

dabl® Educational Trust

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  Oct 12, 2010 Company Stamp/Seal
Name Jia Zhenning
Date Oct 12, 2010
Signature of Witness  Oct. 2010
Name Zhu Wenjun
Address Rm.C, Floor 22, ZhiYuan Bldg, No. 768 Xieta Road, Shanghai, China



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 Mark Beaton 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

BIOS BD209
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

LD - 578
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

Yi Zhang, Jie Wang, Qi-Fang Huang, Chang-Sheng 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 June 2009 - Volume 14 - Issue 3 - pp 128-131
Publication 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 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 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 checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Brief explanations of differences and further relevant details: see Appendix A

10) BD209: includes 2 memory buttons (memory 1, memory 2) LD-578 has only 1 memory button

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Signature of Director _____

Company Stamp/Seal

Name Mark Beaton

Date November 8, 2010

Signature of Witness _____

Name _____



Address Thermor Limited
16975 Leslie Street, Newmarket, Ontario
Canada, L3Y 9A1



Appendix A

11) BD209 includes symbol for M1 and M2 (memory 1 and memory 2), symbol for WHO classification and symbol for Date/Time while LD-578 does not.

12) BD209 includes the function of two stored memories, WHO classification and Date and time with each measurement, LD-30 does not.

13) BD209 includes 2 x 60 sets of memory (total 120 sets). LD-578 has capacity for 90 sets of memory

Comparison of the Honsun LD-30 with the Honsun LD-578

Devices	Honsun LD-30	Honsun LD-578
Pictures		
Validation		ESH
Device 1 Criteria	<p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>BP classification (ESH) 10, 11, 13</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>WHO Guidelines 13</p>	
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>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>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>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>

Devices	Honsun LD-30	Honsun LD-578
Same Criteria (continued)	<p>Measurement (continued)</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 to 32 cm) 6</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurement 18</p> <p>During Measurement: BP Level & 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 (⏏ Ir) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Case</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>Measurement (continued)</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 to 32 cm) 6</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurement 18</p> <p>During Measurement: BP Level & 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 (⏏ Ir) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Case</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>
Comparable Criteria	<p>Measurement</p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements × 2 zones 14</p>	<p>Measurement</p> <p><i>Measurement Records</i></p> <p>Memory: 90 measurements 14</p>

Devices	Honsun LD-30	Honsun LD-578
Comparable Criteria (continued)	<p>Buttons/Switches <i>Measurement Records</i> Memory × 2 (Includes Date/Time set) 10</p> <p>Display/Symbols/Indicators <i>Measurement Records</i> Last 3 measurements mean × 2 11 Memory zone (“M1” and “M2” symbols) 11</p> <p>Algorithms <i>Averages and Differences</i> Last 3 measurements memory zone means 13</p>	<p>Buttons/Switches <i>Measurement Records</i> Memory 10</p> <p>Display/Symbols/Indicators <i>Measurement Records</i> Last 3 measurements mean 11 Memory “M” symbol 11</p> <p>Algorithms <i>Averages and Differences</i> Last 3 measurements mean 13</p>
Device 2 Criteria		
Web link		http://www.asian-medical.com/product/?n=32&pid=7

Comments	<p>In addition to the above, both manuals provide detailed electromagnetic information which is the same in each case. The LD-30 appears identical from a measurement perspective, the only additions being the two memory zones, the date & time and the WHO classification indicator.</p> <p>Honsun is a manufacturer that distributes models under its own name (http://www.asian-medical.com). 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 (http://biosexactly.com/) and supplies blood pressure monitors from, among others, Honsun.</p>
Recommendation	Equivalence is recommended
Date	14/01/2011