

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, **Natallie,**
Name of European Director

a Director of **K-jump Health Co., Ltd,**
Company Name

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

Manufacturer **K-jump Health Co., Ltd** Brand **POLYGREEN** Model **KP-7770**
Manufacturer brand name device for which validation is claimed. If alternative model names are used, include all

blood pressure measuring device and the

Manufacturer **K-jump Health Co., Ltd** Brand **Spengler** Model **KP7500 D**
Existing reference brand name device which is published in a peer-reviewed journal or other published source

blood pressure measuring device, which has previously passed the ESH 2002 protocol, the results of which were published as follows:

Jalil Belghazi, Ramzi N El Feghali, Thérèse Moussalem, Maya Rejdych, Roland G Asmar
Reference

Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension

Vascular Health and Risk Management
Publication

2007:3(4) 389-400.

Year Volume Pages

The only differences between the devices involve the following components:

When comparing 'Yes' and 'No' responses, both 'Yes' and 'No' should be left blank. It is necessary to provide additional information if 'Yes' or 'No' is ticked. Tick 'Yes' or 'No' in 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 type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input 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 type="checkbox"/>	No <input checked="" type="checkbox"/>
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input 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 type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input 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@dableducational.org.

Signature of Director

K-JUMP HEALTH CO. LTD.

Company Stamp/Seal

Name

Natallie Kuo

Date

June 23, 2011

Signature of Witness



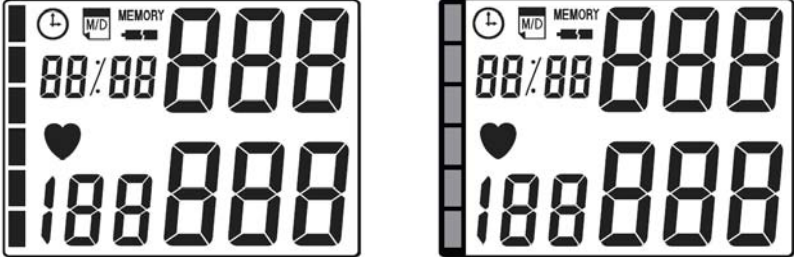
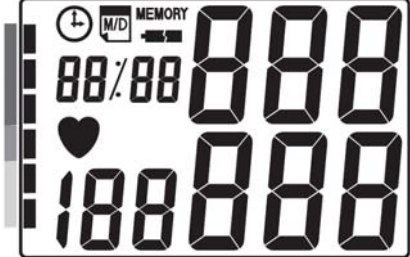
Name

Kimmy Wang

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.

- 9) Model Number: Different model number indicates different appearance design
- 10) Casing: In addition to different casing designs, KP7500D has two buttons and KP-7770 has three buttons.
- 11) Display: KP-7770 has same LCD display icons with KP7500 D but larger in dimension. Also, KP-7770 have two types of display, one is without backlight while another is with backlight.
- 13) Software other than algorithm: The display method of colored WHO indicator is different from the one without backlight.
- 14) KP7500 D has memory storage for single user and KP-7770 has separate memory storage for multi-user.

Comparison of the Polygreen K-Jump KP-7770 with the Spengler K-Jump KP7500 D

Devices	Polygreen K-Jump KP-7770	Spengler K-Jump KP7500 D
Pictures	<p style="text-align: center;"><i>No Backlight</i> <i>Backlight</i></p> 	
Display		
Validation		ESH 2002
Device 1 Criteria	<p>Buttons/Switches</p> <ul style="list-style-type: none"> Measurement Records User ID 10 <p>Display/Symbols/Indicators</p> <ul style="list-style-type: none"> Preparation Target (User) selection 11 Measurement Records User 11 <p>Casing</p> <ul style="list-style-type: none"> Display Backlight version available 	
Same Criteria	<p>Measurement</p> <ul style="list-style-type: none"> Accuracy BP accuracy ± 3 mmHg 1, 5 Pulse accuracy $\pm 5\%$ 1, 5 	<p>Measurement</p> <ul style="list-style-type: none"> Accuracy BP accuracy ± 3 mmHg or $\pm 2\%$ 1, 5 Pulse accuracy $\pm 5\%$ 1, 5

Devices	Polygreen K-Jump KP-7770	Spengler K-Jump KP7500 D
Same Criteria (continued)	Measurement (continued)	Measurement (continued)
	<i>Method</i>	<i>Method</i>
	Oscillometric measurement method	Oscillometric measurement method
	BP 20 mmHg - 300 mmHg	BP 20 mmHg - 300 mmHg
	Pulse 40 bpm -200 bpm	Pulse 40 bpm -200 bpm
	Manually initiated measurements	Manually initiated measurements
	Measurements are from single inflations	Measurements are from single inflations
	<i>Inflation</i>	<i>Inflation</i>
	Inflation 0 mmHg - 300 mmHg	Inflation 0 mmHg - 300 mmHg
	Automatic Inflation – “Electronic Rolling Pump” ^{Query 1}	Automatic Inflation – “Micro Rolling Pump” ^{Query 1}
	<i>Deflation</i>	<i>Deflation</i>
	Safety release valve “Rapid Exhaust - Electronic solenoid valve”	Safety release valve “Rapid Exhaust - Electronic solenoid valve”
	<i>Cuffs</i>	<i>Cuffs</i>
	Medium (Arm circ. 22 to 32 cm)	Medium (Arm circ. 22 to 32 cm)
	Buttons/Switches	Buttons/Switches
	<i>Power</i>	<i>Power</i>
	On/Off with Start/Stop (I/O Label)	On/Off with Start/Stop (POWER Label)
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory	Memory
	Display/Symbols/Indicators	Display/Symbols/Indicators
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	Inflation symbol <i>P</i>	Inflation symbol <i>P</i>
	During Measurement: BP Level & Heartbeat ^{Query 3}	During Measurement: BP Level & Heartbeat
	<i>Post Measurement</i>	<i>Post Measurement</i>
	SBP, DBP and Pulse	SBP, DBP and Pulse
	Measurement error <i>LL Err, UU Err, P Err, rrErr</i> and <i>Hi</i>	Measurement error <i>LL Err, UU Err, P Err, rrErr</i> and <i>Hi</i>
	Hypertension (Indicator strip)	Hypertension (Indicator strip)
	BP classification (WHO)	BP classification (WHO)
	Body movement error	Body movement error
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory	Memory
	Memory recall number	Memory recall number
	<i>Date and Time</i>	<i>Date and Time</i>
Date and Time	Date and Time	
Date and Time (During memory recall) ^{Query 4}	Date and Time (During memory recall) ^{Query 4}	
Setting of Date and Time	Setting of Date and Time	

Devices	Polygreen K-Jump KP-7770	Spengler K-Jump KP7500 D
Same Criteria (continued)	<p>Display/Symbols/Indicators (continued)</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Normotension/Hypertension 13</p> <p>WHO Guidelines 13</p> <p>Body movement error detection 3, 13</p> <p>Casing</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 250 measurements 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 150 seconds 17</p>	<p>Display/Symbols/Indicators (continued)</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Normotension/Hypertension 13</p> <p>WHO Guidelines 13</p> <p>Body movement error detection 3, 13</p> <p>Casing</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 250 measurements 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 150 seconds 17</p>
Comparable Criteria	<p>Measurement</p> <p><i>Measurement Records</i></p> <p>Memory: 100 total, 2 to 5 users – 2x50, 3x33, 4x25 or 5x20 14</p>	<p>Measurement</p> <p><i>Measurement Records</i></p> <p>Memory: Optional 42, 85 or 99 sets ^{Query 2} 14</p>
Device 2 Criteria		none

Comments	<p>The K-Jump KP7500 D, sold under the brand Spengler, is supplied with memory for 42, 85 or 99 measurements. The K-Jump KP-7770, sold under the brand Polygreen, is supplied with memory for 100 measurements but with a one to five user capacity – with facilities for selecting the user and the number of users. Two versions are available, one with a backlight and one without. Though slightly larger, the screen has the same layout as stat of the KP7500 D, with the backlit version having built in colours in the WHO indicator.</p> <p>Other than that there appears to be no differences in the devices. A few clarifications were sought and answered satisfactorily.</p>	
	1	<p>Query The inflation method described for the KP7500 D is a “Micro rolling pump”. The method described for the KP-7770 is an “Electrical rolling pump”. Are they the same?</p> <p>Response Yes, they are the same.</p>
	2	<p>Query The memory for the KP7500 D is described as “42, 85, 99 sets”. What does this mean?</p> <p>Response The actual number of memory capacity could be adjusted as 42, 85, or 99 sets for different order request.</p>
	3	<p>Query In the KP-7770, are BP level and heartbeat displayed during deflation? This is not stated in the manual.</p> <p>Response Yes, KP-7770 has same display of BP level and heartbeat during deflation as KP7500 D.</p>
	4	<p>Query From the diagrams in the KP7500 D manual, it appears that, during memory recall, measurement number date and time are shown in sequence for each measurement. Is this interpretation correct? Does this also hold for the KP-7770?</p> <p>Response Yes, the interpretation is correct and also hold for KP-7770 except the user number is also shown together with measurement number.</p>
	5	<p>Query Fuzzy logic is stated in the title of the manual for the KP7500 D but not elsewhere and not at all for the KP-7770. Please explain.</p> <p>Response The “Fuzzy Logic” is a marketing name regarding the type of oscillometric measurement and the KP-7770 manual just has no emphasis on this area. As declared in the equivalence form, both devices utilize same measurement algorithm.</p>
	6	<p>Query No information is provided regarding the sensors used. Are they the same for both devices?</p> <p>Response Yes, both of them use the same sensor as declared in the equivalence form.</p>
Recommendation	Equivalence is recommended	
Date	22/08/2011	