

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,** 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

Manufacturer **Nissei** Brand **Nissei** Model **WSK-1021**

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 **WSK-1011**

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 WSK-1011 wrist blood pressure monitor, for self measurement, according to the European Society of Hypertension International Protocol revision 2010 [Online]

Title

Available from URL: <http://www.dableducational.org/pdfs/FTS/FT1103> 2011 Sep 09 [2012 Dec 18].

Nissei WSK-1011.pdf

Publication

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <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 checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	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 type="checkbox"/>	No <input checked="" type="checkbox"/>
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" 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 checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <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"/>

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

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@dablededucational.org.

Signature of Director 

Name Yasutomo Kimiura

Date 19.12.2012

Company Stamp/Seal
Japan Precision Instruments Inc.
2508-13, Nakago, Shibukawa,
Gunma 377-0293, Japan

Signature of Witness _____



Name

Address





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 WSK-1021 with the Nissei WSK-1011

Devices	Nissei WSK-1021 (Device 1)	Nissei WSK-1011 (Device 2)
Pictures		
Validation	ESH 2010 Protocol	
Comparable Criteria	For the following functions	
Software Others Than Algorithm	For the following functions	
Display		
Temprature H/L Symbol	○	X
Locking Key Symbol	○	X
Reliability Ssymbol	○	X
Memory		
Morning/Evening Memory	○	X
Memory Banks & Readings	2 x 120	2 x 60
Memory Average Readings	Recent 3 times readings	All readings

Comparison of the Nissei WSK-1021 with the Nissei WSK-1011

Devices	Nissei WSK-1021	Nissei WSK-1011
Pictures		
Display		
Validation		ESH-IP 2010
Device 1 Criteria	<p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>Morning/Evening mean 11, 13</p> <p>Ambient Temperature outside accuracy limits warming 11, 13</p> <p>Measurement Reliability (Blue LED) 13</p> <p><i>Date and Time</i></p> <p>Alarm reminder (one per memory zone) 18</p> <p><i>Features</i></p> <p>Key Lock 11, 18</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements taken over 15 min memory zone mean 13</p> <p>Last 3 morning meas. taken over 15 min memory zone mean 13</p> <p>Last 3 evening meas. taken over 15 min memory zone mean 13</p>	

Devices	Nissei WSK-1021	Nissei WSK-1011
Same Criteria	Measurement	Measurement
	<i>Accuracy</i>	<i>Accuracy</i>
	BP accuracy ± 3 mmHg 1, 5	BP accuracy ± 3 mmHg 1, 5
	Pulse accuracy ± 5% 1, 5	Pulse accuracy ± 5% 1, 5
	<i>Method</i>	<i>Method</i>
	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
	<i>Inflation</i>	<i>Inflation</i>
	Inflation 0 mmHg – 300 mmHg 1, 5, 7	Inflation 0 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
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation 8	Automatic Deflation 8
	Automatic safety release valve 8	Automatic safety release valve 8
	<i>Cuffs</i>	<i>Cuffs</i>
	Wrist circ. 12.5 cm – 22.5 cm 6	Wrist circ. 12.5 cm – 22.5 cm 6
	Buttons/Switches	Buttons/Switches
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory/Zone × 2 10	Memory/Zone × 2 10
	<i>Settings</i>	<i>Settings</i>
	Set 10	Set 10
	Display/Symbols/Indicators	Display/Symbols/Indicators
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	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
Beeps after measurement 18	Beeps after measurement 18	
<i>Date and Time</i>	<i>Date and Time</i>	
Date and Time 11	Date and Time 11	
Date and Time (During memory recall) 11	Date and Time (During memory recall) 11	

Devices	Nissei WSK-1021	Nissei WSK-1011		
Same Criteria (continued)	Display/Symbols/Indicators (continued)			
	<i>Post Measurement</i>			
	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 \bar{A}	11, 13, 14	Average \bar{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
	<i>Measurement Records</i>		<i>Measurement Records</i>	
	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
	<i>Power</i>		<i>Power</i>	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		Algorithms	
	<i>Diagnostic</i>		<i>Diagnostic</i>	
	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
	Casing		Case	
	<i>Display</i>		<i>Display</i>	
	Single screen display	10	Single screen display	10
Segment LCD	10	Segment LCD	10	
<i>Power</i>		<i>Power</i>		
2 "AAA" batteries	17	2 "AAA" batteries	17	
Automatic switch-off when not used for 3 min	17	Automatic switch-off when not used for 3 min	17	
Comparable Criteria	Measurement		Measurement	
	<i>Measurement Records</i>		<i>Measurement Records</i>	
	Memory: 120 measurements × 2 zones	14	Memory: 60 measurements × 2 zones	14
Buttons/Switches		Buttons/Switches		
<i>Power</i>		<i>Power</i>		
On/Off with Start/Stop and Key Lock/Unlock (Start/Stop Label)	10	On/Off with Start/Stop (Start/Stop Label)	10	

Devices	Nissei WSK-1021	Nissei WSK-1011
Comparable Criteria (continued)	Display/Symbols/Indicators <i>Post Measurement</i> Hypertension (Flashing SBP and DBP) 11, 13 Normotension (Steady SBP and DBP) 11, 13	Display/Symbols/Indicators <i>Post Measurement</i> Hypertension (Indicator squares) 11, 13 Normotension 11, 13
	Device 2 Criteria	Algorithms <i>Averages and Differences</i> Memory zone mean 13

Comments	1	The WSK-1021 is designed for the Japanese market. Blood pressure detection is identical to that of the WSK-1011 but it provides more post-measurement analysis as described above. Translation of Japanese symbols (top down): 測定時刻: Measurement time. 最高血压: Systolic blood pressure. 月: Month. 年: Year. 日: Day. 拍/分: Beats/minute. 最低血压: Diastolic blood pressure. 脈圧: Pulse pressure. 体動: Body motion.
	2	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	02/01/2013	