**DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013**

**SECTION A** - Please complete all items.

<table>
<thead>
<tr>
<th>1</th>
<th>Hideki Ura,</th>
<th>a Director of JAPAN PRECISION INSTRUMENTS INC.,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of a Company Director</td>
<td>Company name</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Maker</th>
<th>Nissei</th>
<th>Address</th>
<th>2508-13 Nakago Shibukawa Gunma 377-0293 Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Nissei</td>
<td>Address</td>
<td>2508-13 Nakago Shibukawa Gunma 377-0293 Japan</td>
</tr>
<tr>
<td>Brand</td>
<td>Nissei</td>
<td>Model</td>
<td>DS-S10</td>
</tr>
</tbody>
</table>

blood pressure measuring device and the validated blood pressure measuring device

<table>
<thead>
<tr>
<th>Maker</th>
<th>Nissei</th>
<th>Address</th>
<th>2508-13 Nakago Shibukawa Gunma 377-0293 Japan</th>
</tr>
</thead>
<tbody>
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<td>Nissei</td>
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<td>2508-13 Nakago Shibukawa Gunma 377-0293 Japan</td>
</tr>
<tr>
<td>Brand</td>
<td>Nissei</td>
<td>Model</td>
<td>DSK-1031</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Part I</th>
<th>1 Algorithm for Oscillometric Measurements</th>
<th>Yes ☑</th>
<th>No ☐</th>
<th>N/A* ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Algorithm for Auscultatory Measurements</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A* ☐</td>
</tr>
<tr>
<td>3</td>
<td>Artefact/Error Detection</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Microphone(s)</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Pressure Transducer</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Cuffs or Bladders</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Inflation Mechanism</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Deflation Mechanism</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part II</th>
<th>9 Model Name or Number</th>
<th>Yes ☑</th>
<th>No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Casing</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>11</td>
<td>Display</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>12</td>
<td>Carrying/Mounting Facilities</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>13</td>
<td>Software other than Algorithm</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>14</td>
<td>Memory Capacity/Number of stored measurements</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>15</td>
<td>Printing Facilities</td>
<td>Yes ☐</td>
<td>No ☐</td>
</tr>
<tr>
<td>16</td>
<td>Communication Facilities</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>17</td>
<td>Power Supply</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>18</td>
<td>Other Facilities</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
</tbody>
</table>

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.
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

Name: Hideki Ura
Date: 20th Feb 2015

Signature of Witness

Name: Teruka Fukushima
Address: 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

Company Stamp/Seal

2508-13 Nakago, Shibukawa, Gunma-ken
JAPAN
PRECISION INSTRUMENTS INC.
## Comparison of the NISSEI DS-S10 with the NISSEI DSK-1031

<table>
<thead>
<tr>
<th>Devices</th>
<th>NISSEI DS-S10</th>
<th>NISSEI DSK-1031</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pictures</strong></td>
<td><img src="image1" alt="NISSEI DS-S10 Picture" /></td>
<td><img src="image2" alt="NISSEI DSK-1031 Picture" /></td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td><img src="image3" alt="NISSEI DS-S10 Display" /></td>
<td><img src="image4" alt="NISSEI DSK-1031 Display" /></td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>ESH 2010</td>
<td></td>
</tr>
<tr>
<td>Device 1 Criteria</td>
<td>Device 2 Criteria</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------</td>
<td></td>
</tr>
</tbody>
</table>
| **Display/Symbols/Indicators** | WHO classification  *WHO: World Health Organization  
Deflation symbol  
Unit SYS/mmHg, DIA/mmHg, PUL/1/min |
| **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  
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Measurement Result  
Systolic blood pressure (SYS)  
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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 |
<table>
<thead>
<tr>
<th>Memory1/2 symbol</th>
<th>Memory1/2 symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>Average</td>
</tr>
<tr>
<td>*when review saved readings</td>
<td>*when review saved readings</td>
</tr>
<tr>
<td>Measurement errors</td>
<td>Measurement errors</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Comparable Criteria</th>
<th>Measurement Records</th>
<th>Measurement Records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average</td>
<td>Average</td>
</tr>
<tr>
<td></td>
<td>The average is for up to 3 readings within 15 minutes before the last measurement</td>
<td>All measurement mean</td>
</tr>
</tbody>
</table>

**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

**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**
### Pressure Transducer
**Model**
MMR901XA
- Pressure range: 0mmHg - 300 mmHg
- Safety overload: 600 mmHg
- Resolution: 0.05 mmHg

**Model**
CS-20A
- Pressure range: 0mmHg - 300 mmHg
- Safety overload: 390 mmHg
- Resolution: 0.05 mmHg

### Cuffs or Bladders
**Air Plug**

**Air Plug**

---

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Page 4 of 6
**Carring /Mounting Facilities**

<table>
<thead>
<tr>
<th>Pouch</th>
<th>Carrying Bag</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material: Non-woven textile fabrics</td>
<td>Material: Nylon</td>
</tr>
<tr>
<td>Outline</td>
<td>Outline</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Power Supply</th>
<th>DC PLUG</th>
<th>DC PLUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outline</td>
<td>Outline</td>
<td>Outline</td>
</tr>
<tr>
<td>DC PLUG tip resin</td>
<td>DC PLUG tip resin</td>
<td>DC PLUG tip resin</td>
</tr>
<tr>
<td>(color: YELLOW)</td>
<td>(color: BLACK)</td>
<td>(color: BLACK)</td>
</tr>
<tr>
<td>EIAJ TYPE 2</td>
<td>EIAJ RC-007/5</td>
<td>EIAJ RC-007/5</td>
</tr>
<tr>
<td>Plus(+) side</td>
<td>Plus(+) side</td>
<td>Plus(+) side</td>
</tr>
<tr>
<td>Minus(-) side</td>
<td>Minus(-) side</td>
<td>Minus(-) side</td>
</tr>
<tr>
<td>Comments</td>
<td>Query</td>
<td>Please provide more information on the different air plug on DS-S10.</td>
</tr>
<tr>
<td>----------</td>
<td>-------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Reply</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Comment</td>
<td>Accepted</td>
</tr>
<tr>
<td>Recommendation</td>
<td>Recommended</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>4th March 2015</td>
<td></td>
</tr>
</tbody>
</table>