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 Hideki Ura, (Name of a Company Director) a Director of JAPAN PRECISION INSTRUMENTS INC., (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-S10

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-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 ☐	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.

Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.
Form DET7 130102

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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 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-S10 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

16) Communication Facilities

DS-S10 has a function to transfer measurement data to a smartphone by Bluetooth connection.

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@dableducational.org.

Signature of Director Hideki Ura

Company Stamp/Seal

2508-13 Nakago,Shibukawa,Gunma-ken
JAPAN
PRECISION INSTRUMENTS INC.

Name Hideki Ura

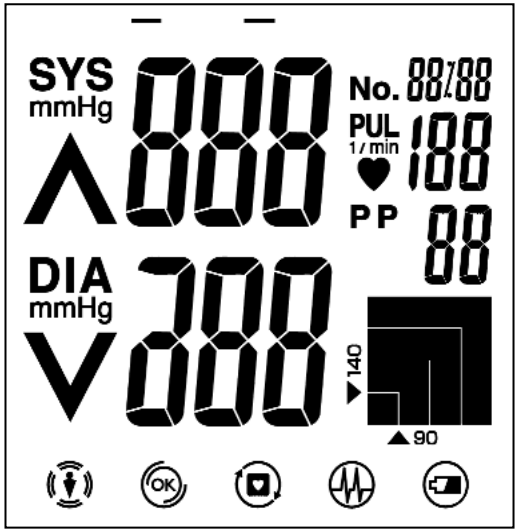
Date 20th Feb 2015

Signature of Witness T. Fukushima

Name Teruka Fukushima

Address 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

Comparison of the NISSEI DS-S10 with the NISSEI DSK-1031

Devices	*NISSEI DS-S10*	*NISSEI DSK-1031*
Pictures		
Display		
Validation		ESH 2010

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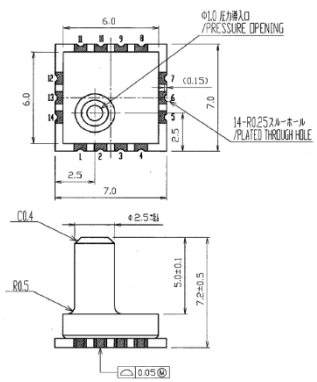
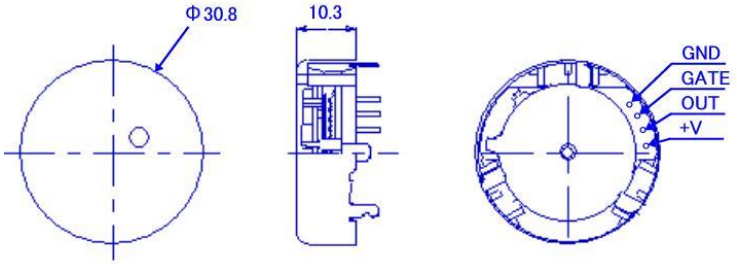
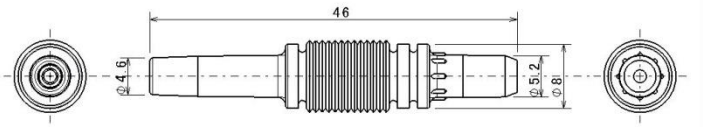
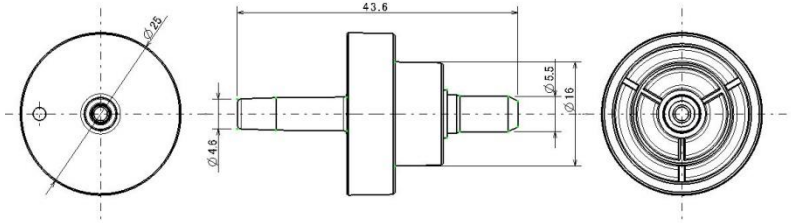
Device 1 Criteria		***Display/Symbols/Indicators*** WHO classification *WHO: World Health Organization Deflation symbol Unit SYS/mmHg, DIA/mmHg, PUL/1/min
Device 2 Criteria	***Display/Symbols/Indicators*** Morning Reading/Night Reading symbol Bluetooth symbol ID indicator ***Casing*** print Unit 最高血圧(SYS)/mmHg, 最低血圧(DIA)/mmHg, 拍／分(PUL)/1/min ***Communication facilities*** Bluetooth *To transfer data to Smartphone	
Same Criteria	***Measurement Accuracy*** Blood pressure accuracy ± 3 mmHg Pulse accuracy ± 5% ***Inflation*** Inflation 0 mmHg - 300 mmHg ***Measurement range*** Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg Pulse rate 40 bpm - 160 bpm ***Display/Symbols/Indicators*** 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	***Measurement Accuracy*** Blood pressure accuracy ± 3 mmHg Pulse accuracy ± 5% ***Inflation*** Inflation 0 mmHg - 300 mmHg ***Measurement range*** Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg Pulse rate 40 bpm - 160 bpm ***Display/Symbols/Indicators*** 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 ***Casing*** Air connector DC Jack ***Cuff*** Universal cuff (Arm circ. 22 to 42cm) ***Power*** Automatic switch-off *when not used for 3min Supply 4 ''AA" batteries AC adapter	Memory1/2 symbol Average *when review saved readings Measurement errors ***Casing*** Air connector DC Jack ***Cuff*** Universal cuff (Arm circ. 22 to 42 cm) ***Power*** Automatic switch-off *when not used for 3min Supply 4 ''AA" batteries AC adapter Measurement Accuracy
Comparable Criteria	***Measurement Records*** Average The average is for up to 3 readings within 15 minutes before the last measurement ***Memory Banks & Readings*** 60 measurement × 2 users 20 measurement × 5 users *for Bluetooth transfer ***Casing*** Button (7) On/Off With Start Memory 1/2 ID select Clock set/Bluetooth connection Morning Reading/Night Reading Up Down	***Measurement Records*** Average All measurement mean ***Memory Banks & Readings*** 60 measurement × 2 users ***Casing*** Button (4) On/Off With Start Memory 1 Memory 2 Clock set

Pressure Transducer	***Model*** MMR901XA Pressure range 0mmHg - 300 mmHg Safety over load 600 mmHg Resolution 0.05 mmHg Outline 	***Model*** CS-20A Pressure range 0mmHg - 300 mmHg Safety over load 390 mmHg Resolution 0.05 mmHg Outline 
Cuffs or Bladders	***Air Plug*** Outline 	***Air Plug*** Outline 

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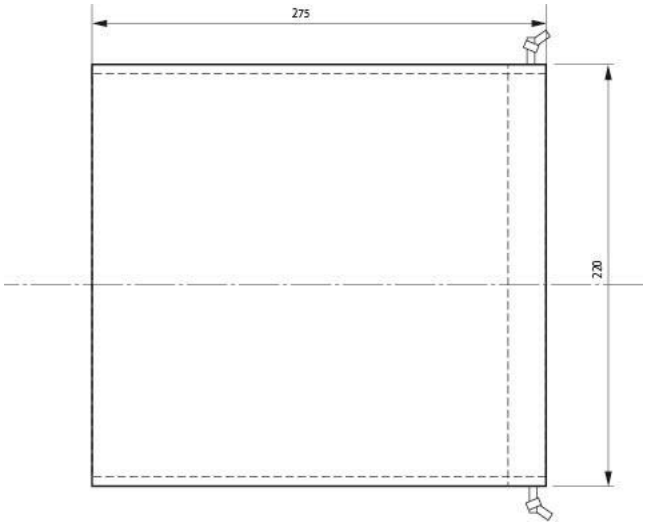
<td>Pouch
Material: Non-woven textile fabrics
Outline
 
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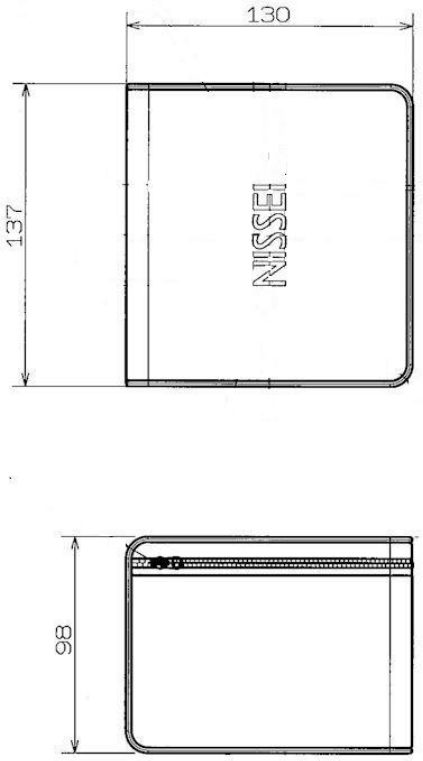
<td>Carrying Bag
Material: Nylon
Outline
 
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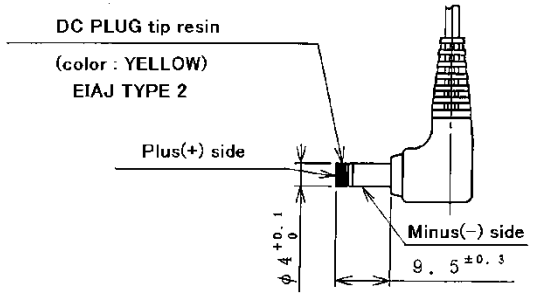
<td>Power Supply</td>
<td>DC PLUG
Outline
 
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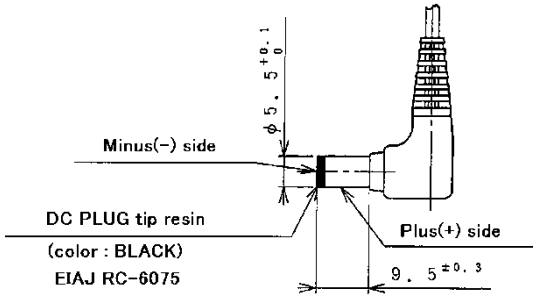
Outline
 
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Comments		Query	Please provide more information on the different air plug on DS-S10.
		Reply	Both of air plugs have the shape of straight. There is no difference of the air flow function. DSK-1031 has a flanged air plug so that the user can easily hold it to insert and remove. Further on it suits more to the design of DSK-1031 main unit. DS-S10 has our normal air plug and only the difference from DSK-1031 is the visual design.
		Comment	Accepted
Recommendation	**Recommended**		
Date	**4th March 2015**		