

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^a **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**
 Manufacturer^b **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**
 Brand^c **Nissei** Model^d **DS-A10(DS-10)**

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^a **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**
 Manufacturer^b **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**
 Brand^c **Nissei** Model^d **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 ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <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 ^f <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 checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <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 ^g <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-A10 for new device and validated device is DSK-1011.

10) Casing

Tact switch of one START/STOP key with function displays last measurement value at measuring start 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 only latest measurement 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 | <input checked="" type="checkbox"/> |
| A manual for the device for which equivalence is being sought | <input checked="" type="checkbox"/> |
| An image of the validated device | <input checked="" type="checkbox"/> |
| An image of the device for which equivalence is being sought | <input checked="" type="checkbox"/> |
| An image of the screen layout of validated device* | <input checked="" type="checkbox"/> |
| An image of the screen layout of the device for which equivalence is being sought* | <input checked="" type="checkbox"/> |

* 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



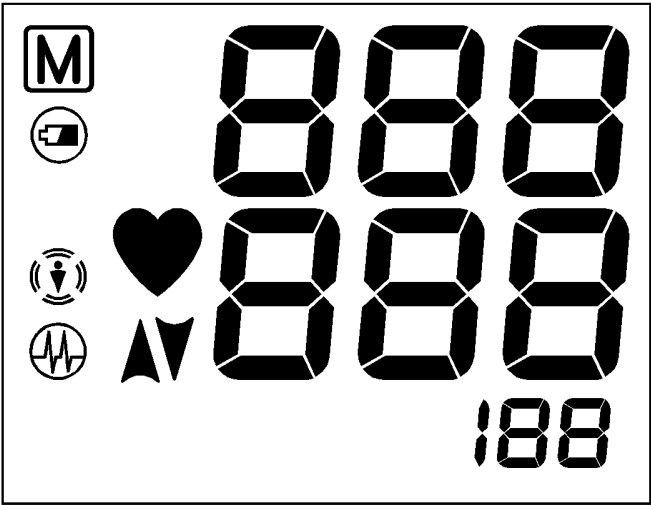

Date 15th Jan 2015

Signature of Witness T. Fukushima

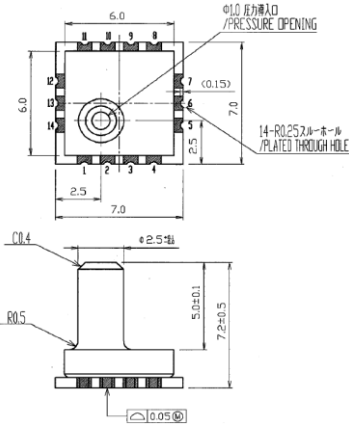
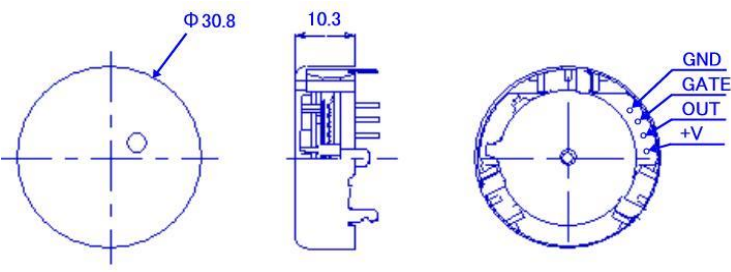
Name Teruka Fukushima

Address 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

Comparison of the Nissei DS-A10 with the Nissei DSK-1011

Devices	Nissei DS-A10(DS-10) (Device 1)	Nissei DSK-1011 (Device 2)
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		

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

<p>Comparable Criteria</p>	<p>Measurement Records Memory: 1 measurement</p> <p>Buttons/Switch On/Off With Start</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>Sensor</p>	<p>Model MMR901XA Pressure range 0 ~ 300 mmHg Safety over load 600 mmHg Resolution 0.05 mmHg</p> <p>Outline</p> 	<p>Model CS-20A Pressure range 0 ~ 300 mmHg Safety over load 390 mmHg Resolution 0.05 mmHg</p> <p>Outline</p> 

Comments		
Recommendation	Equivalence is Recommended	
Date	16/01/2015	