

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-N10**

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-1031**

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 checked="" type="checkbox"/>	No <input 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-N10 for new device and validated device is DSK-1031.

10) Casing

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

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

17) Power Supply

Shapes of DC plug are different. The DC plug of DS-N10 is based on EIAJ Type2.

**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

An image of the validated device

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@dablededucational.org.

Signature of Director Hideki Ura

Company Stamp/Seal

Name Hideki Ura




Date 20<sup>th</sup> Feb 2015

Signature of Witness T. Teruka

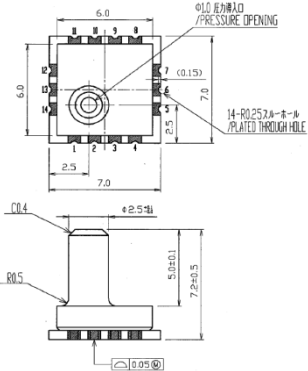
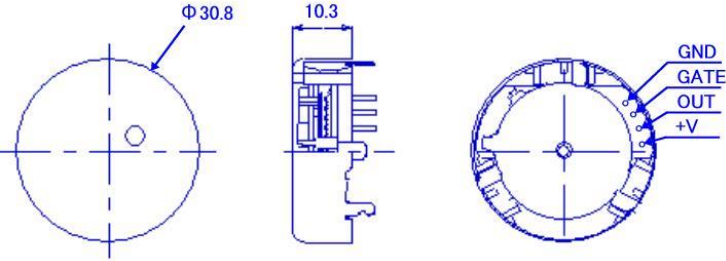
Name Teruka Fukushima

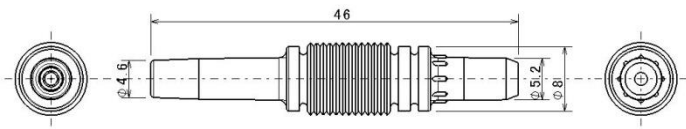
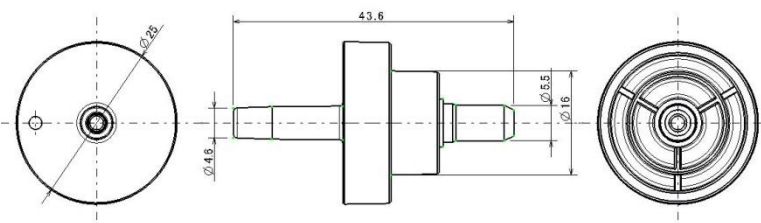
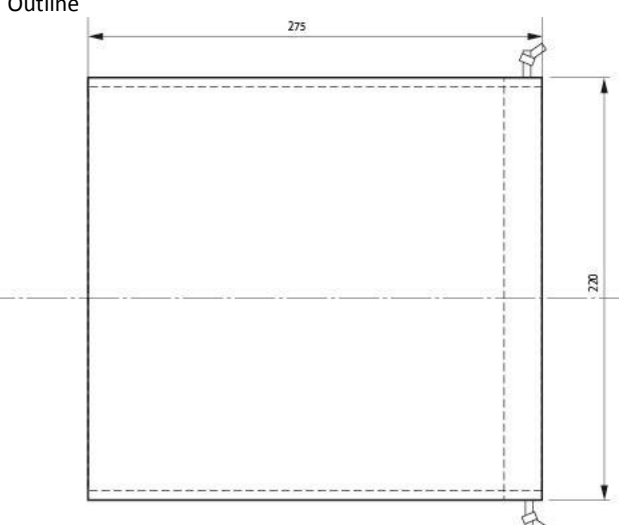
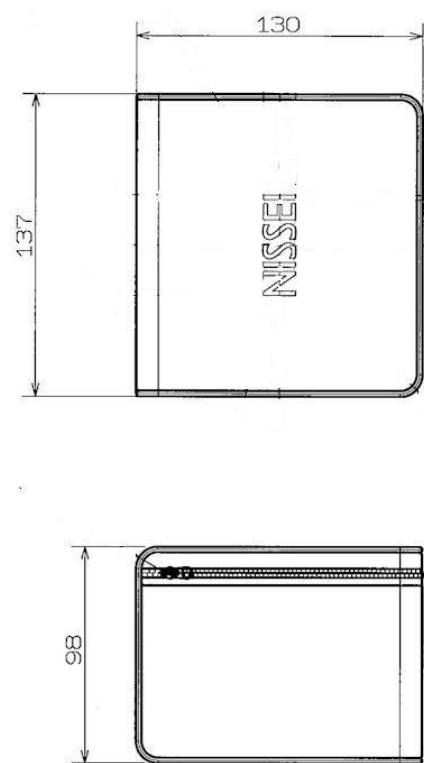
Address 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

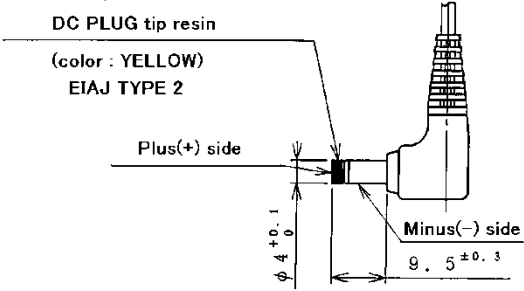
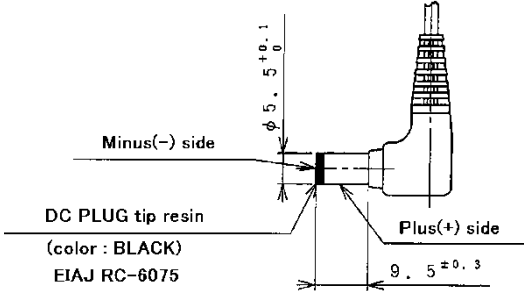
Comparison of the NESSEI DS-N10 with the NESSEI DSK-1031

Devices	NESSEI DS-N10	NESSEI DSK-1031
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>                  Morning Reading/Night Reading symbol</p> <p><b>Casing</b>                  print                  Unit 最高血压(SYS)/mmHg, 最低血压(DIA)/mmHg, 拍/分(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                  Reliability symbol                  Cuff symbol                  Heartbeat symbol *during deflation                  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                  Reliability symbol                  Cuff symbol                  Heartbeat symbol *during deflation                  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> Air connector DC Jack</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 Casing</p>	<p><b>Casing</b> Air connector DC Jack</p> <p><b>Cuff</b> Universal cuff (Arm circ. 22 to 42 cm)</p> <p><b>Power</b> Automatic switch-off *when not used for 3min Supply 4 "AA" batteries AC adapter Measurement Accuracy</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>Casing</b> Button (7) On/Off With Start Memory 1 Memory 2 Clock set Morning Reading/Night Reading Up Down</p>	<p><b>Measurement Records</b> Average All measurement mean</p> <p><b>Casing</b> Button (4) On/Off With Start Memory 1 Memory 2 Clock set</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><b>Model</b> CS-20A Pressure range 0mmHg - 300 mmHg Safety over load 390 mmHg Resolution 0.05 mmHg Outline</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> 

<p><b>Power Supply</b></p>	<p><b>DC PLUG</b> Outline</p>  <p>DC PLUG tip resin (color : YELLOW) EIAJ TYPE 2</p> <p>Plus(+) side</p> <p>Minus(-) side</p> <p><math>\phi 4.0 \pm 0.1</math></p> <p><math>9.5 \pm 0.3</math></p>		<p><b>DC PLUG</b> Outline</p>  <p>Minus(-) side</p> <p>DC PLUG tip resin (color : BLACK) EIAJ RC-6075</p> <p>Plus(+) side</p> <p><math>\phi 5.5 \pm 0.1</math></p> <p><math>9.5 \pm 0.3</math></p>
<p><b>Comments</b></p>	<p>1</p>	<p>Query Please provide more information on the different air plug on DS-N10.</p> <p>Reply Both of air plugs have the shape of straight. There is no difference of the air flow function. DSK-1031 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-1031 main unit. DS-N10 has our normal air plug and only the difference from DSK-1031 is the visual design.</p> <p>Comment Accepted</p>	
<p><b>Recommendation</b></p>	<p><b>Recommended</b></p>		
<p><b>Date</b></p>	<p><b>4<sup>th</sup> March 2015</b></p>		