

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 **Ryo Maruhashi**, 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

Make^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 SAFETY PRONTEX **Model^d** SYNTESI (NISSEI DS-B23-03)

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

Make^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:

de Greeff A, Shennan AH. Validation of the Nissei DSK-1011 upper arm blood pressure monitor, for clinic use and self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010

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 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 checked="" type="checkbox"/>	No <input type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" 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 checked="" type="checkbox"/>	No <input 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.

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 for SYNTESI (NISSEI DS-B23-03) instead of capacitance sensor for DSK-1011.

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. SYNTESI (NISSEI DS-B23-03) for new device and validated device is DSK-1011.

10) Casing

The designs of the housing are different. A number and the kind of the buttons are different.

11) Display

The size and displayed data are different.

12) Carrying/Mounting Facilities

Pouch is enclosed for SYNTESI (NISSEI DS-B23-03) instead of carrying bag for DSK-1011.

13) Software other than Algorithm

No function of WHO classification indicator for SYNTESI (NISSEI DS-B23-03). ※WHO : World Health Organization

Difference of memory function

Difference of display etc.

14) Memory Capacity/Number of stored measurement

SYNTESI (NISSEI DS-B23-03) stores 1 x 60 measurement data while DSK-1011 stores 2 x 60 measurement data.

17) Power Supply

Shapes of DC plug are different. The DC plug of SYNTESI (NISSEI DS-B23-03) 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 

Name Ryo Maruhashi

Date 23rd August 2017

Signature of Witness 





Name Mitsuo Kanai

Address 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

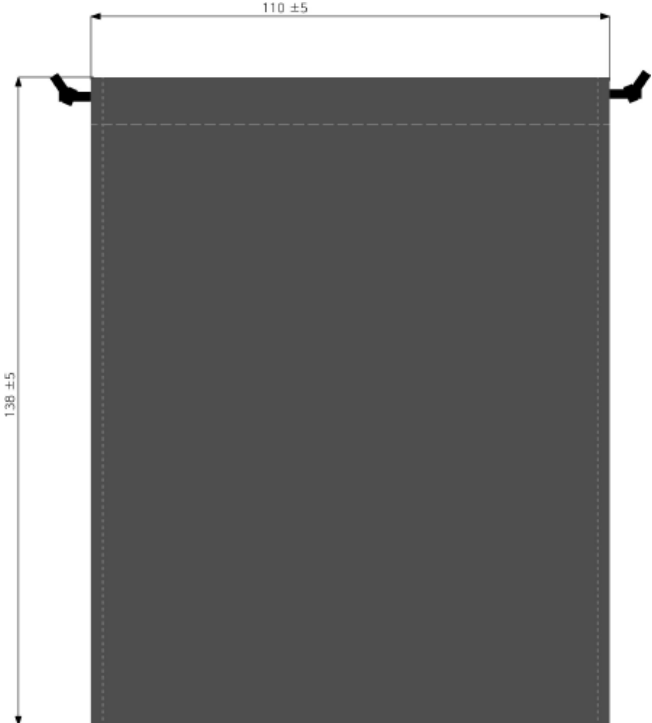
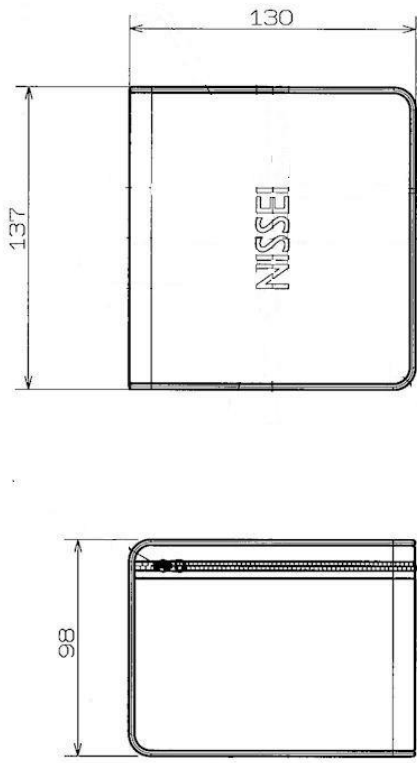
Company Stamp/Seal

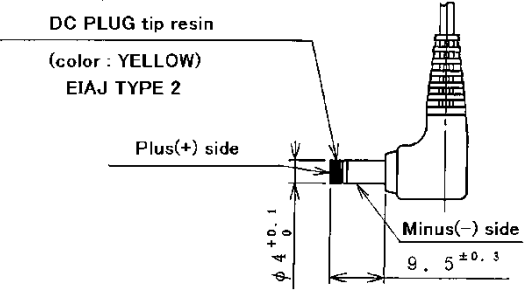
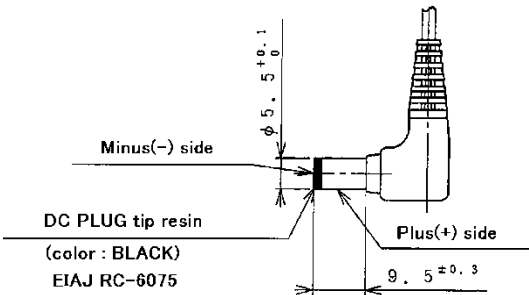
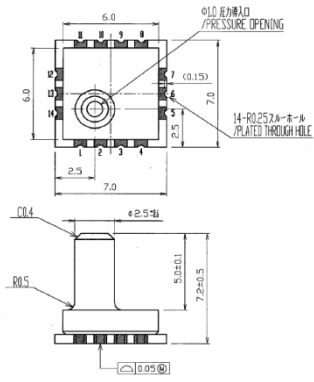
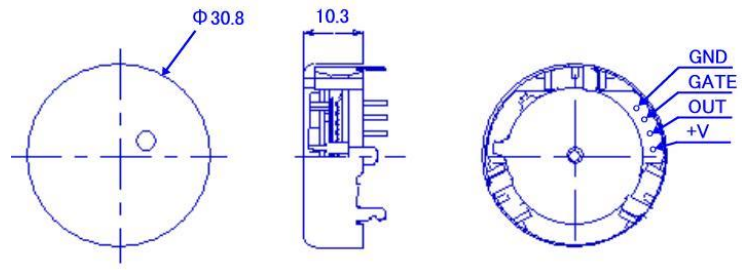
JAPAN PRECISION INSTRUMENTS INC.

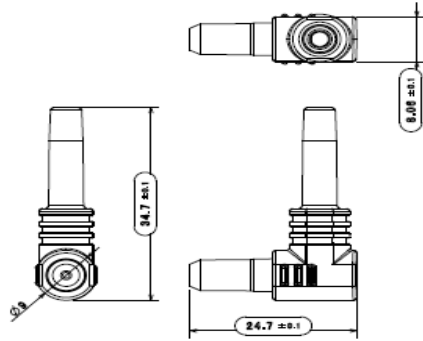
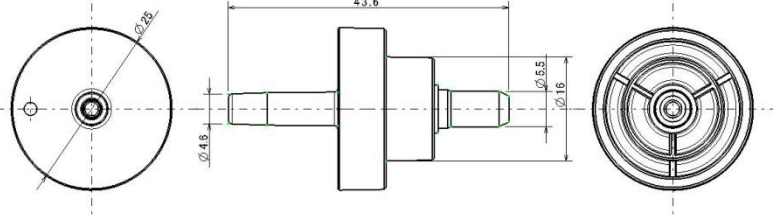
Comparison of the SAFETY PRONTEX SYNTESI (Nissei DS-B23-03) with the Nissei DSK-1011

Devices – Item 9	SAFETY PRONTEX SYNTESI (Nissei DS-B23-03)	Nissei DSK-1011
Pictures		
Display Image		
Validation		ESH IP2010
Category	Upper arm device for self measurement of blood pressure	Upper arm device for self measurement of blood pressure
Casing – Item 10	<i>Dimensions</i>	<i>Dimensions</i>

	<p>114 x 174 x 70.4 mm (W x D x H)</p> <p><i>Ports</i> Upper & bottom housing, battery cover, display panel, 2 buttons (Start/stop,, Memory)</p> <p><i>Features</i> Cuff and AC adaptor connectors Brand logo printing Model name printing Button printing SYS, DIA, PUL printing</p>	<p>115 x 115 x 65.9 mm (W x D x H)</p> <p><i>Ports</i> Upper & bottom housing, battery cover, display panel (Buttons are touch keys, Start/stop, Set, Memory 1 & 2)</p> <p><i>Features</i> Cuff and AC adaptor connectors Brand logo printing Model name printing Button printing Touch keys</p>
Display – Item 11	<p><i>Type</i> LCD</p>	<p><i>Type</i> LCD</p>
Carrying/Mounting Facilities – Item 12	<p><i>Pouch</i> Material: Non-woven textile fabrics Outline</p>	<p><i>Carrying Bag</i> Material: Nylon Outline</p>

		
<p>Software other than Algorithm – Item 13</p>	<p>Difference of memory function Difference of display etc.</p>	<p>Difference of memory function Difference of display etc.</p>
<p>Memory Capacity Item 14</p>	<p>60 measurement results x 2 banks</p>	<p>60 measurement results x 2 banks</p>
<p>Printing Facilities Item 15</p>	<p>None</p>	<p><i>None</i></p>
<p>Communication Facilities – Item 16</p>	<p>None</p>	<p><i>None</i></p>

<p>Power Supply Item 17</p>	<p>4 x 1.5V LR6 (size AA) alkaline batteries or AC adaptor ADP-W5 series (not included in the product)</p> <p>Difference in AC adaptor plug shape:</p>  <p>DC PLUG tip resin (color : YELLOW) EIAJ TYPE 2</p> <p>Plus(+) side</p> <p>Minus(-) side</p> <p>$\phi 4.0 \pm 0.1$</p> <p>9.5 ± 0.3</p>	<p>4 x 1.5V LR6 (size AA) alkaline batteries or AC adaptor ADP-W5 series (not included in the product)</p> <p>Difference in AC adaptor plug shape:</p>  <p>Minus(-) side</p> <p>Plus(+) side</p> <p>DC PLUG tip resin (color : BLACK) EIAJ RC-6075</p> <p>$\phi 5.5 \pm 0.1$</p> <p>9.5 ± 0.3</p>
<p>Other differences</p>	<p>Pressure Sensors Model MMR901XA Pressure range 0mmHg - 300 mmHg Safety over load 600 mmHg Resolution 0.05 mmHg Outline</p>  <p>Cuff air plug Outline</p>	<p>Display/Symbols/Indicators WHO classification *WHO: World Health Organization Pulse Pressure Display Memory Average Display</p> <p>Pressure Sensors CS-20A Pressure range 0mmHg - 300 mmHg Safety over load 390 mmHg Resolution 0.05 mmHg Outline</p>  <p>Cuff air plug Outline</p>

		
<p>Same Criteria</p>	<p>Measurement</p> <p><i>Accuracy</i> Blood pressure accuracy ± 3 mmHg Pulse accuracy $\pm 5\%$</p> <p><i>Method</i> Oscillometric measurement while inflation</p> <p><i>Ranges</i> Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg</p> <p><i>Inflation</i> Inflation 0 mmHg - 300 mmHg</p> <p><i>Deflation</i> Rapid deflation by electric valve</p> <p><i>Cuffs (Please state sizes and materials used)</i> Universal cuff (Arm circ. 22 to 42cm)</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p><i>Measurement Records</i> Measurement data storage</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p>	<p>Measurement</p> <p><i>Accuracy</i> Blood pressure accuracy ± 3 mmHg Pulse accuracy $\pm 5\%$</p> <p><i>Method</i> Oscillometric measurement while inflation</p> <p><i>Ranges</i> Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg</p> <p><i>Inflation</i> Inflation 0 mmHg - 300 mmHg</p> <p><i>Deflation</i> Rapid deflation by electric valve</p> <p><i>Cuffs (Please state sizes and materials used)</i> Universal cuff (Arm circ. 22 to 42cm)</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p><i>Measurement Records</i> Measurement data storage</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p>

	<p>Automatic Zero setting</p> <p><i>Measurement Procedure</i> Inflation symbol Pressure value indication Heart mark blinking</p> <p><i>Post Measurement</i> Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Irregular pulse rhythm symbol Body motion Symbol Measurement time</p> <p><i>Measurement Records</i> Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Irregular pulse rhythm symbol Body motion Symbol Measurement date/time</p> <p><i>Date and Time</i> Indicated at power off, measurement completion and memory recall</p> <p><i>Power</i> See Power Supply Item 17</p> <p><i>Function</i> Blood pressure measurement Pulse rate measurement Irregular pulse rhythm symbol Body motion Symbol Memory function Error indication</p> <p>Algorithms Equivalent device has the identical measurement algorithm as the validated device.</p>	<p>Automatic Zero setting</p> <p><i>Measurement Procedure</i> Inflation symbol Pressure value indication Heart mark blinking</p> <p><i>Post Measurement</i> Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Irregular pulse rhythm symbol Body motion Symbol Measurement time</p> <p><i>Measurement Records</i> Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Irregular pulse rhythm symbol Body motion Symbol Measurement date/time</p> <p><i>Date and Time</i> Indicated at power off, measurement completion and memory recall</p> <p><i>Power</i> See Power Supply Item 17</p> <p><i>Function</i> Blood pressure measurement Pulse rate measurement Irregular pulse rhythm symbol Body motion Symbol Memory function Error indication</p> <p>Algorithms Equivalent device has the identical measurement algorithm as the validated device.</p>
--	---	---

<p>Comparable Criteria</p>	<p>Measurement range Pulse rate 40 bpm - 180 bpm</p> <p>Display/Symbols/Indicators Memory symbol SYS/mmHg, DIA/mmHg, PUL/1/min are printed on housing.</p> <p>Memory Banks & Readings 60 measurement</p> <p>Measurement Records No average indication</p> <p>Casing Buttons Start / stop Memory</p> <p>Power Automatic switch-off *when not used for 2min</p> <p>Cuff Cuff dimensions: 138 x 580mm</p>	<p>Measurement range Pulse rate 40 bpm - 160 bpm</p> <p>Display/Symbols/Indicators Memory1/2 symbol SYS/mmHg, DIA/mmHg, PUL/1/min are digitally displayed on LCD.</p> <p>Memory Banks & Readings 60 measurement × 2 users</p> <p>Measurement Records Average of all stored data</p> <p>Casing Touch Key switches Start / stop Memory 1 Memory 2 Clock set</p> <p>Power Automatic switch-off *when not used for 3min</p> <p>Cuff Cuff dimensions: 135 x 580mm</p>
-----------------------------------	---	---

<p>Comments</p>	
<p>Recommendation</p>	<p>RECOMMENDED</p>
<p>Date</p>	<p>30th August 2017</p>