

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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SECTION A - Please complete all items.

I, **Liu Yi,** a Director of **Andon Health 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 **Beurer** **Address** **Soeflinger Strasse 218 * 89077 Ulm / Germany**
Manufacturer^b **Andon** **Address** **Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China**
Brand^c **Beurer** **Model^d** **BM85**
Model^d includes 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 **Andon** **Address** **Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China**
Manufacturer^b **Andon** **Address** **Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China**
Brand^c **iHealth** **Model^d** **BP3**
Listing validated blood pressure measuring device.

which has previously passed the ESH2010 protocol, the results of which were published as follows:

Chen C, Shang F,Wang J,Chen J, Ji N,Wan Y. Validation of the iHealth BP3 upper-arm blood pressure monitor,for clinic use and self-measurement, according to the European Society of Hypertension International Protocol revision 2010. Blood Press Monit 2012;17(6):253-256.

The only differences between the devices involve the following components:

Use this for each item 1-15

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 type="checkbox"/>	No <input checked="" 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"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^g <input type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section B or on a separate sheet.

1. Provide the name and address of the actual maker of the device.
2. Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
3. Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
4. Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
5. Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
6. Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
7. 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.

(10) 3 buttons: START/STOP button, Memory button M1 and M2;

(11) Have the HSD symbol;

(13) Have the function of HSD; Have the function of Bluetooth;

(14) Stores 60*2 readings;

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 [Signature] Company Stamp/Seal

Name Liu Yi

Date 23 Oct. 2013



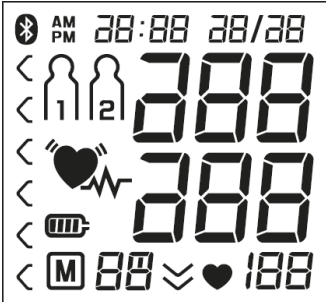

Signature of Witness [Signature]

Name Zhang Fei

Address Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China



Comparison of the Beurer BM85 with the iHealth BP3

Devices	Beurer BM85	iHealth BP3
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria	<p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (I symbol) 10</p> <p><i>Measurement Records</i></p> <p>Memory × 2 inc Date/Time set 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Release air (≡ symbol) ^{Query 3} 11, 14</p> <p><i>Post Measurement</i></p> <p>7-day morning memory-zone mean (AM symbol) 11, 13, 14</p> <p>7-day evening memory-zone mean (PM symbol) 11, 13, 14</p> <p>Haemodynamic stability indicator (Red/Green LED) 11, 13, 18</p> <p><i>Communication</i></p> <p>PC connection (IX symbol) 11, 16</p> <p>Bluetooth data transfer 11, 16</p>	

Devices	Beurer BM85	iHealth BP3
	<p>Algorithms <i>Averages and Differences</i> 7-day morning and evening memory zone means 13 <i>Diagnostic</i> Haemodynamic stability detection 13</p> <p>Casing <i>Ports</i> USB port, cable and downloadable PC software 16, 18 Bluetooth receiver and downloadable App 16, 18 <i>Power</i> Automatic switch-off when not used for 3 min 17</p>	
<p>Device 1 Criteria Device 2 App</p>	<p>Measurement <i>Measurement Records</i> Memory: 60 measurements × 2 users 14</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i> During Measurement: BP Level & Heartbeat 11 <i>Post Measurement</i> SBP, DBP and Pulse 11 Measurement error EE, E1, E2, E3, Er 11 Memory-zone mean (A symbol) 11, 13, 14 Hypertension (Indicator strip) 11, 13 BP classification (WHO 1999) 10, 11, 13 Irregular heartbeat 11, 13, 18</p> <p><i>Measurement Records</i> Memory “M” symbol 11 Memory recall number 11 User (1 or 2) 11</p> <p><i>Date and Time</i> Date and Time 11 Date and Time (During memory recall) 11</p> <p>Algorithms <i>Averages and Differences</i> Memory zone means 13 <i>Diagnostic</i> WHO Guidelines 1999 13</p>	<p>Measurement <i>Measurement Records</i> Memory: xx measurements × nn users 14</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i> During Measurement: 11 <i>Post Measurement</i> SBP, DBP and Pulse ^{Query 5} 11 Measurement error Error 11 Means 11, 13, 14 Hypertension Indicator 11, 13 BP classification (WHO 1999) 10, 11, 13 Irregular heartbeat 11, 13, 18</p> <p><i>Measurement Records</i> Memory symbol 11 Memory recall number 11 User 11</p> <p><i>Date and Time</i> Date and Time 11 Date and Time (During memory recall) 11</p> <p>Algorithms <i>Averages and Differences</i> means 13 <i>Diagnostic</i> WHO Guidelines 1999 13</p>

Devices	Beurer BM85	iHealth BP3
	Irregular heartbeat detection 13 Casing <i>Display</i> Single screen display 10 Segment LCD 10	Irregular heartbeat detection 13 Casing <i>Display</i> Single screen display on iPhone/iPad/iPod 10 LED backlit IPS TFT LCD (on iPhone/iPad/iPod) 10
Same Criteria	Measurement <i>Accuracy</i> BP accuracy ± 3 mmHg 1, 5 Pulse accuracy $\pm 5\%$ 1, 5 <i>Method</i> Oscillometric during inflation 1, 5 SBP 60 mmHg – 260 mmHg, DBP 40 mmHg – 199 mmHg ^{Query 1} 1, 5, 7, 8 Pulse 40 bpm – 180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 <i>Inflation</i> Inflation 0 mmHg – 300 mmHg 1, 5, 7 Automatic Inflation 7 Zero pressure check before inflation ^{Query 3} 7 <i>Deflation</i> Automatic Deflation 8 <i>Cuffs</i> Large (Arm circ. 35 cm to 44 cm) (Optional) Ref. 163.387 ^{Query 2} 6 Medium (Arm circ. 22 cm to 36 cm) ^{Query 2} 6	Measurement <i>Accuracy</i> BP accuracy ± 3 mmHg 1, 5 Pulse accuracy $\pm 5\%$ 1, 5 <i>Method</i> Oscillometric during ? ^{Query 4} 1, 5 BP 45 mmHg – 250 mmHg ^{Query 1} 1, 5, 7, 8 Pulse 40 bpm – 180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 <i>Inflation</i> Inflation 0 mmHg – 295 mmHg 1, 5, 7 Automatic Inflation 7 Zero pressure check before inflation ^{Query 3} 7 <i>Deflation</i> Automatic Deflation 8 <i>Cuffs</i> Large (Arm circ. 30 cm to 42 cm) (Optional) ^{Query 2} 6 Medium (Arm circ. 22 cm to 30 cm) ^{Query 2} 6
Comparable Criteria	Display/Symbols/Indicators <i>Power</i> Low..charged battery (5 levels) 11, 17 Casing <i>Power</i> Rechargeable battery (DC 5V 600mA Li ion 3.7V/400 mAh) via charger or PC ~ 50 measurements 17	Display/Symbols/Indicators <i>Power</i> LED (Red/Yellow/Green Steady/Twinkling/Pulsing Combinations) (Plus symbol and level indicator on app) 11, 17 Casing <i>Power</i> Rechargeable battery (DC 5V 1A Li ion 3.7V/400 mAh) and charger ~ 100 measurements 17

Devices	Beurer BM85	iHealth BP3
Device 2 Criteria		<p>Buttons/Switches Power Device connection button 10</p> <p>Display/Symbols/Indicators Communication Different LED combinations when iOS device connected 11, 16</p> <p>Casing Ports iOS device port and downloadable app 16, 18</p>
Web link		http://www.

Comments	1	<p>Query According to the respective manuals, the measurement range for the BM85 is 60 mmHg to 260 mmHg for SBP and 40 mmHg to 199 mmHg for DBP whereas, for the BP3, it is 45 mmHg to 250 mmHg, with no breakdown for SBP and DBP. What are the rated ranges and technical alarm conditions, for both SBP and DBP, for each device?</p> <p>Response There is no technical alarm conditions in BP3, because BP3 was released before ISO 80601-2-30; The rated ranges SBP and DBP of BM85 are the ranges that described in the manual. If the measurement result is out of the ranges, it will active the technical alarm. The BP3 also can measure SBP from 60mmHg to 260mmHg, DBP from 40mmHg to 190mmHg, because BP3 is ours first inflation-measurement model, we reduced the public range of it's measurement.</p> <p>Comment Accepted</p>
	2	<p>Query The cuff provided with the BM85 is for arm circumferences 22 cm to 36 cm. An optional large (arm circ. 35 cm to 44 cm) cuff (order no. 163.387) is also available. The cuff provided with the BP3 is for arm circumferences 22 cm to 30 cm. An optional large (arm circ. 30 cm to 42 cm) cuff is also available. Despite the differences, item 6 "Cuffs or Bladders", in Part I, of Section A in the Declaration of Equivalence, is ticked as "No".</p> <p>a) Please supply the order numbers for all of the cuffs for each device.</p> <p>b) Please explain the differences in the cuffs provided, or available for, each device.</p> <p>Reply a) BP3: 22-30 cm, included no extra order number; 30-42 cm, not included, no extra order number BM85: 22-30 cm, included no extra order number 30-42 cm, order number 162.795</p> <p>b) No differences</p>

		Comment	Accepted
	3	Query	Is a zero pressure check used in the BM85 and is the \approx symbol for this purpose? No information is provided in the manual.
		Reply	Yes, that symbol is designed for the zero pressure check in the BM85
		Comment	Accepted
	4	Query	Does the BP3 record blood pressure during cuff inflation or during cuff deflation?
		Response	The BP3 that was validated in the science paper " Validation of iHealth BP3 upper-arm blood pressure monitor, for clinic use and self-measurement, according to European Society of Hypertension International Protocol revision 2010 " records blood pressure during inflation.
		Comment	Accepted
	5	Query	What pressure sensors are used in the BM85 and in the BP3?
		Response	Sensor:KD-2107-006G or KD-2107-006GR
		Comment	Accepted
	6	Query	The software for the iPhone app, used to process signals from the BP3, must have been developed separately from the firmware for the BM85. Please provide evidence of the validation and QA carried out proving that identical signals from the sensors result in identical blood pressure and pulse measurements or identical error notifications, as appropriate.
		Response	iOS app will not process signals from the BP3. All the measurement of SBP and DBP are finished in the BP3. iOS app and iOS device are only to show the measurement and manage the measurement results.
		Comment	Accepted
	7	Query	Please provide a manual of the iHealth BP3 App.
		Response	Submitted
		Comment	Accepted
	8	Query	The description, in Section B in Declaration of Equivalence, of the differences between the devices is inadequate. There is no mention that most of the functionality on the BP3 is provided via an app on an iOS device whereas, on the BM85, it is provided on device firmware. These devices appear to be very different. Please provide details of

		<p>i) Features provided on the BM85 but neither on the BP3 device nor on the iHealth BP3 App.</p> <p>ii) Comparable features provided on the BM85 and on the iHealth BP3 App.</p> <p>iii) Comparable features provided on the BM85 and on the BP3 device.</p> <p>iv) Features provided on the BP3 device and not on the BM85.</p> <p>Response i) BM85 have the function of HSD and Bluetooth, BP3 device and the iHealth app don't have;</p> <p>ii) iHealth BP3 App can manage the measurement result in visually charts, can share results instantly with friends, family, or your doctor. BM85 can't do that.</p> <p>iii) BM85 have the screen to show the result, the BP3 device don't have .</p> <p>iv) The BP3 device can connect to the iOS device and send the result to the iOS device.</p> <p>Comment Accepted</p>
Recommendation	Recommended	
Date	9 February 2015	