dabl® Educational Trust

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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

SECTION A - Please complete all items online.

I John Hutchings (Name of a Company Director) Director of Nissei Healthcare (UK) Ltd (Company name)

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Nissei model DS-500
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Nissei model DS-400
Existing validated blood pressure measuring device

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

Kate E Duhig Annemarie De Greeff Andrew Van Der Westhuizen Elinor Baker and Andrew H. Shennan
Authors(s)

Validation of the Nissei DS-400 in a low-resource setting
Title

Blood Pressure Monitoring (Publication) 2009 Vol. 14 No.3 Pages 132 to 135 (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. Please provide details on any differences below.)

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 ☐

Brief explanations of differences and further relevant details: Only differences are automatic inflation for the DS-500 and manual inflation for the DS-400. The casings and displays are of different sizes

SECTION B - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director _____ Company Stamp/Seal

Name John Hutchings

Nissei Healthcare (UK) Ltd
Rede House, New Barn Lane,
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Date 27.01.2010

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Signature of Witness _____

Name Robert Moore

Address 54 Parsonage Road, Henfield, West Sussex. BN5 9FG

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Comparison of the Nissei DS-500 with the Nissei DS-400

Devices	Nissei DS-500	Nissei DS-400
Pictures		
Validation		ESH
Device 1 Criteria	***Display/Symbols/Indicators*** *Post Measurement* Irregular heartbeat 11, 13 *Measurement Records* Memory zone 11 *Date and Time* Date and Time 11 ***Algorithms*** *Diagnostic* Atrial fibrillation detection 13 ***Case*** *Power* AC adapter (Optional) 17	
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5 Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg - 300 mmHg 1, 5, 7 *Deflation* Automatic Deflation 8	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5 Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg - 300 mmHg 1, 5, 7 *Deflation* Automatic Deflation 8

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Devices	Nissei DS-500		Nissei DS-400	
Same Criteria	*Cuffs*		*Cuffs*	
	Medium cuff (Arm circ. 22 to 32 cm)	6	Medium cuff (Arm circ. 22 to 32 cm)	6
	Large cuff (Arm circ. 32-43 cm) (Optional) *(Info. on website)*	6	Large cuff (Arm circ. 32-43 cm) (Optional) *(Info. on website)*	6
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Inflation symbol	11	Inflation symbol	11
	Deflation symbol	11	Deflation symbol	11
	Heartbeat symbol during deflation	11	Heartbeat symbol during deflation	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Average	11, 13	Average	11, 13
	Measurement Records		*Measurement Records*	
	Memory recall number	11	Memory recall number	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Power		*Power*	
	Automatic switch-off when not used for 3 min	17	Automatic switch-off when not used for 3 min	17
Comparable Criteria	***Measurement***		***Measurement***	
	Method		*Method*	
	SBP 50 mmHg - 259 mmHg, DBP 40 mmHg -140 mmHg	1, 5, 7, 8	SBP 50 mmHg - 259 mmHg, DBP 40 mmHg -180 mmHg	1, 5, 7, 8
	Inflation		*Inflation*	
	Automatic Inflation	7	Manual (bulb) Inflation	7
	Manually (electronic) controllable inflation pressure	7		
	Measurement Records		*Measurement Records*	
	Memory: 30 measurements × 2 users	14	Memory: 30 measurements	14
	Buttons/Switches		***Buttons/Switches***	
	On/Off with Start/Stop	10	On/Off	10
	Memory × 2	10	Memory	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Post Measurement		*Post Measurement*	
	Measurement error(Err -1, Err -2, Err -3, Err 300, 0 0)	11	Measurement error (Err, Err 330, 0 0)	11
	Algorithms		***Algorithms***	
	Averages		*Averages*	
	Memory zone mean	13	All measurements mean	13

Devices	Nissei DS-500	Nissei DS-400
	Case *Power* 4 "AA" batteries 17	***Case*** *Power* 1 "AA" battery 17
Device 2 Criteria		***Display/Symbols/Indicators*** *Measurement Procedure* Audible pulse indicator during deflation 18 Beeps after measurement 18
Web link	http://www.nissei-jp.com/html/seihin-medical-e.html	http://www.nissei-jp.com/html/seihin-medical-e.html

Comments	Queries: 1. The DBP range for the DS-500 (40-140 mmHg) is less than that of the DS-400 (40-180 mmHg). This change could be due to hardware or software changes. Please explain. A *The difference in DBP range is neither hardware or software but merely production specification of the DS-500 but the device will actually record DBP up to 180 mmHg.* 2. Some of the errors are different for both devices. The DS-400 has a measurement error Err whereas the DS-500 has three errors, a measurement error Err-1, an inflation error Err-2 and a deflation error Err-3 though the causes and remedies of Err-1 and Err-3 are identical. The causes of a DS-400 measurement error appear to encompass those of these three DS-500 errors plus an error due to insufficient inflation. Please explain. A *Yes, The error messages of the DS-400 encompass those three of the DS-500, plus an additional message for insufficient inflation. This is because with the automatic inflation of the DS-500 if there is insufficient inflation the monitor automatically recognises this and re-inflates to a further 30 mmHg but no error is recorded. Whereas with the DS-400 if there is insufficient inflation it is necessary for the User to re-inflate manually to a higher value, so this requirement is indicated by an error message.* 3. What is the minimum pressure that the cuff needs to be inflated above SBP for the value of SBP to be accepted? In the DS-400, insufficient inflation is included as one reason for the measurement error Err. In the DS-500, there is an inflation error, Err-2, but insufficient inflation is not listed as a possible cause. A *Between 20 to 30 mmHg above SBP for the value to be accepted. Insufficient inflation with the DS-400 is an error indication because the User must re-inflate manually. With the DS-500 re-inflation to a higher level is automatic so no error need be indicated.* *I hope that this explains the differences in the User Manuals of the two products which do not in any way effect the resultant BP values, since both devices use the same algorithm and measure during automatic deflation.*
Recommendation	The DS-400 recommendation is "The Nissei DS-400 can be recommended for use in the adult population, particularly in the developing world. Its impressive performance may be related to theoretical factors within the patient population and environment (e.g. temperature, humidity and altitude) that could influence the device's performance."[1] The DS-500 can be recommended as equivalent under the same conditions. 1 Duhig KE, de Greeff A, van der Westhuizen A, Baker E, Shennan AH. Validation of the Nissei DS-400 in a low-resource setting. Blood Press Monit 2009;14:132-135
Date	08/03/2010