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 David Gong, (Name of a Company Director) a Director of Shenzhen Kingyield Technology Co., Ltd, (Company name)

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

Maker[a]	Shenzhen Kingyield Technology Co., Ltd	*Address*	Section C, FuHai Industrial Zone, Fuhai Road, FuYong, Baoan, Shenzhen, China	
Manufacturer[b]	Shenzhen Kingyield Technology Co., Ltd	*Address*	Section C, FuHai Industrial Zone, Fuhai Road, FuYong, Baoan, Shenzhen, China	
Brand[c]	Braun	Model[d]	BPW4100	

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]	Shenzhen Kingyield Technology Co., Ltd	*Address*	Section C, FuHai Industrial Zone, Fuhai Road, FuYong, Baoan, Shenzhen, China	
Manufacturer[b]	Shenzhen Kingyield Technology Co., Ltd	*Address*	Section C, FuHai Industrial Zone, Fuhai Road, FuYong, Baoan, Shenzhen, China	
Brand[c]	Kingyield	Model[d]	BP210	

Existing validated blood pressure measuring device.

which has previously passed the ESH protocol, the results of which were published as follows:

Validation of the Kingyield BP210 wrist blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension-International Protocol, which was published to Blood Pressure Monitoring in 2012; 17(1):42-4.

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.

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dabl® Educational Trust

Declaration of Equivalence Form

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.

Refer to "SECTION B of BPW4100"

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 David Gong 2014.02.28 Company Stamp/Seal

Name David Gong

Date 2014-2-28

Signature of Witness Lydia Wong 2014.02.28

Name Lydia Wong

Address 2014-2-28

KINGYIELD TECHNOLOGY CO., LTD. 深圳市金亿帝科技有限公司 SHEN ZHEN

SECTION B of BPW4100

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.

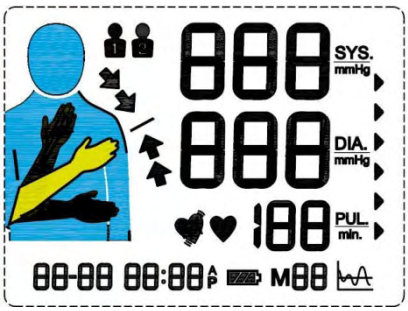
9 Model Name or Number

	BP210	BPW4100
Model Number	BP210	BPW4100C, BPW4100E

10 Casing

	BP210	BPW4100
Casing		

11 Display

	BP210	BPW4100
LCD Display Drawing		

12 Carrying/Mounting Facilities

	BP210	BPW4100
Carrying/Mounting Facilities		

13 Software Other than Algorithm

	BP210	BPW4100
Software Other than Algorithm	• heart level detection uses a (AS101) sensor.	• heart level detect uses a (AS102) sensor.
	• year/month/day/hour/time setting	• month/day/hour/minute setting
	• KPa/mmHg switchable	• mmHg only
	•No AVG of past 7 days	• AVG of past 7 days
	• AVG of latest 3 readings	• No AVG of latest 3 readings
	• Err detect (It shows Err when the Cuff too loose; Movement during measurement; SBP>280mmHg; SBP<60mmHg; DBP>250mmHg; DPB<30mmHg and Pressure>299mmHg)	• Err detect (It shows Err1 when the Cuff too loose; Shows Err2 when Movement during measurement; SBP>280mmHg; SBP<60mmHg; DBP>250mmHg; DPB<30mmHg and Pressure>299mmHg)
	•Alternating display of date and time	•Date and time displayed together

14 Memory Capacity/Number of Stored Measurements

	BP210	BPW4100
Memory Number of Stored Measurements	2 x 90 memories (dual users, 90 measurements for each user)	2 x 40 memories (dual users, 40 measurements for each user)

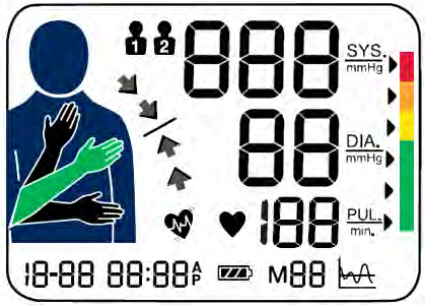
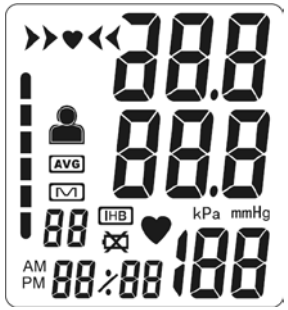
15 N/A

16 N/A

17 N/A

18 N/A

Comparison of the Braun BPW4100 with the Kingyield BP210

Devices	Braun BPW4100	Kingyield BP210
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria	***Display/Symbols/Indicators*** *Measurement Procedure* Beep after measurement 18 ***Algorithms*** *Averages and Differences* 7-day mean 13	
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 SBP 60 mmHg – 280 mmHg, DBP 30 mmHg – 250 mmHg[Query 2] 1, 5, 7, 8 Pulse 40 bpm – 180 bpm 1, 5, 8	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg (0.4 kPa) 1, 5 Pulse accuracy ± 3 bpm or ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 SBP 60 mmHg – 280 mmHg, DBP 30 mmHg – 250 mmHg 1, 5, 7, 8 Pulse 40 bpm – 180 bpm 1, 5, 8

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Devices	Braun BPW4100		Kingyield BP210	
Same Criteria (continued)	***Measurement (continued)***		***Measurement (continued)***	
	Method (continued)		*Method (continued)*	
	Manually initiated measurements	13	Manually initiated measurements	13
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Inflation		*Inflation*	
	Inflation 0 mmHg – 299 mmHg	1, 5, 7, 8	Inflation 0 mmHg – 299 mmHg Query 2	1, 5, 7, 8
	Automatic Inflation (when arm position correct)	7	Automatic Inflation (when arm position correct)	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Automatic safety release valve Query 3	8	Automatic safety release valve	8
	Cuffs		*Cuffs*	
	Wrist circ. 13.5 cm – 21.5 cm	6	Wrist circ. 13.5 cm – 21.5 cm	6
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop	10	On/Off with Start/Stop	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Preparation		*Preparation*	
	Option to change memory zone	11, 14	Option to change memory zone	11, 14
	Measurement Procedure		*Measurement Procedure*	
	Heartbeat symbol during deflation Query 9	11	Heartbeat symbol during deflation	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Hypertension (Indicator strip)	11, 13	Hypertension (Indicator strip)	11, 13
	Measurement Records		*Measurement Records*	
	Memory “M” symbol Query 7	11	Memory “M” symbol	11
	Memory recall number	11	Memory recall number	11
	Date and Time		*Date and Time*	
	Date and Time (During memory recall)	11	Date and Time (During memory recall)	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		***Algorithms***	
	Diagnostic		*Diagnostic*	
	WHO Guidelines	13	WHO Guidelines	13
	135 / 85 mmHg thresholds	13	135 / 85 mmHg thresholds	13
	Irregular heartbeat detection Query 4	13	Irregular heartbeat detection Query 4	13
	Parameter Settings		*Parameter Settings*	
	Correct wrist positioning detection	13	Correct wrist positioning detection	13

Devices	Braun BPW4100		Kingyield BP210	
Same Criteria (continued)	***Casing***		***Casing***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Segment LCD	10	Segment LCD	10
	Power		*Power*	
	2 “AAA” batteries	17	2 “AAA” batteries	17
	Automatic switch-off when not used for 2 min	17	Automatic switch-off when not used for 2 min	17
Comparable Criteria	***Measurement***		***Measurement***	
	Sensors		*Sensors*	
	Wrist positioning sensor (AS102 sensor) Query 8	18	Wrist positioning sensor (AS101 sensor) Query 8	18
	Measurement Records		*Measurement Records*	
	Memory: 40 measurements × 2 users	14	Memory: 90 measurements × 2 users	14
	Buttons/Switches		***Buttons/Switches***	
	Measurement Records		*Measurement Records*	
	Memory/Average	10	Memory	10
	User ID	10	X	10
	Settings		*Settings*	
	Date/Time set	10	Set	10
	Adjust	10	X	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Preparation		*Preparation*	
	Wrist position – adjust and OK	11, 13, 18	Wrist position – adjust and OK	11, 13, 18
	Post Measurement		*Post Measurement*	
	Measurement error Err 1, Err2 Query 5	11	Measurement error Err (no error numbers) Query 5	11
	Average	11, 13, 14	Average AVG	11, 13, 14
	Irregular heartbeat (symbol)	11, 13, 18	Irregular heartbeat IHB	11, 13, 18
	Measurement Records		*Measurement Records*	
	User (1 or 2)	11	User (black or white symbol)	11
	Date and Time		*Date and Time*	
	Date and Time (Year, Month, Day, Hour & Minute)	11	Date and Time (Month, Day alternating with Hour & Minute)	11
Device 2 Criteria			***Display/Symbols/Indicators***	
			Settings	
			Current unit (kPa / mmHg) marker	11
			Algorithms	
			Averages and Differences	
			Last 3 measurements mean	13
			Parameter Settings	
			Unit conversion (kPa / mmHg)	13

<table>
<tr>
<td>Comments</td>
<td>1</td>
<td>
Query

There are two different models marketed as the Kingyield BP210, as shown by the images below, labelled “A” and “B” for the purposes of this document. Furthermore, the screen images on page 24 of the manual for model “B” reflect the layout from model “A”.
<table>
<tr>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>Model “A”</td>
<td>Model “B”</td>
</tr>
</table>
a) What are the differences between these devices?
b) It is essential that all models are distinguishable. What are the internal model numbers, or other methods, of distinguishing them?
c) Which one was used for the original validation?
d) Can you supply a manual for the model “A” please?

Reply
a) In fact, we only produced model B; The picture of model A is a draft version under the process of design, only a picture, even we did not make any samples. So we only have 1 model, not 2 models.
b) As we mentioned ABOVE, we only produced one model which is Model B.
c) Model B
d) As we mentioned above, we only produced model B.

Comment
This is accepted. However, the images on page 24 of the Instruction Manual (Ver A00) for the Kingyield BP210 are incorrect. Furthermore, the image used for most advertisements, including http://kingyield.en.ec21.com/Blood_Pressure_Monitor_BP210--924819_3808818.html is of the incorrect design. The model is not advertised at all on www.kingyield.com.
</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>
Query

The blood pressure range for the BPW4100 is described in the specification sections of respective manuals as being from 0 mmHg to 280 mmHg with SBP being from 60 mmHg to 280 mmHg and DBP being from 30 mmHg to 250 mmHg. The range for the BP210 is described in the specification section of respective manual as being from 0 mmHg to 299 mmHg with no details for SBP or DBP.
</td>
</tr>
</table>

2

a) What are the SBP and DBP measurement ranges for the BP210?

b) What are the rated pressure ranges for the BP210 and BPW4100?

c) What are the technical alarm condition ranges for the BP210 and BPW4100?

Reply If the unit detects any pressure higher than 299mmHg, it will open the valve to release the pressure in the cuff and show Err2 on display for safety purposes. So, the pressure will not go above 299mmHg. This is the upper limit.

	Measurement Range	SBP	DBP	Static Pressure
BPW4100	0-299mmHg	60-280mmHg	30-250mmHg	0-299mmHg
BP210	0-299mmHg	60-280mmHg	30-250mmHg	0-299mmHg

The technical alarm condition for BPW4100 is:

- Any pressure exceeds 299mmHg (including SBP,DBP and static pressure).
- SBP is less than 60mmHg or is higher than 280mmHg
- DBP is less than 30 mmHg or is higher than 250mmHg

The technical alarm condition for BP210 is:

- Any pressure exceeds 299mmHg (including SBP,DBP or static pressure).
- SBP is less than 60mmHg or is higher than 280mmHg
- DBP is less than 30 mmHg or is higher than 250mmHg

Query The reply is a little contradictory in parts. If the automatic release valve is opened when the cuff pressure is higher than 299 mmHg, then no pressure will be measured for that inflation and therefore there will be no SBP or DBP outside of the respective rated range to trigger a technical alarm. Nevertheless, the following table appears to summarise the reply and also includes some of the reply to Query 5. Is this table correct?

		Lower TA Range	Rated Range	Upper TA Range	Automatic Release Valve
BPW4100	Cuff Pressure *mmHg*				> 299 (Err 2)
	SBP *mmHg* (Error)	0 to 59 (Err 2)	60 to 280	281 to 299 (Err 2)	
	DBP *mmHg* (Error)	0 to 29 (Err 2)	30 to 250	251 to 299 (Err 2)	
BP210	Cuff Pressure *mmHg*				> 299 (Err)
	SBP *mmHg* (Error)	0 to 59 (Err)	60 to 280	281 to 299 (Err)	
	DBP *mmHg* (Error)	0 to 29 (Err)	30 to 250	251 to 299 (Err)	

Reply Yes, we confirm that this table is correct.

Comment The explanation is accepted.

<table>
<tr><td></td><td>3</td><td>
Query A “Rapid Air Release” is described in the specifications section of the Kingyield BP210 manual.
a) Does this refer to an automatic safety release valve?
b) No such item is described in the BPW4100 manual and item 8 “Deflation Mechanism” is not checked in either of the applications. Does this indicate that the deflation mechanisms differ in these devices from that in the BP210?
Reply a) Yes.
b) Deflation Mechanism is the same, rapid deflation occurs in two cases below: 1.Solenoid valve opens automatically in order to deflate rapidly when error occurs in the process of inflation; 2. Solenoid valve opens automatically in order to deflate rapidly when measurement is finished and comes out a result.
Comment The explanation is accepted.
</td></tr>
<tr><td></td><td>4</td><td>
Query The BP210 describes how the irregular heartbeat symbol may appear with or without blood pressure measurements, depending on whether or not an accurate measurement could be made under this situation. No such description is provided in the BPW4100 manual. This suggests that the IHB mechanism differs between the devices.
a) Is this the case?
b) If so, what is the effect on the BP results?
Reply a) IHB Mechanism is the same.
b) There is no effect on blood pressure measurement results.
Comment The explanation is accepted.
</td></tr>
<tr><td></td><td>5</td><td>
Query A single error, “Err”, is described in the BP210 manual. Two errors “Err 1” and “Err 2” are described in the BPW4100 manual. Why is there a difference?
Reply The reasons and solution of errors described in the instruction of BPW4100 are the same with BP210. Please find the attached picture.
BP210
<table>
<tr><th>Symbol</th><th>Cause</th><th>Correction</th></tr>
<tr><td rowspan="4">Err</td><td rowspan="2">The course of inflating appears error.</td><td>Wrap the cuff correctly and tightly.</td></tr>
<tr><td>Inflate over again after ensuring.</td></tr>
<tr><td rowspan="2">When measurement fails.</td><td>Do not move your arm and body, and keep quiet.</td></tr>
<tr><td>Measure over again according to correct way.</td></tr>
</table>
BPW4100
<table>
<tr><th>Problem</th><th>Reason</th><th>Solution</th></tr>
<tr><td>Battery Icon is flashing</td><td>• Batteries are flat.
• Memory readings can be called up, but measurements are not possible.</td><td>Insert new batteries.</td></tr>
<tr><td>Err 1</td><td>Cuff is not wrapped on the wrist well (too loose).</td><td>Rewrap the cuff tighter on the wrist.</td></tr>
<tr><td>Err 2</td><td>• Arm moved during inflation measurement.
• Systolic pressure is above 280mmHg</td><td>Please do not move arm or speak when you take a measurement.</td></tr>
</table>
</td></tr>
</table>

<table>
<tr>
<td></td>
<td>5</td>
<td>
Comment The reasons are not quite the same. For the BPW4100, Err 2 occurs if SBP is above 280 mmHg. This does not appear to be a reason for an error in the BP210. Furthermore, in the supplied Section B, “Err detect” is listed, in both applications, among the items of software, other than the algorithm, that differ between the devices. This appears to indicate differences in the error detection algorithms. Please clarify.

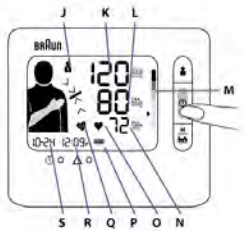
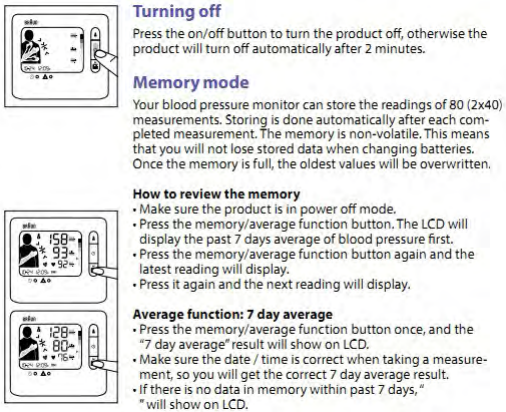
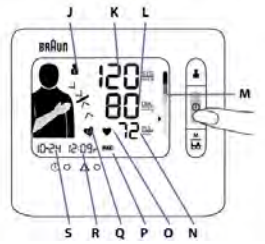
Reply The BP210 only uses 1 Error code, whereas the BPW4100 uses 2 Error codes in order to provide further clarity to the user. They represent the same errors, just with a number entered in the display.
<table>
<tr><th>Cause</th><th>BP210</th><th>BPW4100</th></tr>
<tr><td>Cuff too loose</td><td>Err</td><td>Err1</td></tr>
<tr><td>Movement during measurement</td><td>Err</td><td>Err2</td></tr>
<tr><td>SBP<60 or >280mmHg</td><td>Err</td><td>Err2</td></tr>
<tr><td>DBP<30 or >250mmHg</td><td>Err</td><td>Err2</td></tr>
<tr><td>Any pressure>299 mmHg</td><td>Err</td><td>Err2</td></tr>
</table>
Comment The explanation is accepted.
</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>
Query According to the Kingyield BP210 manual, the display contains a “PC Link” symbol and a “User” symbol. These are not shown in the display screens supplied in Item 11 of Section B for the BP210. Can you explain this anomaly?

Reply The display is not correct; please find the correct LCD display of BP210 in Section B.

Comment The display and explanation are accepted.
</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>
Query According to the respective display screens supplied in Item 11 of Section B for the BPW4100, each screen contains an “M88” and average symbol on the bottom right corner. These do not appear in any of the screen images in either manual and no reference is made to them, even in the sections describing how to display the average and the recorded measurements.

a) Please explain.
b) Can you please supply us with original images of the two screen layouts?

Reply a) Actually, we have mentioned in our instruction manual, please find the pictures below.
b) The attached LCD layout is for your reference.
</td>
</tr>
</table>

	7	   **Product description** A Easy positioning system B User button C On/off button D Memory/average function button E Battery compartment F Time and date setting button G Adjust button H Cuff I Velcro strap K Systolic pressure L Diastolic pressure M WHO/ESH indicator N Pulse rate O Heart rate indicator P Low battery indicator Q Irregular heartbeat R Time S Month and day **Turning off** Press the on/off button to turn the product off, otherwise the product will turn off automatically after 2 minutes. **Memory mode** Your blood pressure monitor can store the readings of 80 (2x40) measurements. Storing is done automatically after each completed measurement. The memory is non-volatile. This means that you will not lose stored data when changing batteries. Once the memory is full, the oldest values will be overwritten. **How to review the memory** • Make sure the product is in power off mode. • Press the memory/average function button. The LCD will display the past 7 days average of blood pressure first. • Press the memory/average function button again and the latest reading will display. • Press it again and the next reading will display. **Average function: 7 day average** • Press the memory/average function button once, and the "7 day average" result will show on LCD. • Make sure the date / time is correct when taking a measurement, so you will get the correct 7 day average result. • If there is no data in memory within past 7 days, " " will show on LCD. Comment While the manuals explain how to review the memory and how to access the 7-day average, they do not contain any references to the existence of an "M" symbol, and the memory item number, nor to the symbol for the average. Their existences, however, are accepted.
	8	Query The Kingyield BP210 has an arm positioning facility which appears to work analogously to that in the BPW4100, though the displays are very different. Can you provide details to show that these are equivalent? Comment Satisfactory details were provided to dablEducational.
	9	Query The BP210 manual provides details of what is displayed during the measurement process. The BPW4100 manual does not provide any information on this. Can you please provide his information (e.g. Are pressures shown? Is a heartbeat symbol shown when a pulse is detected? Are there any other features?) Reply The process of inflation is the same with BP210. Pressures and heart symbol is showed: Comment The explanation is accepted. 
	10	Query What are the differences between the BPW4100, BPW4100C and BPW4100E, as noted in the Section B? Reply The difference is in the outer packaging only. The device itself is exactly the same. Comment The explanation is accepted.
Recommendation	Equivalence is Recommended	
Date	14 July 2014	