dabl®Educational Trust **Declaration of Equivalence Form**

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

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]	SAFETY PRONTEX	Model[d]	INTEGRA (NISSEI DS-B33-03)

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

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:

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 ☐	No ☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐	N/A[f] ☒
	3	Artefact/Error Detection	Yes ☐	No ☒	
	4	Microphone(s)	Yes ☐	No ☐	N/A[f] ☒
	5	Pressure Transducer	Yes ☒	No ☐	
	6	Cuffs or Bladders	Yes ☒	No ☐	
	7	Inflation Mechanism	Yes ☐	No ☒	
	8	Deflation Mechanism	Yes ☐	No ☒	
Part II	9	Model Name or Number	Yes ☒	No ☐	
	10	Casing	Yes ☒	No ☐	
	11	Display	Yes ☒	No ☐	
	12	Carrying/Mounting Facilities	Yes ☒	No ☐	
	13	Software other than Algorithm	Yes ☒	No ☐	
	14	Memory Capacity/Number of stored measurements	Yes ☐	No ☒	
	15	Printing Facilities	Yes ☐	No ☐	N/A[g] ☒
	16	Communication Facilities	Yes ☐	No ☐	N/A[g] ☒
	17	Power Supply	Yes ☒	No ☐	
	18	Other Facilities	Yes ☐	No ☒	N/A[g] ☐

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.

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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.

PleaseBrief 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 INTEGRA (NISSEI DS-B33-03) 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. INTEGRA (NISSEI DS-B33-03) 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 same.

11) Display

The size and displayed data are different.

12) Carrying/Mounting Facilities

The shape and material of the carrying bags are different between INTEGRA (NISSEI DS-B33-03) and DSK-1011.

13) Software other than Algorithm

Difference of memory function

Difference of display etc.

17) Power Supply

Shapes of DC plug are different. The DC plug of INTEGRA (NISSEI DS-B33-03) 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@dableducational.org.

Signature of Director _____ Company Stamp/Seal

Name Ryo Maruhashi JAPAN PRECISION INSTRUMENTS INC.

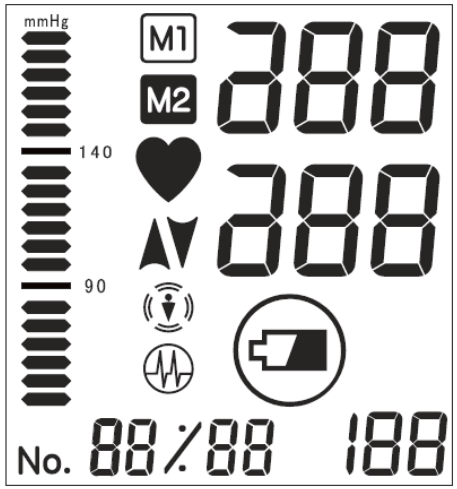
Date 23rd August 2017

Signature of Witness _____

Name Mitsuo Kanai

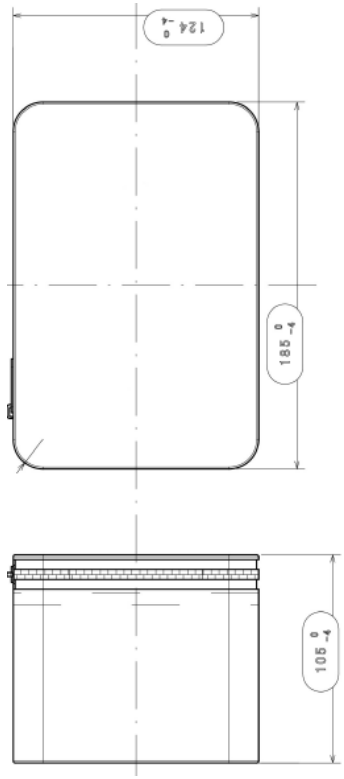
Address 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

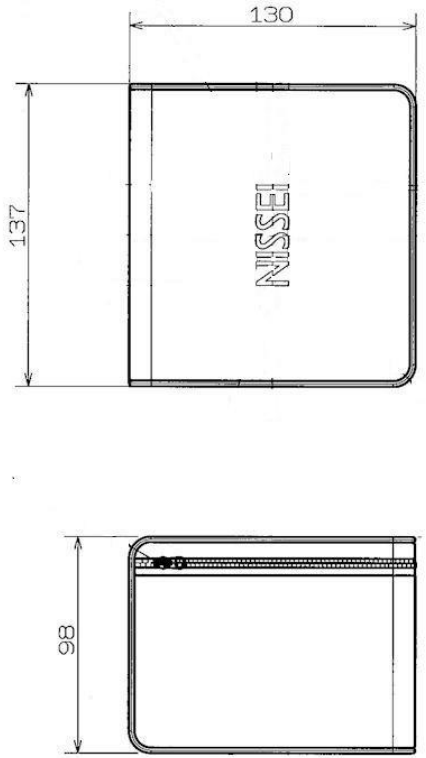
Comparison of the SAFETY PRONTEX INTEGRA (Nissei DS-B33-03) with the Nissei DSK-1011

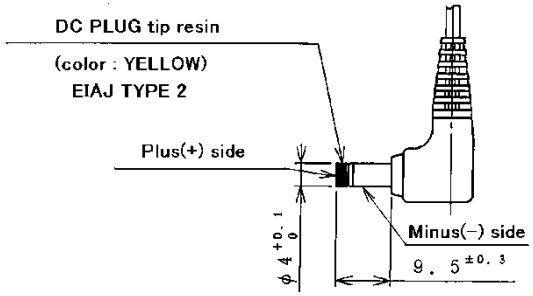
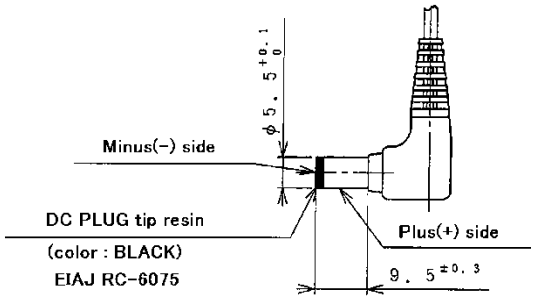
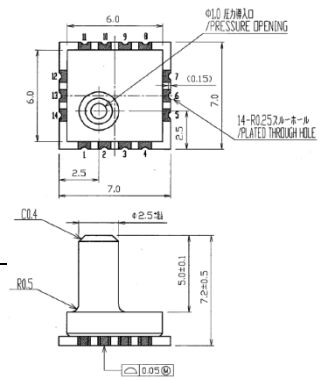
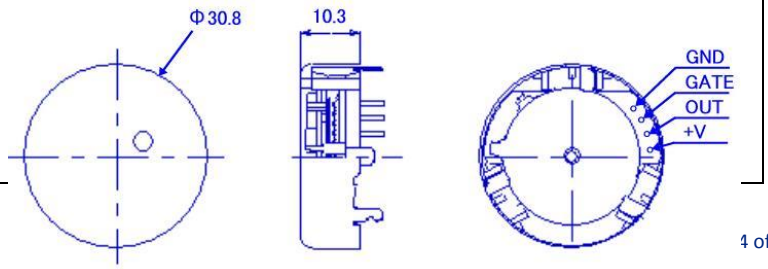
Devices – Item 9	*SAFETY PRONTEX INTEGRA (Nissei DS-B33-03)*	*Nissei DSK-1011*
Pictures		
Display Image		
Validation		ESH IP2010
Category	Upper arm device for self measurement of blood pressure	Upper arm device for self measurement of blood pressure
Casing – Item 10	*Dimensions*	*Dimensions*

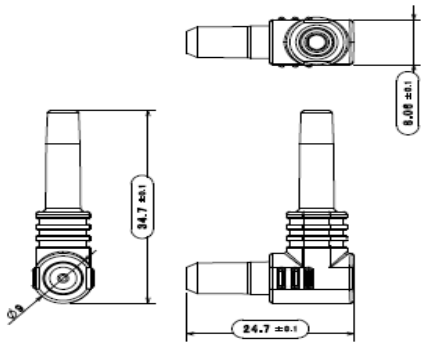
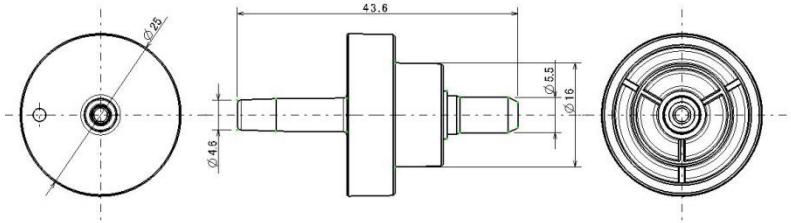
Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

	114 x 174 x 70.4 mm (W x D x H) *Ports* Upper & bottom housing, battery cover, display panel, 4 buttons (Start/stop, Set, Memory 1 & 2) *Features* Cuff and AC adaptor connectors Brand logo printing Model name printing Button printing SYS, DIA, PUL printing	115 x 115 x 65.9 mm (W x D x H) *Ports* Upper & bottom housing, battery cover, display panel (Buttons are touch keys, Start/stop, Set, Memory 1 & 2) *Features* Cuff and AC adaptor connectors Brand logo printing Model name printing Button printing Touch keys
Display – Item 11	*Type* LCD	*Type* LCD
Carrying/Mounting Facilities – Item 12	***Carrying Bag*** Material: Polyester Outline	***Carrying Bag*** Material: Nylon Outline





Software other than Algorithm – Item 13	Difference of memory function Difference of display etc.	Difference of memory function Difference of display etc.
Memory Capacity Item 14	60 measurement results x 2 banks	60 measurement results x 2 banks
Printing Facilities Item 15	None	*None*
Communication Facilities – Item 16	None	*None*
Power Supply Item 17	4 x 1.5V LR6 (size AA) alkaline batteries or AC adaptor ADP-W5 series (not included in the product) Difference in AC adaptor plug shape:  	4 x 1.5V LR6 (size AA) alkaline batteries or AC adaptor ADP-W5 series (not included in the product) Difference in AC adaptor plug shape: 
Other differences	***Display/Symbols/Indicators*** Pressure column indication ***Pressure Sensors*** ***Model*** MMR901XA Pressure range 0mmHg - 300 mmHg Safety over load 600 mmHg Resolution 0.05 mmHg Outline  	***Display/Symbols/Indicators*** WHO classification *WHO: World Health Organization ***Pressure Sensors*** CS-20A Pressure range 0mmHg - 300 mmHg Safety over load 390 mmHg Resolution 0.05 mmHg Outline 

	Cuff air plug Outline  	***Cuff air plug*** Outline 
Same Criteria	***Measurement*** *Accuracy* Blood pressure accuracy ± 3 mmHg Pulse accuracy ± 5% *Method* Oscillometric measurement while inflation *Ranges* Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg *Inflation* Inflation 0 mmHg - 300 mmHg *Deflation* Rapid deflation by electric valve *Cuffs (Please state sizes and materials used)* Universal cuff (Arm circ. 22 to 42cm) *Measurements other than Blood Pressure* Pulse pressure Pulse rate ***Buttons/Switches***	***Measurement*** *Accuracy* Blood pressure accuracy ± 3 mmHg Pulse accuracy ± 5% *Method* Oscillometric measurement while inflation *Ranges* Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg *Inflation* Inflation 0 mmHg - 300 mmHg *Deflation* Rapid deflation by electric valve *Cuffs (Please state sizes and materials used)* Universal cuff (Arm circ. 22 to 42cm) *Measurements other than Blood Pressure* Pulse pressure Pulse rate ***Buttons/Switches***

	Start / stop Memory 1 Memory 2 Clock set *Measurement Records* 60 x 2 memory storage ***Display/Symbols/Indicators*** *Preparation* Automatic Zero setting *Measurement Procedure* Inflation symbol Pressure value indication Heart mark blinking *Post Measurement* Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse pressure Pulse rate Irregular pulse rhythm symbol Body motion Symbol Memory bank Measurement time *Measurement Records* Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse pressure Pulse rate Irregular pulse rhythm symbol Body motion Symbol Memory bank Measurement date/time *Date and Time* Indicated at power off, measurement completion and memory recall *Power*	Start / stop Memory 1 Memory 2 Clock set *Measurement Records* 60 x 2 memory storage ***Display/Symbols/Indicators*** *Preparation* Automatic Zero setting *Measurement Procedure* Inflation symbol Pressure value indication Heart mark blinking *Post Measurement* Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse pressure Pulse rate Irregular pulse rhythm symbol Body motion Symbol Memory bank Measurement time *Measurement Records* Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse pressure Pulse rate Irregular pulse rhythm symbol Body motion Symbol Memory bank Measurement date/time *Date and Time* Indicated at power off, measurement completion and memory recall *Power*

	See Power Supply Item 17 *Function* Blood pressure measurement Pulse rate measurement Pulse pressure calculation Irregular pulse rhythm symbol Body motion Symbol Memory function Error indication ***Algorithms*** Equivalent device has the identical measurement algorithm as the validated device.	See Power Supply Item 17 *Function* Blood pressure measurement Pulse rate measurement Pulse pressure calculation Irregular pulse rhythm symbol Body motion Symbol Memory function Error indication ***Algorithms*** Equivalent device has the identical measurement algorithm as the validated device.
Comparable Criteria	***Measurement range*** Pulse rate 40 bpm - 180 bpm ***Display/Symbols/Indicators*** SYS/mmHg, DIA/mmHg, PUL/1/min are printed on housing. ***Measurement Records*** Average of last 3 measurement ***Casing*** Buttons ***Power*** Automatic switch-off *when not used for 2min ***Cuff*** Cuff dimensions: 138 x 580mm	***Measurement range*** Pulse rate 40 bpm - 160 bpm ***Display/Symbols/Indicators*** SYS/mmHg, DIA/mmHg, PUL/1/min are digitally displayed on LCD. ***Measurement Records*** Average of all stored data ***Casing*** Touch Key switches ***Power*** Automatic switch-off *when not used for 3min ***Cuff*** Cuff dimensions: 135 x 580mm

Comments		
Recommendation	**RECOMMENDED**	
Date	**30th August 2017**	