, the only addition being the date and time.</p> <p>Honsun is a manufacturer that distributes models under its own name (<a href="http://www.asian-medical.com">http://www.asian-medical.com</a>). It is also an OEM company that distributes the same models to other distributors for sale under different brand names some of which use the same model number and some of which do not. The Canadian company Thermor uses BIOS as its brand name (<a href="http://biosexactly.com/">http://biosexactly.com/</a>) and supplies blood pressure monitors from, among others, Honsun.</p>	
<b>Date</b>	17/10/2011	

Comparison of the BIOS BD204 with the Honsun LD-578

Devices	BIOS BD204	Honsun LD-578
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p><b>Display/Symbols/Indicators</b></p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p>	
Same Criteria	<p><b>Measurement</b></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>BP 40 mmHg - 260 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm -160 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p>	<p><b>Measurement</b></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>BP 40 mmHg - 260 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm -160 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p>

<i>Inflation</i>		<i>Inflation</i>	
4 inflation levels (190, 230, 270, 300 mmHg)	1, 5, 7	4 inflation levels (190, 230, 270, 300 mmHg)	1, 5, 7
Automatic Inflation	7	Automatic Inflation	7
Fuzzy Logic	7	Fuzzy Logic	7
<i>Deflation</i>		<i>Deflation</i>	
Automatic Deflation	8	Automatic Deflation	8
<i>Cuffs</i>		<i>Cuffs</i>	
Large (Arm circ. 32-43 cm) (Optional)	6	Large (Arm circ. 32-43 cm) (Optional)	6
Medium (Arm circ. 22 to 32 cm)	6	Medium (Arm circ. 22 to 32 cm)	6
<i>Measurement Records</i>		<i>Measurement Records</i>	
Memory: 90 measurements	14	Memory: 90 measurements	14
<b>Display/Symbols/Indicators</b>		<b>Display/Symbols/Indicators</b>	
<i>Preparation</i>		<i>Preparation</i>	
Correct cuff wrapping indicator on cuff	6	Correct cuff wrapping indicator on cuff	6
<i>Measurement Procedure</i>		<i>Measurement Procedure</i>	
Beeps before measurement	18	Beeps before measurement	18
During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
Beeps after measurement	18	Beeps after measurement	18
<i>Post Measurement</i>		<i>Post Measurement</i>	
SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
Measurement error $\bar{E}_{rr}$ (no error numbers)	11	Measurement error $\bar{E}_{rr}$ (no error numbers)	11
<i>Measurement Records</i>		<i>Measurement Records</i>	
Memory "M" symbol	11	Memory "M" symbol	11
Memory recall number (Replaces pulse rate momentarily)	11	Memory recall number (Replaces pulse rate momentarily)	11
Delete memory $\bar{I}_r$	11	Delete memory $\bar{I}_r$	11
Average "A" symbol	11, 13, 14	Average "A" symbol	11, 13, 14
Last 3 measurements mean	13	Last 3 measurements mean	13
<i>Power</i>		<i>Power</i>	
Low battery	11, 17	Low battery	11, 17
<b>Algorithms</b>		<b>Algorithms</b>	
<i>Averages and Differences</i>		<i>Averages and Differences</i>	
Last 3 measurements mean	13	Last 3 measurements mean	13
<b>Casing</b>		<b>Casing</b>	
<i>Display</i>		<i>Display</i>	
Single screen display	10	Single screen display	10
Segment LCD	10	Segment LCD	10
Automatic switch-off when not used for 3 min	17	Automatic switch-off when not used for 3 min	17
Rechargeable batteries not permitted	17	Rechargeable batteries not permitted	17

<b>Comparable Criteria</b>	<b>Buttons/Switches</b>		<b>Buttons/Switches</b>	
	<i>Power</i>		<i>Power</i>	
	On/Off with Start/Stop and Enter (O/I Label)	10	On/Off with Start/Stop (O/I Label)	10
	<i>Measurement Records/Settings</i>		<i>Measurement Records/Settings</i>	
	Memory with Date/Time Set	10	Memory	10
	<b>Casing</b>		<b>Casing</b>	
	<i>Power</i>		<i>Power</i>	
	4 "AA" batteries (Optional)	17	4 "AA" batteries	17
	AC adapter	17	AC adapter (Optional)	17
<b>Device 2 Criteria</b>				

<b>Comments</b>	1	Query	In the manual for the BD204, the use of the two triangles is described as indicating insufficient inflation or deflation. The LD-578 screen contains up and down arrow symbols analogous to the triangles on the BD204. However, these are not mentioned in the manual. Are these symbols used in this device?
		Response	After confirming the two arrows are not included as features in the BD204, we have removed this from our instructions.
		Comment	Explanation accepted
<p>Honsun, as well as supplying devices under its own brand name, is also an OEM supplier of devices. BIOS Diagnostics supplies OEM devices under its own brand. Honsun is one of the companies that it uses.</p> <p>Apart from the casing, the only difference is the BD204 allows for the date and time of measurements to be recorded. The memory and O/I buttons are given extra functionality to enable this.</p>			
<b>Recommendation</b>	Equivalence is Recommended		
<b>Date</b>	19/12/2011		