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 Stefano Chiesa, (Name of a Company Director) a Director of CA-MI SRL, (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]	CA-MI Srl	*Address*	Via Ugo La Malfa 13 - 43010 Pilastro (PR) - Italy
Brand[c]	CHIESI FARMACEUTICI SPA	Model[d]	CHIESI 0100000329 (DIESIS)

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:

Dublin:dablEducationalTrust;2011-Sep-01.-9p.

Available from: http://www.dableducational.org/Publications/2011/ESH-IP 2010 Validation of Nissei DSK-1011.pdf.

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.

Brief 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.

9) Model name

The model names are different. CHIESI 0100000329 (DIESIS) for new device, for validated device is DSK-1011. On the validated device DSK-1011, the name was printed on front panel of device too, instead in the new model the name is printed on the rating label that is applied on the bottom (in compliance with commitments of CE certification).

10) Casing

Tact switch of one START/STOP key and one memory key on new model, instead of touch type keys with one clock key, two memory keys, and one START/STOP key for the validated device. Shape of new device is different but with very similar volume.

11)Display

The size and displayed data are different due to the different function except measurement function.

13) Software other than Algorithm

On new model no function of cuff condition indicator and no function of pulse pressure display.

14) Memory Capacity/Number of stored measurements

On the new model the memory capacity is 60 times x 1 way instead of 60 times x 2 ways of derivated device

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 Stefano Chiesa

Date 07/09/2015

Signature of Witness _____

Name Mario Attolini

Address Via Ugo La Malfa 13 - 43010 Pilastro (PR) - Italy

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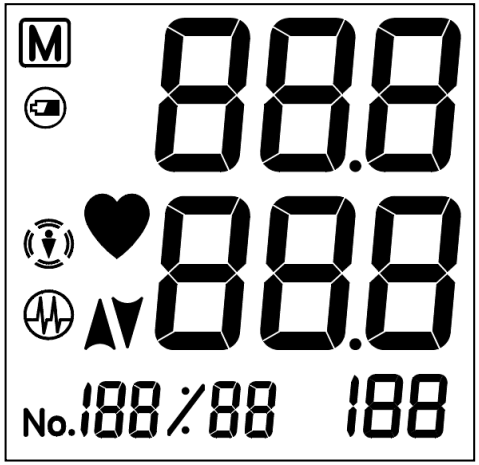
Fax +39 0521 639041

Comparison of the *CHIESI 0100000329(DIESIS)* with the NISSEI DSK-1011

Devices	*CHIESI 0100000329 (DIESIS) (Device 2)*	*NISSEI DSK-1011 (Device1)*
Pictures		
Display		
Validation		ESH 2010

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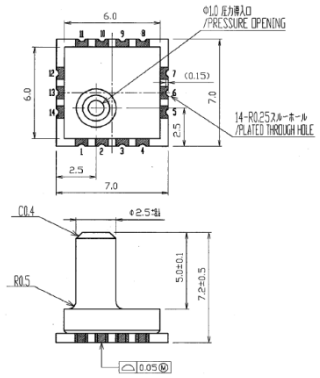
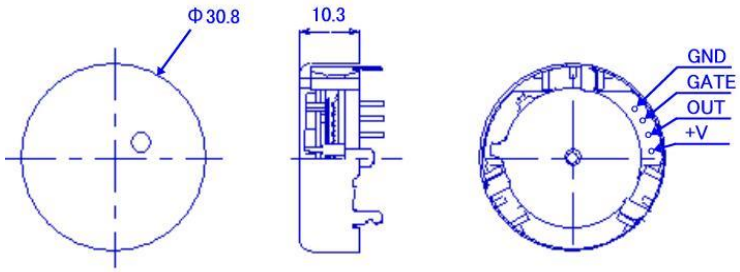
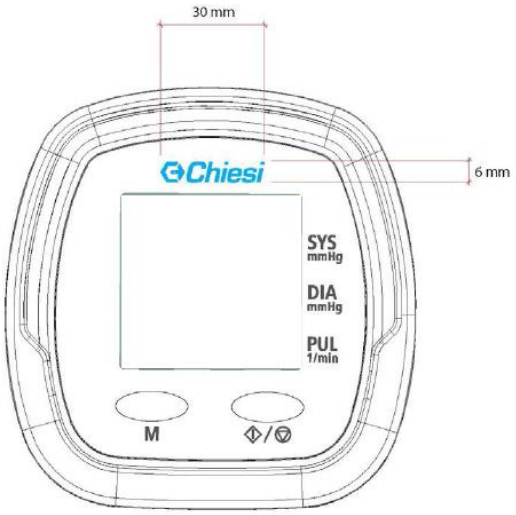
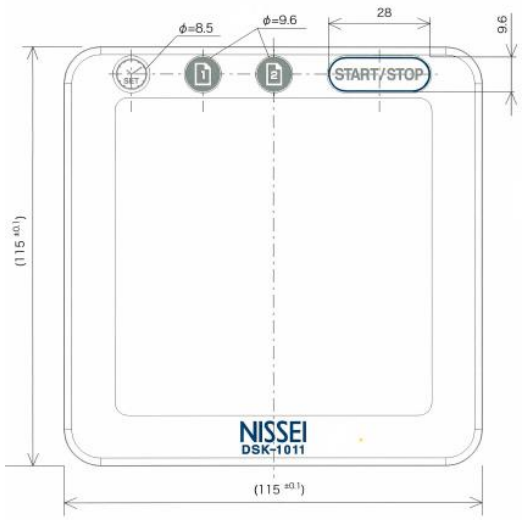
Device 1 Criteria		***Display/Symbols/Indicators*** *Measurement Procedure* WHO classification Pulse pressure
Device 2 Criteria		
Same Criteria	***Measurement*** *Accuracy* Blood pressure accuracy ± 3 mmHg Pulse accuracy ± 5% *Method* Oscillo-Metric Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg *Inflation* Automatic Inflation System (Air Pump) Inflation 0 mmHg - 300 mmHg *Deflation* Automatic speed deflation system *Cuffs* Universal cuff(Arm circ. 22 to 42cm) *Measurements other than Blood Pressure* Pulse rate ***Buttons/Switches*** *Power* On/Off With Start ***Display/Symbols/Indicators*** *Measurement Procedure* Inflation symbol Deflation symbol Heartbeat symbol during inflation Irregular pulse rhythm symbol Body motion Symbol *Post Measurement* Systolic blood pressure	***Measurement*** *Accuracy* Blood pressure accuracy ± 3 mmHg Pulse accuracy ± 5% *Method* Oscillo-Metric Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg *Inflation* Automatic Inflation System (Air Pump) Inflation 0 mmHg - 300 mmHg *Deflation* Automatic speed deflation system *Cuffs* Universal cuff(Arm circ. 22 to 42cm) *Measurements other than Blood Pressure* Pulse rate ***Buttons/Switches*** *Power* On/Off With Start ***Display/Symbols/Indicators*** *Measurement Procedure* Inflation symbol Deflation symbol Heartbeat symbol during inflation Irregular pulse rhythm symbol Body motion Symbol *Post Measurement* Systolic blood pressure

	Diastolic blood pressure Pulse rate Average *Measurement Records* Memory recall number *Date and Time* Date and Time *Power* Low Battery detection symbol *Function* Measurement errors *Features* WHO classification *WHO: World Health Organization ***Casing*** *Display* Segment LCD Single screen display *Ports* Air connector DC Jack *AC adapter is optional *Power* 4 ''AA" batteries	Diastolic blood pressure Pulse rate Average *Measurement Records* Memory recall number *Date and Time* Date and Time *Power* Low Battery detection symbol *Function* Measurement errors *Features* WHO classification *WHO: World Health Organization ***Casing*** *Display* Segment LCD Single screen display *Ports* Air connector DC Jack *AC adapter is optional *Power* 4 ''AA" batteries
Comparable Criteria	***Measurement*** *Method* Pulse rate 40 bpm - 180 bpm *Sensors* MMR901XA *Measurement Records* 60 measurement × 1 user	***Measurement*** *Method* Pulse rate 40 bpm - 160 bpm *Sensors* CS-20A *Measurement Records* 60 measurement × 2 users

	Buttons/Switches *Measurement Records* Memory × 1 ***Display/Symbols/Indicators*** *Function* Memory symbol ***Algorithms*** *Averages and Differences* Last 3 measurements	***Buttons/Switches*** *Measurement Records* Memory × 2, Clock set ***Display/Symbols/Indicators*** *Function* Memory1/2 symbol ***Algorithms*** *Averages and Differences* All measurement mean
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 

Casing	Outline 	Outline 

Comments		Replies to queries; Accepted
Recommendation	***Equivalence Recommended***	
Date	7 October 2015	