dabl®Educational Trust — Declaration of Equivalence Form

Declaration of Blood Pressure Measuring Device Equivalence 2011

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I Yasutomo Kimiura, (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

Manufacturer Nissei Brand Nissei Model DSK-1051

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the

Manufacturer Nissei Brand Nissei Model DSK-1031

Existing validated blood pressure measuring device. If alternative model names are used, include all.

blood pressure measuring device, which has previously passed the ESH-IP 2010 protocol, the results of which were published as follows:

de Greeff A, Shennan AH.
Authors(s)

Validation of the Nissei DSK-1031 upper arm oscillometric blood pressure monitor intended for clinic use and self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010 [Online]
Title

Available from URL: http://www.dableducational.org/pdfs/ESHIP_Online_Validations/11-003 Nissei DSK-1031.pdf
Publication

2011 Oct 28 [2012 Dec 18].
Year Volume Pages

The only differences between the devices involve the following components:

When a component is not relevant, both Yes and No should be left blank. It is necessary to provide details on each item ticked "Yes" in Section C or on a separate sheet.

Part I	1	Algorithm for Oscillometric Measurements	Yes ☐	No ☒
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☒
	3	Artefact/Error Detection	Yes ☐	No ☒
	4	Microphone(s)	Yes ☐	No ☒
	5	Pressure Transducer	Yes ☐	No ☒
	6	Cuff or Bladder	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 ☒
	16	Communication Facilities	Yes ☐	No ☒
	17	Power Supply	Yes ☐	No ☒
	18	Other Facilities	Yes ☐	No ☒

An explanation of each item ticked "Yes" must be included in *Section C* on the next page

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Form DET7 110110

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SECTION B 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 manuals and images for both devices to info@dableducational.org.

Signature of Director _____

Name Yasutomo Kimiura

Date 19.12.2012

Signature of Witness _____

Name

Address

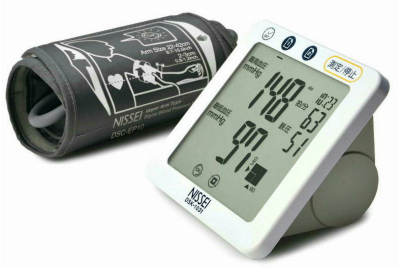
Company Stamp/Seal

Japan Precision Instruments Inc.
2508-13, Nakago, Shibukawa,
Gunma 377-0293, Japan

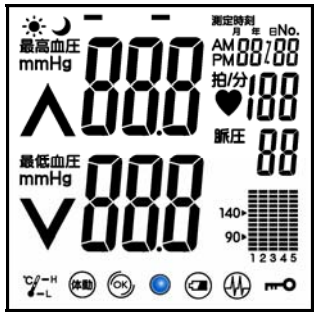
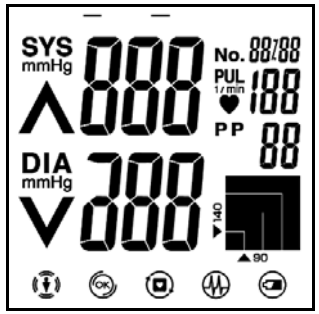
SECTION C An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

Please refer to a comparison table.

Comparison of the Nissei DSK-1051 with the Nissei DSK-1031

Devices	Nissei DSK-1051 (Device 1)	Nissei DSK-1031 (Device 2)
Pictures		
Validation	ESH 2010 Protocol	
Comparable Criteria		
Software Other Than Algorithm	For the following functions	
Display		
WHO Indication	Flashing LCD at SYS and DIA	Graphic LCD
Trend Display	○	X
Temperature H/L Symbol	○	X
Locking Key symbol	○	X
Reliability Symbol	LED Light Indication	LCD Symbol Indication
Memory function		
Morning/Evening Memory	○	X
Memory Banks & Readings	2 x 120	2 x 60
Memory Avarage Readings	Recent 3 times readings	All readings

Comparison of the Nissei DSK-1051 with the Nissei DSK-1031

Devices	Nissei DSK-1051	Nissei DSK-1031
Pictures		
Display		
Validation		ESH-IP 2010
Device 1 Criteria	***Display/Symbols/Indicators*** *Measurement Procedure* Pulse level indicator 11, 13 *Post Measurement* Morning/Evening mean 11, 13 Ambient Temperature outside accuracy limits warming 11, 13 Last 5 measurements trend 11, 13 *Date and Time* Alarm reminder (one per memory zone) 18 *Features* Key Lock 11, 18 ***Algorithms*** *Averages and Differences* Last 3 measurements taken over 15 min memory zone mean 13 Last 3 morning meas. taken over 15 min memory zone mean 13	

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Devices	Nissei DSK-1051		Nissei DSK-1031	
Device 1 Criteria (continued)	***Algorithms (continued)***			
	Averages and Differences (continued)			
	Last 3 evening meas. taken over 15 min memory zone mean	13		
Same Criteria	***Measurement***		***Measurement***	
	Accuracy		*Accuracy*	
	BP accuracy ± 3 mmHg	1, 5	BP accuracy ± 3 mmHg	1, 5
	Pulse accuracy ± 5%	1, 5	Pulse accuracy ± 5%	1, 5
	Method		*Method*	
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	SBP 50 mmHg – 250 mmHg, DBP 40 mmHg – 180 mmHg	1, 5, 7, 8	SBP 50 mmHg – 250 mmHg, DBP 40 mmHg – 180 mmHg	1, 5, 7, 8
	Pulse 40 bpm – 160 bpm	1, 5, 8	Pulse 40 bpm – 160 bpm	1, 5, 8
	Manually initiated measurements	13	Manually initiated measurements	13
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Automatic repeat on movement error	13	Automatic repeat on movement error	13
	Inflation		*Inflation*	
	Inflation 3 mmHg – 300 mmHg	1, 5, 7	Inflation 3 mmHg – 300 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Fuzzy Logic	7	Fuzzy Logic	7
	Zero pressure check before inflation	7	Zero pressure check before inflation	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Automatic safety release valve	8	Automatic safety release valve	8
	Cuffs		*Cuffs*	
	Single Cuff: Arm circumference 22 cm – 42 cm (DSC-EP10)[Query 2]	6	Single Cuff: Arm circumference 22 cm – 42 cm (DSC-EP10)	6
	Buttons/Switches		***Buttons/Switches***	
	Measurement Records		*Measurement Records*	
	Memory/Zone × 2	10	Memory/Zone × 2	10
	Settings		*Settings*	
	Set	10	Set	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Beeps before measurement	18	Beeps before measurement	18
	Inflation symbol	11	Inflation symbol	11
	Deflation symbol	11	Deflation symbol	11
	Audible pulse indicator during deflation	18	Audible pulse indicator during deflation	18
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11

Devices	Nissei DSK-1051		Nissei DSK-1031	
Same Criteria (continued)	***Display/Symbols/Indicators (continued)***		***Display/Symbols/Indicators (continued)***	
	Measurement Procedure (continied)		*Measurement Procedure*	
	Beeps after measurement	18	Beeps after measurement	18
	Correct cuff wrapping indicator (OK symbol)	11, 13, 18	Correct cuff wrapping indicator (OK symbol)	11, 13, 18
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	PP	11	PP	11
	Measurement error Err 300, Err 1, Err 2, Err 3	11	Measurement error Err 300, Err 1, Err 2, Err 3	11
	BP classification (WHO)	10, 11, 13	BP classification (WHO)	10, 11, 13
	Average A	11, 13, 14	Average A	11, 13, 14
	Body movement error (体動 symbol)	3, 11, 13, 18	Body movement error (Leftmost symbol)	3, 11, 13, 18
	Irregular heartbeat	11, 13, 18	Irregular heartbeat	11, 13, 18
	Date and Time		*Date and Time*	
	Date and Time	11	Date and Time	11
	Date and Time (During memory recall)	11	Date and Time (During memory recall)	11
	Measurement Records		*Measurement Records*	
	Memory, number of stored measurements	11	Memory, number of stored measurements	11
	Memory recall number	11	Memory recall number	11
	Memory zone	11	Memory zone	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		***Algorithms***	
	Diagnostic		*Diagnostic*	
	WHO Guidelines	13	WHO Guidelines	13
	Irregular heartbeat detection	13	Irregular heartbeat detection	13
	Body movement error detection	3, 13	Body movement error detection	3, 13
	Measurement Reliability	13	Measurement Reliability	13
	Parameter Settings		*Parameter Settings*	
	Correct cuff wrapping detection	13	Correct cuff wrapping detection	13
	Casing		***Case***	
	Display		*Display*	
	Single screen Segment LCD display	10	Single screen Segment LCD display	10
	Power		*Power*	
	4 “AA” batteries	17	4 “AA” batteries	17
	AC adapter	17	AC adapter (Optional)	17
	Automatic switch-off when not used for 3 min	17	Automatic switch-off when not used for 3 min	17

Devices	Nissei DSK-1051	Nissei DSK-1031
Comparable Criteria	***Measurement*** *Measurement Records* Memory: 120 measurements × 2 zones 14 ***Buttons/Switches*** *Power* On/Off with Start/Stop and Key Lock/Unlock (Start/Stop Label) 10 ***Display/Symbols/Indicators*** *Post Measurement* Hypertension (Flashing SBP and DBP) 11, 13 Measurement Reliability (LED) 13	***Measurement*** *Measurement Records* Memory: 60 measurements × 2 zones 14 ***Buttons/Switches*** *Power* On/Off with Start/Stop (Start/Stop Label) 10 ***Display/Symbols/Indicators*** *Post Measurement* Hypertension (Indicator squares) 11, 13 Measurement Reliability (Centre symbol) 13
Device 2 Criteria		***Algorithms*** *Averages and Differences* Memory zone mean 13

Comments	1	The DSK-1051 is designed for the Japanese market. Blood pressure detection is identical to that of the DSK-1031 but it provides more post-measurement analysis as described above. During measurement, the grid, on the right, shows the pulse level. After measurement, it shows a plot of the BP level along with that of the previous four measurements. Translation of Japanese symbols (top down): 測定時刻: Measurement time. 月: Month. 年: Year. 日: Day. 最高血圧: Systolic blood pressure. 拍/分: Beats/minute. 脈圧: Pulse pressure. 最低血圧: Diastolic blood pressure. 体動: Body motion.
	2	Query Is the DSC-EP10 cuff, used with the DSK-1031, also used with the DSK-1051? Response Yes, the cuff using for DSK-1031 and DSK-1051 is same. (DSC-EP10 cuff). Comment The confirmation is accepted.
	3	Query The manuals do not provide views of the full screen layouts. Please provide complete display screens for both devices. Response Images were provided as shown.
Recommendation	Equivalence is recommended	
Date	07/01/2013	