

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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

SECTION A - Please complete all items.

I **Hideki Ura**, a Director of **JAPAN PRECISION INSTRUMENTS INC.**,  
Name of a Company Director Company name

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

Maker<sup>a</sup> **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**  
 Manufacturer<sup>b</sup> **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**  
 Brand<sup>c</sup> **Nissei** Model<sup>d</sup> **DS-G10**

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<sup>a</sup> **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**  
 Manufacturer<sup>b</sup> **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**  
 Brand<sup>c</sup> **Nissei** Model<sup>d</sup> **DSK-1011**

Existing validated blood pressure measuring device.

which has previously passed the **ESH 2010** protocol, the results of which were published as follows:

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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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 <sup>f</sup> <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input checked="" 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 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 checked="" type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" 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 <sup>g</sup> <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.

Please Brief explanation of differences: Further details are shown on the attached "Section B comparison sheet".

5) Pressure Transducer

A/D conversion function built-in piezoelectric sensor is used instead of capacitance sensor.

However their fundamental characteristics of resolution capability and sampling cycle are same and the accuracy of pressure measurement is equivalent.

6) Cuffs or Bladders

The shapes of the connector are different.

9) Model name

Their model name is different. DS-G10 for new device and validated device is DSK-1011.

10) Casing

The designs of the case are different. A number and the kind of the switch are same.

11) Display

The size and displayed data are different.

12) Carrying/Mounting Facilities

Pouch instead of carrying bag.

13) Software other than Algorithm

No function of WHO classification indicator. ※WHO : World Health Organization

SECTION C Please check that the following are included with the application

- A manual for the validated device [x]
A manual for the device for which equivalence is being sought [x]
An image of the validated device [x]
An image of the device for which equivalence is being sought [x]
An image of the screen layout of validated device\* [x]
An image of the screen layout of the device for which equivalence is being sought\* [x]

\* 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 [Signature] Company Stamp/Seal

Name Hideki Ura




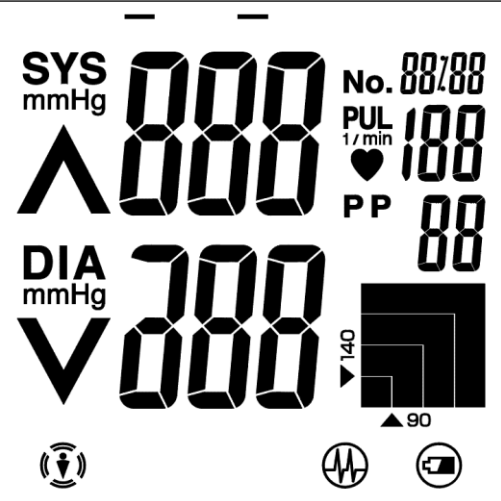
Date 20th Feb 2015

Signature of Witness [Signature]

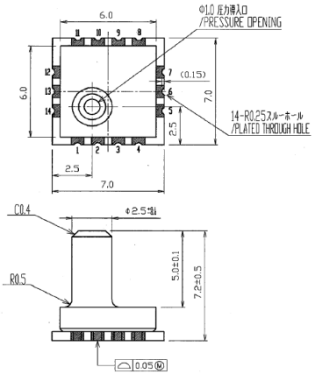
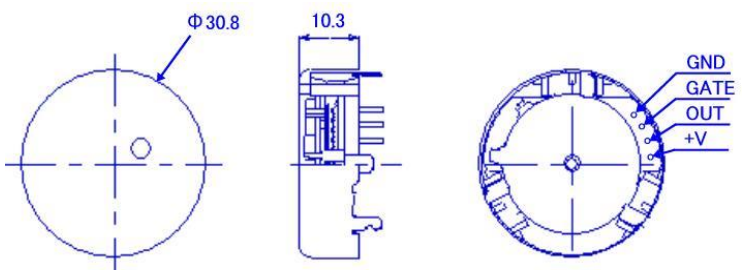
Name Teruka Fukushima

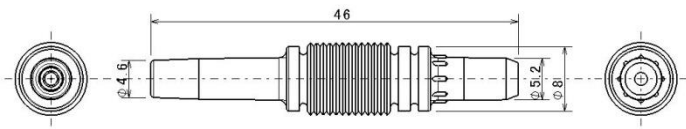
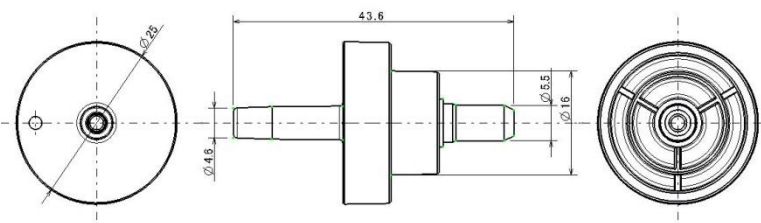
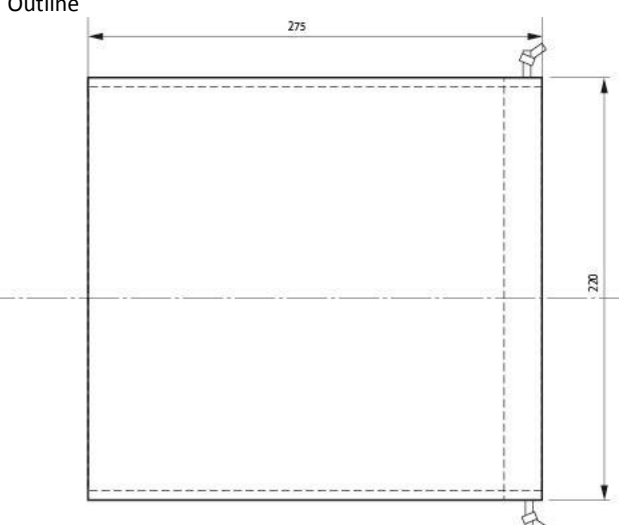
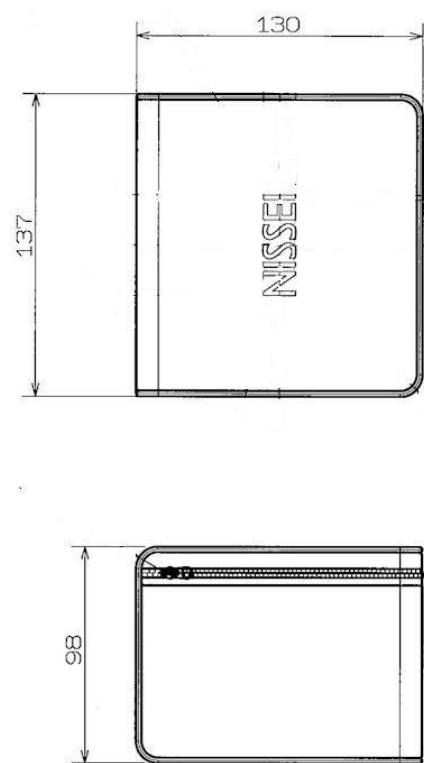
Address 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

Comparison of the NISSEI DS-G10 with the NISSEI DSK-1011

Devices	NISSEI DS-G10	NISSEI DSK-1011
Pictures		
Display		
Validation		ESH 2010

<p><b>Device 1 Criteria</b></p>		<p><b>Display/Symbols/Indicators</b>                  WHO classification *WHO: World Health Organization                  Deflation symbol                  Unit SYS/mmHg, DIA/mmHg, PUL/1/min</p>
<p><b>Device 2 Criteria</b></p>	<p><b>Display/Symbols/Indicators</b>                  Reliability symbol</p> <p><b>Casing</b>                  print                  Unit (SYS)/mmHg, (DIA)/mmHg, (PUL)/1/min</p>	
<p><b>Same Criteria</b></p>	<p><b>Measurement Accuracy</b>                  Blood pressure accuracy <math>\pm</math> 3 mmHg                  Pulse accuracy <math>\pm</math> 5%</p> <p><b>Inflation</b>                  Inflation 0 mmHg - 300 mmHg</p> <p><b>Measurement range</b>                  Systolic blood pressure (SYS) 50 mmHg - 250 mmHg                  Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg                  Pulse rate 40 bpm - 160 bpm</p> <p><b>Display/Symbols/Indicators</b>                  Measurement Result                  Systolic blood pressure (SYS)                  Diastolic blood pressure (DIA)                  Pulse pressure                  Pulse rate                  Inflation symbol                  Heartbeat symbol *during inflation                  Irregular pulse rhythm symbol                  Body motion Symbol                  Low Battery detection symbol                  Memory1/2 symbol                  Average *when review saved readings                  Measurement errors</p> <p><b>Memory Banks &amp; Readings</b>                  60 measurement <math>\times</math> 2 users</p>	<p><b>Measurement Accuracy</b>                  Blood pressure accuracy <math>\pm</math> 3 mmHg                  Pulse accuracy <math>\pm</math> 5%</p> <p><b>Inflation</b>                  Inflation 0 mmHg - 300 mmHg</p> <p><b>Measurement range</b>                  Systolic blood pressure (SYS) 50 mmHg - 250 mmHg                  Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg                  Pulse rate 40 bpm - 160 bpm</p> <p><b>Display/Symbols/Indicators</b>                  Measurement Result                  Systolic blood pressure (SYS)                  Diastolic blood pressure (DIA)                  Pulse pressure                  Pulse rate                  Inflation symbol                  Heartbeat symbol *during inflation                  Irregular pulse rhythm symbol                  Body motion Symbol                  Low Battery detection symbol                  Memory1/2 symbol                  Average *when review saved readings                  Measurement errors</p> <p><b>Memory Banks &amp; Readings</b>                  60 measurement <math>\times</math> 2 users</p>

	<p><b>Casing</b>                  Button (4)                  On/Off With Start                  Memory 1                  Memory 2                  Clock set                  Air connector                  DC Jack *AC adapter is optional</p> <p><b>Cuff</b>                  Universal cuff (Arm circ. 22 to 42cm)</p> <p><b>Power</b>                  Automatic switch-off *when not used for 3min                  Supply                  4 "AA" batteries                  AC adapter *optional</p>	<p><b>Casing</b>                  Button (4)                  On/Off With Start                  Memory 1                  Memory 2                  Clock set                  Air connector                  DC Jack *AC adapter is optional</p> <p><b>Cuff</b>                  Universal cuff (Arm circ. 22 to 42cm)</p> <p><b>Power</b>                  Automatic switch-off *when not used for 3min                  Supply                  4 "AA" batteries                  AC adapter *optional</p>
<p><b>Comparable Criteria</b></p>	<p><b>Measurement Records</b>                  Average                  The average is for up to 3 readings within 15 minutes before the last measurement</p>	<p><b>Measurement Records</b>                  Average                  All measurement mean</p>
<p><b>Pressure Transducer</b></p>	<p><b>Model</b>                  MMR901XA                  Pressure range 0mmHg - 300 mmHg                  Safety over load 600 mmHg                  Resolution 0.05 mmHg                  Outline</p>  <p>Technical drawing of the MMR901XA pressure transducer. It includes a top view showing a square footprint with a 6.0 mm side length and a central pressure opening of diameter 1.0 mm. A detail view shows a 14-RO.257.0-8-11 plated through hole. A side view shows a cylindrical body with a total height of 7.2 ± 0.5 mm and a diameter of 2.5 mm. A bottom view shows a 0.05 mm thickness. Labels include '0.0 8mm 1.0 PRESSURE OPENING' and '14-RO.257.0-8-11 PLATED THROUGH HOLE'.</p>	<p><b>Model</b>                  CS-20A                  Pressure range 0mmHg - 300 mmHg                  Safety over load 390 mmHg                  Resolution 0.05 mmHg                  Outline</p>  <p>Technical drawing of the CS-20A pressure transducer. It includes a front view showing a circular face with a diameter of 30.8 mm. A side view shows a cylindrical body with a diameter of 10.3 mm. A back view shows the electrical connections labeled GND, GATE, OUT, and +V.</p>

<p><b>Cuffs or Bladders</b></p>	<p><b>Air Plug</b> Outline</p> 	<p><b>Air Plug</b> Outline</p> 
<p><b>Carring /Mounting Facilities</b></p>	<p><b>Pouch</b> Material: Non-woven textile fabrics Outline</p> 	<p><b>Carrying Bag</b> Material: Nylon Outline</p> 

<b>Comments</b>	1	<p>Query Please provide more information on the different air plug on DS-G10.</p> <p>Reply Both of air plugs have the shape of straight. There is no difference of the air flow function. DSK-1011 has a flanged air plug so that the user can easily hold it to insert and remove. Further on it suits more to the design of DSK-1011 main unit. DS-G10 has our normal air plug and only the difference from DSK-1011 is the visual design.</p> <p>Comment Accepted</p>
<b>Recommendation</b>	<b>Recommended</b>	
<b>Date</b>	<b>4<sup>th</sup> March 2015</b>	