

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**, a Director of **Shenzhen Kingyield Technology Co., Ltd**,
Name of a Company Director Company name

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

Maker^a	Shenzhen Technology Co., Ltd	Kingyield	Address	Section C, FuHai Industrial Zone, Fuhai Road, FuYong, Baoan, Shenzhen, China
Manufacturer^b	Shenzhen Technology Co., Ltd	Kingyield	Address	Section C, FuHai Industrial Zone, Fuhai Road, FuYong, Baoan, Shenzhen, China
Brand^c	Braun	Model^d	BPW4300	

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 Technology Co., Ltd	Kingyield	Address	Section C, FuHai Industrial Zone, Fuhai Road, FuYong, Baoan, Shenzhen, China
Manufacturer^b	Shenzhen Technology Co., Ltd	Kingyield	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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" 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"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	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 checked="" type="checkbox"/>	No <input 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 checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <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"/>	N/A ^g <input checked="" type="checkbox"/>

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.

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 BPW4300"

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



SECTION B of BPW4300

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	BPW4300
Model Number	BP210	BPW4300C, BPW4300E

10 Casing

	BP210	BPW4300
Casing		

11 Display

	BP210	BPW4300
LCD Display Drawing		

12 Carrying/Mounting Facilities

	BP210	BPW4300
Carrying/Mounting Facilities		

13 Software Other than Algorithm

	BP210	BPW4300
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)
	• No morning hypertension detect	• morning hypertension detect
	•Alternating display of date and time	•Date and time displayed together

14 N/A

15 N/A



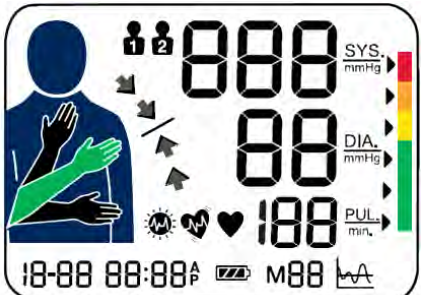
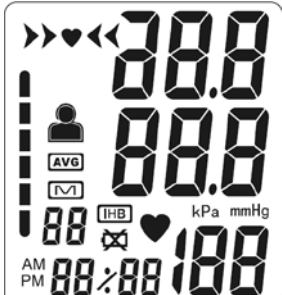
16 Communication Facilities

	BP210	BPW4300
Communication Facilities	Without USB data transfer function	With USB data transfer function

17 N/A

18 N/A



Comparison of the Braun BPW4300 with the Kingyield BP210

Devices	Braun BPW4300	Kingyield BP210
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria	<p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Beep after measurement 18</p> <p><i>Post Measurement</i></p> <p>Morning hypertension 11, 13</p> <p><i>Communication</i></p> <p>PC connection (PC) 11, 16</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>7-day mean 13</p> <p><i>Diagnostic</i></p> <p>Morning hypertension (Morning mean ≥ 120% Evening mean) 13</p> <p>Casing</p> <p><i>Ports</i></p> <p>USB port, cable and PC software 16, 18</p>	

Devices	Braun BPW4300	Kingyield BP210
Same Criteria	Measurement	Measurement
	<i>Accuracy</i>	<i>Accuracy</i>
	BP accuracy ± 3 mmHg	BP accuracy ± 3 mmHg (0.4 kPa)
	Pulse accuracy $\pm 5\%$	Pulse accuracy ± 3 bpm or $\pm 5\%$
	<i>Method</i>	<i>Method</i>
	Oscillometric measurement method	Oscillometric measurement method
	SBP 60 mmHg – 280 mmHg, DBP 30 mmHg – 250 mmHg ^{Query 2}	SBP 60 mmHg – 280 mmHg, DBP 30 mmHg – 250 mmHg
	Pulse 40 bpm – 180 bpm	Pulse 40 bpm – 180 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 – 299 mmHg	Inflation 0 mmHg – 299 mmHg ^{Query 2}
	Automatic Inflation (when arm position correct)	Automatic Inflation (when arm position correct)
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation	Automatic Deflation
	Automatic safety release valve ^{Query 3}	Automatic safety release valve
	<i>Cuffs</i>	<i>Cuffs</i>
	Wrist circ. 13.5 cm – 21.5 cm	Wrist circ. 13.5 cm – 21.5 cm
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory: 90 measurements \times 2 users	Memory: 90 measurements \times 2 users
	Buttons/Switches	Buttons/Switches
	<i>Power</i>	<i>Power</i>
	On/Off with Start/Stop	On/Off with Start/Stop
	Display/Symbols/Indicators	Display/Symbols/Indicators
	<i>Preparation</i>	<i>Preparation</i>
	Option to change memory zone	Option to change memory zone
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
Heartbeat symbol during deflation ^{Query 9}	Heartbeat symbol during deflation	
<i>Post Measurement</i>	<i>Post Measurement</i>	
SBP, DBP and Pulse	SBP, DBP and Pulse	
Hypertension (Indicator strip)	Hypertension (Indicator strip)	
<i>Measurement Records</i>	<i>Measurement Records</i>	
Memory “M” symbol ^{Query 7}	Memory “M” symbol	
Memory recall number	Memory recall number	
<i>Date and Time</i>	<i>Date and Time</i>	
Date and Time (During memory recall)	Date and Time (During memory recall)	

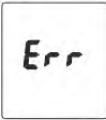

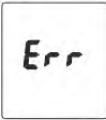

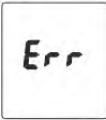

Devices	Braun BPW4300	Kingyield BP210
Same Criteria (continued)	<p>Display/Symbols/Indicators (continued)</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>WHO Guidelines 13</p> <p>135 / 85 mmHg thresholds 13</p> <p>Irregular heartbeat detection ^{Query 4} 13</p> <p><i>Parameter Settings</i></p> <p>Correct wrist positioning detection 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>2 “AAA” batteries 17</p> <p>Automatic switch-off when not used for 2 min 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>WHO Guidelines 13</p> <p>135 / 85 mmHg thresholds 13</p> <p>Irregular heartbeat detection ^{Query 4} 13</p> <p><i>Parameter Settings</i></p> <p>Correct wrist positioning detection 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>2 “AAA” batteries 17</p> <p>Automatic switch-off when not used for 2 min 17</p>
	Comparable Criteria	<p>Measurement</p> <p><i>Sensors</i></p> <p>Wrist positioning sensor (AS102 sensor) ^{Query 8} 18</p> <p>Buttons/Switches</p> <p><i>Measurement Records</i></p> <p>Memory/Average 10</p> <p>User ID 10</p> <p><i>Settings</i></p> <p>Date/Time set 10</p> <p>Adjust 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Wrist position – adjust and OK 11, 13, 18</p> <p><i>Post Measurement</i></p> <p>Measurement error $Err 1, Err 2$ ^{Query 5} 11</p> <p>Average 11, 13, 14</p> <p>Irregular heartbeat (symbol) 11, 13, 18</p> <p><i>Measurement Records</i></p> <p>User (1 or 2) 11</p> <p><i>Date and Time</i></p> <p>Date and Time (Year, Month, Day, Hour & Minute) 11</p>

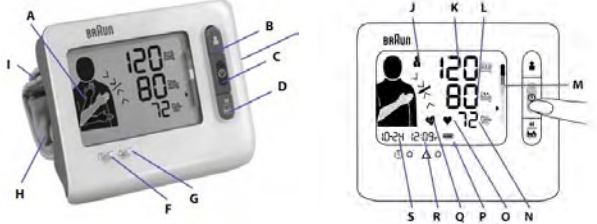
Devices	Braun BPW4300	Kingyield BP210
Device 2 Criteria		<p>Display/Symbols/Indicators</p> <p><i>Settings</i></p> <p>Current unit (kPa / mmHg) marker 11</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p> <p><i>Parameter Settings</i></p> <p>Unit conversion (kPa / mmHg) 13</p>

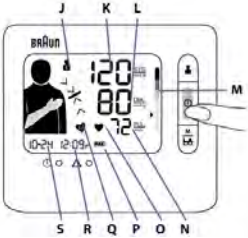
Comments	
1	<p>Query</p> <p>There are two different models marketed as the Kingyield BP210, as shown by the images below, labelled “A” and “B” for the purposes of this document. Furthermore, the screen images on page 24 of the manual for model “B” reflect the layout from model “A”.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Model “A”</p> </div> <div style="text-align: center;">  <p>Model “B”</p> </div> </div> <p>a) What are the differences between these devices?</p> <p>b) It is essential that all models are distinguishable. What are the internal model numbers, or other methods, of distinguishing them?</p> <p>c) Which one was used for the original validation?</p> <p>d) Can you supply a manual for the model “A” please?</p> <p>Reply</p> <p>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.</p> <p>b) As we mentioned ABOVE, we only produced one model which is Model B.</p> <p>c) Model B</p>

1	<p>d) As we mentioned above, we only produced model B.</p> <p>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.</p>															
2	<p>Query The blood pressure range for the BPW4300 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.</p> <p>a) What are the SBP and DBP measurement ranges for the BP210? b) What are the rated pressure ranges for the BP210 and BPW4300? c) What are the technical alarm condition ranges for the BP210 and BPW4300?</p> <p>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.</p> <table border="1" data-bbox="689 754 2007 855"> <thead> <tr> <th></th> <th>Measurement Range</th> <th>SBP</th> <th>DBP</th> <th>Static Pressure</th> </tr> </thead> <tbody> <tr> <td>BPW4300</td> <td>0-299mmHg</td> <td>60-280mmHg</td> <td>30-250mmHg</td> <td>0-299mmHg</td> </tr> <tr> <td>BP210</td> <td>0-299mmHg</td> <td>60-280mmHg</td> <td>30-250mmHg</td> <td>0-299mmHg</td> </tr> </tbody> </table> <p>The technical alarm condition for BPW4300 is:</p> <ul style="list-style-type: none"> 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 <p>The technical alarm condition for BP210 is:</p> <ul style="list-style-type: none"> 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 <p>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?</p>		Measurement Range	SBP	DBP	Static Pressure	BPW4300	0-299mmHg	60-280mmHg	30-250mmHg	0-299mmHg	BP210	0-299mmHg	60-280mmHg	30-250mmHg	0-299mmHg
	Measurement Range	SBP	DBP	Static Pressure												
BPW4300	0-299mmHg	60-280mmHg	30-250mmHg	0-299mmHg												
BP210	0-299mmHg	60-280mmHg	30-250mmHg	0-299mmHg												

	2			Lower TA Range	Rated Range	Upper TA Range	Automatic Release Valve	
		BPW4300	Cuff Pressure <i>mmHg</i>				> 299 (Err 2)	
			SBP <i>mmHg</i> (Error)	0 to 59 (Err 2)	60 to 280	281 to 299 (Err 2)		
			DBP <i>mmHg</i> (Error)	0 to 29 (Err 2)	30 to 250	251 to 299 (Err 2)		
		BP210	Cuff Pressure <i>mmHg</i>				> 299 (Err)	
			SBP <i>mmHg</i> (Error)	0 to 59 (Err)	60 to 280	281 to 299 (Err)		
			DBP <i>mmHg</i> (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.					
	3	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 BPW4300 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.					
	4	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 BPW4300 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.					

		<p>Query A single error, “Err”, is described in the BP210 manual. Two errors “Err 1” and “Err 2” are described, relating to BP measurement, in the BPW4300 manual. Why is there a difference?</p> <p>Reply The reasons and solution of errors described in the instruction of BPW4300 are the same with BP210. Please find the attached picture.</p> <table border="1" data-bbox="600 327 1951 670"> <thead> <tr> <th colspan="3">BP210</th> <th colspan="3">BPW4300</th> </tr> <tr> <th>Symbol</th> <th>Cause</th> <th>Correction</th> <th>Problem</th> <th>Reason</th> <th>Solution</th> </tr> </thead> <tbody> <tr> <td rowspan="2"></td> <td>The course of inflating appears error.</td> <td>Wrap the cuff correctly and tightly. Inflate over again after ensuring.</td> <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>When measurement fails.</td> <td>Do not move your arm and body, and keep quiet. Measure over again according to correct way.</td> <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></td> <td></td> <td></td> <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> </tbody> </table> <p>5 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.</p> <p>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.</p> <table border="1" data-bbox="763 935 1668 1185"> <thead> <tr> <th>Cause</th> <th>BP210</th> <th>BPW4300</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>Comment The explanation is accepted.</p>	BP210			BPW4300			Symbol	Cause	Correction	Problem	Reason	Solution		The course of inflating appears error.	Wrap the cuff correctly and tightly. Inflate over again after ensuring.	Battery Icon is flashing 	• Batteries are flat. • Memory readings can be called up, but measurements are not possible.	Insert new batteries.	When measurement fails.	Do not move your arm and body, and keep quiet. Measure over again according to correct way.	Err 1	Cuff is not wrapped on the wrist well (too loose).	Rewrap the cuff tighter on the wrist.				Err 2	• Arm moved during inflation measurement. • Systolic pressure is above 280mmHg	Please do not move arm or speak when you take a measurement.	Cause	BP210	BPW4300	Cuff too loose	Err	Err1	Movement during measurement	Err	Err2	SBP<60 or >280mmHg	Err	Err2	DBP<30 or >250mmHg	Err	Err2	Any pressure>299 mmHg	Err	Err2
BP210			BPW4300																																														
Symbol	Cause	Correction	Problem	Reason	Solution																																												
	The course of inflating appears error.	Wrap the cuff correctly and tightly. Inflate over again after ensuring.	Battery Icon is flashing 	• Batteries are flat. • Memory readings can be called up, but measurements are not possible.	Insert new batteries.																																												
	When measurement fails.	Do not move your arm and body, and keep quiet. Measure over again according to correct way.	Err 1	Cuff is not wrapped on the wrist well (too loose).	Rewrap the cuff tighter on the wrist.																																												
			Err 2	• Arm moved during inflation measurement. • Systolic pressure is above 280mmHg	Please do not move arm or speak when you take a measurement.																																												
Cause	BP210	BPW4300																																															
Cuff too loose	Err	Err1																																															
Movement during measurement	Err	Err2																																															
SBP<60 or >280mmHg	Err	Err2																																															
DBP<30 or >250mmHg	Err	Err2																																															
Any pressure>299 mmHg	Err	Err2																																															
	6	<p>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?</p> <p>Reply The display is not correct; please find the correct LCD display of BP210 in Section B.</p> <p>Comment The display and explanation are accepted.</p>																																															

<p>7</p>	<p>Query</p> <p>Reply</p>	<p>According to the respective display screens supplied in Item 11 of Section B for the BPW4300, each screen contains an “M” 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.</p> <p>a) Please explain.</p> <p>b) Can you please supply us with original images of the two screen layouts?</p> <p>a) Actually, we have mentioned in our instruction manual, please find the pictures below.</p> <p>b) The attached LCD layout is for your reference.</p> <div style="text-align: center;">  <p>Product description</p> <table border="0"> <tr> <td style="vertical-align: top;"> <p>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</p> </td> <td style="vertical-align: top;"> <p>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</p> </td> </tr> </table> </div> <div style="text-align: right;"> <p>Turning off Press the on/off button to turn the product off, otherwise the product will turn off automatically after 2 minutes.</p> <p>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.</p> <p>How to review the memory</p> <ul style="list-style-type: none"> • 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. <p>Average function: 7 day average</p> <ul style="list-style-type: none"> • 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. </div>	<p>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</p>	<p>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</p>
<p>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</p>	<p>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</p>			
<p>8</p>	<p>Query</p> <p>Comment</p>	<p>The Kingyield BP210 has an arm positioning facility which appears to work analogously to that in the BPW4300, though the displays are very different. Can you provide details to show that these are equivalent?</p> <p>Satisfactory details were provided to dablEducational.</p>		

	9	<p>Query The BP210 manual provides details of what is displayed during the measurement process. The BPW4300 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?)</p> <p>Reply The process of inflation is the same with BP210. Pressures and heart symbol is showed:</p> <p>Comment The explanation is accepted.</p>	
	10	<p>Query What are the differences between the BPW4300, BPW4300C and BPW4300E, as noted in the Section B?</p> <p>Reply The difference is in the outer packaging only. The device itself is exactly the same.</p> <p>Comment The explanation is accepted.</p>	
Recommendation	Equivalence is Recommended		
Date	14 July 2014		