

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://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-B10(DS-11)

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 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 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 checked="" type="checkbox"/>	No <input 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.

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.

9) Model name

Their model name is different. DS-B10 for new device and validated device is DSK-1011.

10) Casing

Tact switch of one START/STOP key and one memory key instead of touch keys of one clock key, two memory keys, and one START/STOP key.

11) Display

The size and displayed data are different due to the different function except measurement function.

12) Carrying/Mounting Facilities

Pouch instead of carrying bag.

13) Software other than Algorithm

No function of cuff condition indicator and no function of pulse pressure display.

14) Memory Capacity/Number of stored measurements

Memory capacity is 60 times x 1 way instead of 60 times x 2 ways.

**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](mailto:info@dablededucational.org).

Signature of Director Hideki Ura Company Stamp/Seal

Name Hideki Ura



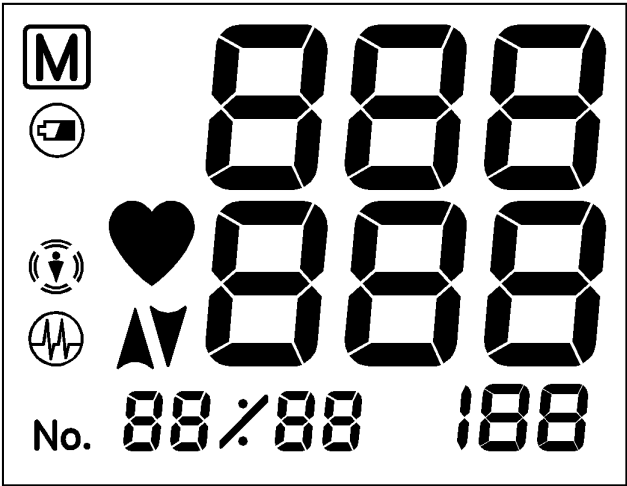

Date 15<sup>th</sup> Jan 2015

Signature of Witness T. Fukushima

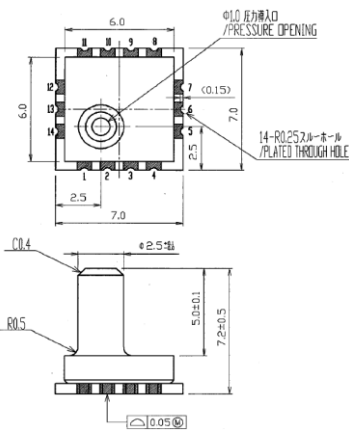
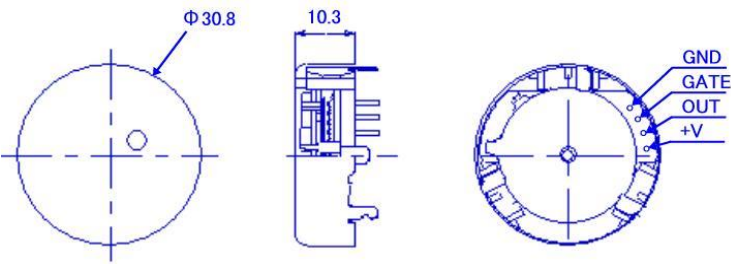
Name Teruka Fukushima

Address 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

Comparison of the Nissei DS-B10 with the Nissei DSK-1011

Devices	Nissei DS-B10(DS-11) (Device 1)	Nissei DSK-1011 (Device 2)
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		

<p><b>Device 2 Criteria</b></p>		<p><b>Display/Symbols/Indicators</b>          WHO classification          Pulse pressure          Time  <b>Measurement Records</b>          Memory recall number</p>
<p><b>Same Criteria</b></p>	<p><b>Measurement</b>  <i>Accuracy</i>  <i>BP accuracy ± 3 mmHg</i>  <i>Pulse accuracy ± 5%</i>  <i>Inflation</i>  <i>Inflation 0 mmHg - 300 mmHg</i>  <i>Display/Symbols/Indicators</i>  <i>Measurement Procedure</i>  <i>Inflation symbol</i>  <i>Deflation symbol</i>  <i>Hertbeat symbol durring inflation</i>  <i>Irregular pulse rhythm symbol</i>  <i>Body motion Symbol</i>  <i>Post Measurement</i>  <i>SBP,DBP and Pulse</i>  <i>Average</i>  <i>Power</i>  <i>Low Battery</i>  <i>Case</i>  <i>Display</i>  <i>Single screen display</i>  <i>Power</i>  <i>Automatic swith-off when not used for 3min</i>  <i>Measurement</i>  <i>Method</i>  <i>SBP 50 mmHg - 250 mmHg, DBP 40 mmHg - 180 mmHg</i>  <i>Display/Symbols/indicators</i>  <i>Post Measurement</i>  <i>Measurment errors</i>  <i>Case</i>  <i>Power</i>  <i>4 "AA" batteries</i>  <i>Cuff</i>  <i>Universal cuff (Arm circ. 22 to 42cm)</i></p>	<p><b>Measurement</b>  <i>Accuracy</i>  <i>BP accuracy ± 3 mmHg</i>  <i>Pulse accuracy ± 5%</i>  <i>Inflation</i>  <i>Inflation 0 mmHg - 300 mmHg</i>  <i>Display/Symbols/Indicators</i>  <i>Measurement Procedure</i>  <i>Inflation symbol</i>  <i>Deflation symbol</i>  <i>Hertbeat symbol durring inflation</i>  <i>Irregular pulse rhythm symbol</i>  <i>Body motion Symbol</i>  <i>Post Measurement</i>  <i>SBP,DBP and Pulse</i>  <i>Average</i>  <i>Power</i>  <i>Low Battery</i>  <i>Case</i>  <i>Display</i>  <i>Single screen display</i>  <i>Power</i>  <i>Automatic swith-off when not used for 3min</i>  <i>Measurement</i>  <i>Method</i>  <i>SBP 50 mmHg - 250 mmHg, DBP 40 mmHg -180 mmHg</i>  <i>Display/Symbols/indicators</i>  <i>Post Measurement</i>  <i>Measurment errors</i>  <i>Case</i>  <i>Power</i>  <i>4 "AA" batteries</i>  <i>Cuff</i>  <i>Universal cuff (Arm circ. 22 to 42 cm)</i></p>

<p><b>Comparable Criteria</b></p>	<p>Measurement Records                  Memory: 60 measurement × 1 users                  Average                  All measurement mean</p> <p>Buttons/Switch                  On/Off With Start                  Memory × 1</p> <p>Measurement Method                  Oscillometric measurement method                  Pulse 40 bpm - 180 bpm                  Measurements are from signal</p>	<p>Measurement Records                  Memory: 60 measurement × 2 users                  Average                  All measurement mean</p> <p>Buttons/Switch                  On/Off With Start                  Memory × 2                  Clock set</p> <p>Measurement Method                  Oscillometric measurement method                  Pulse 40 bpm - 160 bpm                  Measurements are from signal</p>
<p><b>Sensor</b></p>	<p>Model                  MMR901XA                  Pressure range                  0 ~ 300 mmHg                  Safety over load                  600 mmHg                  Resolution                  0.05 mmHg</p> <p>Outline</p>  <p>Technical drawing of the MMR901XA sensor. The top view shows a square package with a side length of 6.0 mm. It features a central pressure opening with a diameter of 1.0 mm. The package has 14 pins, with 14-R0.252mm-related through holes. The side view shows a height of 7.2 ± 0.5 mm and a base diameter of 7.0 mm. A surface finish of Ra 0.4 is indicated.</p>	<p>Model                  CS-20A                  Pressure range                  0 ~ 300 mmHg                  Safety over load                  390 mmHg                  Resolution                  0.05 mmHg</p> <p>Outline</p>  <p>Technical drawing of the CS-20A sensor. The top view shows a circular package with a diameter of 30.8 mm. The side view shows a height of 10.3 mm. The bottom view shows four pins labeled GND, GATE, OUT, and +V.</p>

<p><b>Comments</b></p>	
------------------------	--

<b>Recommendation</b>	Equivalence is recommended
<b>Date</b>	16/01/2015