

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 Marco Bühler Director of Beurer GmbH
Name of a Company Director Company name

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

BM60
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Nissei DS-400
Existing validated blood pressure measuring device

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

Duhig KE, de Greeff A, van der Westhuizen A, Baker E, Shennan AH.
Authors(s)

Validation of the Nissei DS-400 in a low-resource setting.

Blood Press Monit 2009;14:132-135
Title 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 each item ticked "Yes" either below or on a separate sheet.)

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input 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 type="checkbox"/>
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	6	Cuff or Bladder	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	7	Inflation Mechanism	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input 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 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 type="checkbox"/>

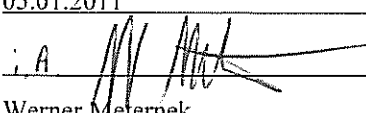
Brief explanations of each item ticked "Yes" to cover all differences between the devices: The inflation mechanism is different (DS-400 manual inflation; BM60 automatic inflation). The optical design is different

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 

Name Marco Bühler

Date 05.01.2011

Signature of Witness 

Name Werner Meternek

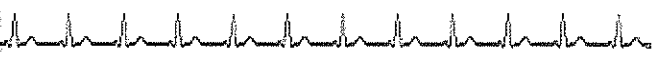
Company Stamp/Seal

Beurer GmbH
 Söllinger Straße 218 • 89077 Ulm

dabl[®] Educational Trust

Address

Soeflinger Strasse 218, 89077 Ulm, Germany





JAPAN PRECISION INSTRUMENTS INC.

2508-13 Nakago, Shibukawa, Gunma 377-0293 Japan

Phone +81 (0) 279 20 2311 Fax +81 (0) 279 20 2411

MAR. 31, 2010

Declaration of Identity

To whom it may concern,

We Japan Precision Instruments Inc. hereby declare that the Beurer upper arm type blood pressure monitor BM 60 (Nissei model name DS-800-03) has the same measurement algorithm as Nissei upper arm type blood pressure monitor DS-500.

Sincerely yours,



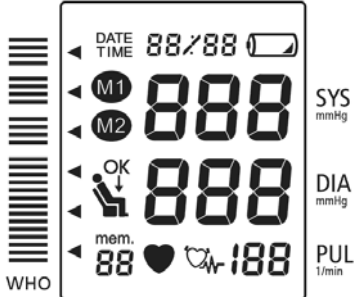

A handwritten signature in blue ink that reads "J. Yamashita". The signature is written in a cursive style.

Tsuneo Yamashita, Engineering Director



Display / Symbols / Indications	Irregular heart beat detection	No	Yes	Yes
	Memory	30 / average	2 x 30 / average	2 x 60 / average
	Date & Time	No	Yes	Yes (AM/PM & 24hr. Interchangeable at production line) *only for Canada & US version at the moment (we also plan to change the EU version to the same LCD and software as Canada & US in future.)
	HSD	No	No	Yes
	WHO guide	No	No	Yes
	Inflation symbol	Yes	Yes	No
	Deflation symbol	Yes	Yes	No
	Heart symbol during deflation	Yes	Yes	Yes
	Measurement result	SBP, DBP and Pulse	SBP, DBP and Pulse	SBP, DBP, Pulse and HSD result
	Error	Err, Err 330, Low battery	Err-1, Err-2, Err-3, Err 300, Low battery	Err-1, Err-2, Err-3, Err 300, Low battery
Measurement	Automatic power off	Yes	Yes	Yes
	buzzer	During measurement with pulse, after measurement	No	No
	Method	Oscillometric	Oscillometric	Oscillometric
	Inflation	Manual	Auto	Auto
	Deflation	Constant air release valve / Manual valve (Auto for deflation & measurement / Manual for rapid exhaust)	ECV	ECV
	BP accuracy	+/- 3mmHg	+/- 3mmHg	+/- 3mmHg
	Pulse accuracy	+/- 5%	+/- 5%	+/- 5%
	BP measuring range	SYS: 50~250mmHg, DIA: 40~180mmHg	SYS: 50~250mmHg, DIA: 40~150mmHg	SYS: 50~250mmHg, DIA: 40~180mmHg
	Pulse measuring range	40-160bpm	40-160bpm	40-160bpm
	Pressure range	0~300mmHg	0~300mmHg	0~300mmHg
Cuff	M: 22~32cm	M: 22~32cm	M: 22~32cm	
Large cuff	L: 32~43cm (Optional)	L: 32~43cm (Optional)	L: 32~42cm (Optional)	
Buttons / switches	Buttons / switches	ON/OFF, Memory x 2	ON/OFF, Memory x 2	
Power	Power	4 x AA battery	4 x AA battery	

Comparison of the Beurer BM60 with the Nissei DS-400

Devices	Beurer BM60	Nissei DS-400
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>Hypertension (Indicator strip) 11, 13</p> <p>BP classification (WHO) 10, 11, 13</p> <p>Irregular heartbeat 11, 13</p> <p>Haemodynamic stability 11, 13</p> <p><i>Measurement Records</i></p> <p>Memory zone 11</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> <p>Atrial fibrillation detection 13</p>	

Devices	Beurer BM60	Nissei DS-400
Device 1 Criteria	<p>Algorithms <i>Diagnostic</i> Haemodynamic stability detection 13</p> <p>Case <i>Power</i> AC adapter (Optional) 17</p>	
Same Criteria	<p>Measurement <i>Accuracy</i> BP accuracy ± 3 mmHg 1, 5 Pulse accuracy $\pm 5\%$ 1, 5 <i>Method</i> Oscillometric measurement method 1, 5 SBP 50 mmHg - 250 mmHg, DBP 40 mmHg -180 mmHg 1, 5, 7, 8 Pulse 40 bpm -160 bpm 1, 5 Measurements are from single inflations 13 <i>Inflation</i> Inflation 0 mmHg - 300 mmHg 1, 5, 7 <i>Deflation</i> Automatic Deflation 8 <i>Cuffs</i> Large cuff (Arm circ. 32-42 cm) (Optional) 6 Display/Symbols/Indicators <i>Measurement Procedure</i> Heartbeat symbol during deflation 11 <i>Post Measurement</i> SBP, DBP and Pulse 11 Average 11, 13 <i>Measurement Records</i> Memory recall number 11 Average "A" symbol 11 <i>Power</i> Low battery 11, 17 Case <i>Display</i> Single screen display 10 <i>Power</i> Automatic switch-off when not used for 3 min 17</p>	<p>Measurement <i>Accuracy</i> BP accuracy ± 3 mmHg 1, 5 Pulse accuracy $\pm 5\%$ 1, 5 <i>Method</i> Oscillometric measurement method 1, 5 SBP 50 mmHg - 250 mmHg, DBP 40 mmHg -180 mmHg 1, 5, 7, 8 Pulse 40 bpm -160 bpm 1, 5 Measurements are from single inflations 13 <i>Inflation</i> Inflation 0 mmHg - 300 mmHg 1, 5, 7 <i>Deflation</i> Automatic Deflation 8 <i>Cuffs</i> Large cuff (Arm circ. 32-43 cm) (Optional) 6 Display/Symbols/Indicators <i>Measurement Procedure</i> Heartbeat symbol during deflation 11 <i>Post Measurement</i> SBP, DBP and Pulse 11 Average 11, 13 <i>Measurement Records</i> Memory recall number 11 Average "A" symbol 11 <i>Power</i> Low battery 11, 17 Case <i>Display</i> Single screen display 10 <i>Power</i> Automatic switch-off when not used for 3 min 17</p>

Devices	Beurer BM60	Nissei DS-400
Comparable Criteria	<p>Measurement <i>Inflation</i> Automatic Inflation 7</p> <p><i>Cuffs</i> Large cuff (Arm circ. 32-42 cm) (Optional) 6</p> <p><i>Measurement Records</i> Memory: 60 measurements × 2 zones 14</p> <p>Buttons/Switches On/Off with Start/Stop 10 Memory × 2 10</p> <p>Display/Symbols/Indicators <i>Post Measurement</i> Measurement error (Err 1, Err 2, Err 3, Err 300) 11</p> <p>Algorithms <i>Averages</i> Memory zone mean 13</p> <p>Case <i>Power</i> 4 “AA” batteries ~ 300 measurements 17</p>	<p>Measurement <i>Inflation</i> Manual (bulb) Inflation 7</p> <p><i>Cuffs</i> Large cuff (Arm circ. 32-43 cm) (Optional) 6</p> <p><i>Measurement Records</i> Memory: 30 measurements 14</p> <p>Buttons/Switches On/Off 10 Memory 10</p> <p>Display/Symbols/Indicators <i>Post Measurement</i> Measurement error (Err, Err 330, 0 0) 11</p> <p>Algorithms <i>Averages</i> All measurements mean 13</p> <p>Case <i>Power</i> 1 “AA” battery 17</p>
Device 2 Criteria		<p>Display/Symbols/Indicators <i>Measurement Procedure</i> Inflation symbol 11 Deflation symbol 11 Audible pulse indicator during deflation 18 Beeps after measurement 18</p>
Web link	http://www.beurer.com/web/en/product/blood_pressure/upper_arm/detail.php?pk=31&id=13490&bek=112&bct=%26nbsp%3B%26gt%3B%26nbsp%3Bproduct+details%26nbsp%3B%26gt%3B%26nbsp%3BBM60+%28available+from+May+2010%29	http://www.nissei-jp.com/html/seihin-medical-e.html

<p>Comments</p>	<p>Nissei is an OEM manufacturer for the BM60. From the documentation provided, Nissei refer to the device as the DS-800 although they do not appear to market it under the Nissei brand. The BM60 (DS-800) appears to be very similar to the Nissei DS-500 but with more memory and with WHO classification and haemodynamic stability detection added.</p> <p>Relevant queries made in relation to the DS-500 that also apply to the BM60 (DS-800)</p> <ol style="list-style-type: none"> 1. Some of the errors are different for both devices. The DS-400 has a measurement error E_{rr-1} whereas the DS-500 has three errors, a measurement error E_{rr-1}, an inflation error E_{rr-2} and a deflation error E_{rr-3} though the causes and remedies of E_{rr-1} and E_{rr-3} are identical. The causes of a DS-400 measurement error appear to encompass those of these three DS-500 errors plus an error due to insufficient inflation. Please explain. <ul style="list-style-type: none"> A <i>Yes, The error messages of the DS-400 encompass those three of the DS-500, plus an additional message for insufficient inflation. This is because with the automatic inflation of the DS-500 if there is insufficient inflation the monitor automatically recognises this and re-inflates to a further 30 mmHg but no error is recorded. Whereas with the DS-400 if there is insufficient inflation it is necessary for the User to re-inflate manually to a higher value, so this requirement is indicated by an error message.</i> 2. What is the minimum pressure that the cuff needs to be inflated above SBP for the value of SBP to be accepted? In the DS-400, insufficient inflation is included as one reason for the measurement error E_{rr}. In the DS-500, there is an inflation error, E_{rr-2}, but insufficient inflation is not listed as a possible cause. <ul style="list-style-type: none"> A <i>Between 20 to 30 mmHg above SBP for the value to be accepted. Insufficient inflation with the DS-400 is an error indication because the User must re-inflate manually. With the DS-500 re-inflation to a higher level is automatic so no error need be indicated.</i>
<p>Recommendation</p>	<p>The DS-400 recommendation is “The Nissei DS-400 can be recommended for use in the adult population, particularly in the developing world. Its impressive performance may be related to theoretical factors within the patient population and environment (e.g. temperature, humidity and altitude) that could influence the device’s performance.”¹. The Beurer BM60 can be recommended as equivalent under the same conditions.</p> <p>1 Duhig KE, de Greeff A, van der Westhuizen A, Baker E, Shennan AH. Validation of the Nissei DS-400 in a low-resource setting. Blood Press Monit 2009;14:132-135</p>
<p>Date</p>	<p>19/01/2011</p>