

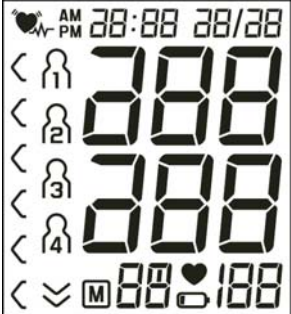



Comparison of the Beurer BM47 with the Andon KD-5915

Devices	Beurer BM47	Andon KD-5915
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Buttons/Switches</p> <p><i>Function</i></p> <p>Backward (– symbol) 10</p> <p>Forward (+ symbol) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation and Measurement Records</i></p> <p>User selection (1, 2, 3 or 4) 11, 14</p> <p><i>Post Measurement</i></p> <p>Memory zone average (M) 11, 13, 14</p> <p>7-day morning memory zone average (AM) 11, 13, 14</p> <p>7-day evening memory zone average (PM) 11, 13, 14</p> <p><i>Measurement Records</i></p> <p>User (1, 2, 3 or 4) 11</p>	

Devices	Beurer BM47	Andon KD-5915
Device 1 Criteria (Continued)	<p>Algorithms <i>Averages and Differences</i></p> <p>Memory zone mean 13</p> <p>7-day morning memory zone mean 13</p> <p>7-day evening memory zone mean 13</p>	
Same Criteria	<p>Measurement <i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm – 180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Automatic Inflation 7</p> <p>Zero pressure check before inflation^{Query 2} 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Medium (Arm circ. 22 to 30 cm)^{Query 3} 6</p> <p>Large (Arm circ. 30-42 cm) (Optional) 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G or KD-2107-006GR^{Query 4} 5</p> <p>Buttons/Switches <i>Power</i></p> <p>On/Off with Start/Stop (ⓘ label) 10</p> <p><i>Measurement Records</i></p> <p>Memory (M label) 10</p> <p>Display/Symbols/Indicators <i>Preparation</i></p> <p>Previous result displayed on BP start (User 1 to 4) 11, 14</p> <p>Release air (≅ symbol)^{Query 2} 11, 14</p> <p><i>Measurement Procedure</i></p> <p>Heartbeat symbol during deflation 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p>	<p>Measurement <i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5%^{Note 1} 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm – 180 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Automatic Inflation 7</p> <p>Zero pressure check before inflation^{Query 2} 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Medium (Arm circ. 22 to 30 cm)^{Query 3} 6</p> <p>Large (Arm circ. 30-42 cm) (Optional) 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G or KD-2107-006GR^{Query 4} 5</p> <p>Buttons/Switches <i>Power</i></p> <p>On/Off with Start/Stop (Start Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory (MEM label) 10</p> <p>Display/Symbols/Indicators <i>Preparation</i></p> <p>Previous result displayed on BP start 11, 14</p> <p>Remnant air in cuff (⬇ symbol) 11, 14</p> <p><i>Measurement Procedure</i></p> <p>Heartbeat symbol during deflation 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p>

Devices	Beurer BM47	Andon KD-5915
Same Criteria (Continued)	<p><i>Post Measurement (Continued)</i></p> <p>Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A) 11</p> <p>Hypertension (Indicator strip) 11, 13</p> <p>BP classification (WHO) 10, 11, 13</p> <p>Irregular heartbeat 11, 13, 18</p> <p><i>Measurement Records</i></p> <p>Memory "M" symbol 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</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>Irregular heartbeat detection 13</p> <p>Case</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 ~ 500 measurements 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 1 min 17</p> <p>Rechargeable batteries not permitted 17</p>	<p><i>Post Measurement (Continued)</i></p> <p>Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A) 11</p> <p>Hypertension (Indicator strip) 11, 13</p> <p>BP classification (WHO) 10, 11, 13</p> <p>Irregular heartbeat 11, 13, 18</p> <p><i>Measurement Records</i></p> <p>Memory "M" symbol 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</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>Irregular heartbeat detection 13</p> <p>Case</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 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 1 min 17</p> <p>Rechargeable batteries not permitted 17</p>
Comparable Criteria	<p>Measurement</p> <p><i>Method</i></p> <p>SBP 60 mmHg - 260 mmHg, DBP 40 mmHg - 199 mmHg^{Query 1} 1, 5, 7, 8</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p><i>Measurement Records</i></p> <p>Memory: 4 x 30 measurement 14</p>	<p>Measurement</p> <p><i>Method</i></p> <p>SBP 60 mmHg - 280 mmHg, DBP 30 mmHg - 199 mmHg^{Query 1} 1, 5, 7, 8</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 295 mmHg 1, 5, 7</p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements 14</p>
Device 2 Criteria		<p>Measurement</p> <p><i>Cuffs</i></p> <p>Extra Large (Arm circ. 42-48 cm) (Optional)^{Query 3} 6</p>

Devices	Beurer BM47	Andon KD-5915
Device 2 Criteria (Continued)		<p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurement 18</p> <p>Optional voiced assistance 18</p> <p><i>Post Measurement</i></p> <p>Error re-inflate (↑ symbol) 11, 14</p> <p>Optional voiced results 18</p> <p><i>Measurement Records</i></p> <p>Memory recall number 11</p> <p>Optional voiced records 18</p> <p><i>Settings</i></p> <p>Current unit (kPa / mmHg) marker ^{Note 2} 11</p> <p>Case</p> <p><i>Power</i></p> <p>AC adapter (Optional) 17</p>

Comments	<p>Andon is an OEM manufacturer for the BM47.</p> <p>The BM47 is functionally the same as the Andon KD-5915 with added dual user, averaging and touch screen but without the voiced results.</p> <p>There were four queries which have been answered satisfactorily.</p>
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Queries	<table border="1"> <tr> <td data-bbox="383 903 450 1420">1</td> <td data-bbox="450 903 2103 1420"> <p>Query</p> <p>Measurement ranges of 60 mmHg to 260 mmHg for SBP and 40 mmHg to 199 mmHg for DBP are described for the BM47. In reply to previous queries (30/04/2012 relating to the BM58, BM65, SBM43 and SBM45), the measurement range for the KD-5915 was stated as being 30 mmHg to 280 mmHg, without a breakdown for SBP and DBP.</p> <p>According to ISO 80601-2-30, the device must be capable (in non-neonatal mode) of indicating at least 60 mmHg to 230 mmHg for SBP and 40 mmHg to 130 mmHg for DBP (201.12.1.103), so specifying these separately is necessary. The maximum pressure allowed is 300 mmHg (201.12.1.104). It also requires that the pressure ranges provided are the rated pressures (201.7.9.2.9 h and 201.12.1.101).</p> <p>The overall rated pressure range for the BM47 is 40 mmHg to 260 mmHg, whereas it is 30 mmHg to 280 mmHg for the KD-5915. This is not explained by ISO 80601-2-30. While the algorithms and the pressure sensors may be the same, is there another reason for this difference? Please provide further details of the KD-5915 measurement range to clarify why the overall range for the BM47 appears to be more restricted.</p> <p>Reply</p> <p>According to ISO 80601-2-30, we have added a TECHNICAL ALARM CONDITION in the BM47; the KD-5915 doesn't have that function. When values of BP are outside the rated range, the BPM will not display the blood pressure value; instead, the</p> </td> </tr> </table>	1	<p>Query</p> <p>Measurement ranges of 60 mmHg to 260 mmHg for SBP and 40 mmHg to 199 mmHg for DBP are described for the BM47. In reply to previous queries (30/04/2012 relating to the BM58, BM65, SBM43 and SBM45), the measurement range for the KD-5915 was stated as being 30 mmHg to 280 mmHg, without a breakdown for SBP and DBP.</p> <p>According to ISO 80601-2-30, the device must be capable (in non-neonatal mode) of indicating at least 60 mmHg to 230 mmHg for SBP and 40 mmHg to 130 mmHg for DBP (201.12.1.103), so specifying these separately is necessary. The maximum pressure allowed is 300 mmHg (201.12.1.104). It also requires that the pressure ranges provided are the rated pressures (201.7.9.2.9 h and 201.12.1.101).</p> <p>The overall rated pressure range for the BM47 is 40 mmHg to 260 mmHg, whereas it is 30 mmHg to 280 mmHg for the KD-5915. This is not explained by ISO 80601-2-30. While the algorithms and the pressure sensors may be the same, is there another reason for this difference? Please provide further details of the KD-5915 measurement range to clarify why the overall range for the BM47 appears to be more restricted.</p> <p>Reply</p> <p>According to ISO 80601-2-30, we have added a TECHNICAL ALARM CONDITION in the BM47; the KD-5915 doesn't have that function. When values of BP are outside the rated range, the BPM will not display the blood pressure value; instead, the</p>
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Query

BPM will give a TECHNICAL ALARM CONDITION to tell the user the blood pressure is outside the rated range (40 mmHg to 199 mmHg for DBP or 60 mmHg to 260 mmHg for SBP).

Item 201.12.1.101 in ISO 80601-2-30 states that “The measuring and display ranges of the CUFF pressure shall be equal to the RATED range for CUFF pressure.” and “Values of BLOOD PRESSURE outside the RATED range for BLOOD PRESSURE shall not be displayed and the AUTOMATED SPHYGMOMANOMETER shall be equipped with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION that indicates when the determined BLOOD PRESSURE is outside the RATED range.” The technical alarm condition occurs, by definition, whenever a blood pressure outside the rated range is detected.

Please reply to each of the following

- 1) What are the measurement ranges for SBP and DBP for the KD-5915?
- 2) Please explain carefully how the measurement ranges can be the same but the displayed measurements different.
- 3) Please explain carefully how the KD-5915 does not have a technical alarm condition.

Reply

- 1) SBP:60mmHg–280mmHg, DBP:30mmHg–199mmHg
- 2) The calculation system, which calculates the SBP and DBP values, and the display system, part of which shows SBP and DBP values on the screen are separate parts of the device software. So even though the calculated values of SBP and DBP are the same, the values shown can be controlled, based on the requirements of relevant standards.
- 3) The KD-5915 was in the market before the release of ISO 80601-2-30. There weren't any standards at that time requiring a technical alarm system and, therefore, one was not designed.

Query

The following is our understanding of the replies:

Essentially both devices measure/calculate the same range of pressures. The KD-5915 was developed before ISO 80601-2 and, therefore, it simply displays blood pressures that occur within the full measurement range. Blood pressures outside that range are not measured at all and the result is an error. With the introduction of ISO 80601-2, some of the range had to be reserved in order to implement the technical alarm. Consequently, the maximum of the SBP rated range had to be reduced and the minimum of the DBP rated range increased. Blood pressures within the technical alarm ranges are measured but, to comply with ISO 80601-2, an error must be displayed.

mmHg	Measurement Range				Display Range			
	TA Low Range	Rated Range		TA High Range	DBP		SBP	
		Min	Max		Min	Max	Min	Max
ISO 80601-2-30	< RR	≤ 40	300	> RR	≤ 40	≥ 130	≤ 60	≥ 230
BM47	30-39	40	260	261-280	40	199	60	260
KD-5915	N/A	30	280	N/A	30	199	60	280

	<p>Is this correct?</p> <p>Reply The table is correct.</p> <p>Comment The explanation is accepted.</p>																																			
2	<p>Query Is the zero pressure check used in the BM47 and is the \approx symbol for this purpose? No information is provided in the manual.</p> <p>Reply Yes, the BM47 has the zero pressure check. Before the measurement, if the pressure is not stable, that symbol will be shown.</p> <p>Comment The explanation is accepted.</p>																																			
3	<p>Query The cuff provided with the BM47 is for arm circumferences 22 cm to 35 cm. An optional large (arm circ. 30 cm to 42 cm) cuff (order no. 162.795) is also available. The cuff provided with the KD-5915 is for arm circumferences 22 cm to 30 cm. Optional large (arm circ. 30 cm to 42 cm) and extra large (arm circ. 42 cm to 48 cm) cuffs are also available.</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 supplied cuffs.</p> <p>c) Can the extra large cuff, optionally available for the KD-5915, be used with the BM47?</p> <p>Reply There are 4 cuffs in total:</p> <p>1) 22-30 cm → bladder size: 120x240 mm.....Included in KD-5915</p> <p>2) 30-42 cm → bladder size: 120x340 mm.....Order number 162.795</p> <p>3) 22-35 cm → bladder size: 120x340 mm.....Included in BM47</p> <p>4) 42-48 cm → bladder size: 120x390 mm.....Can be ordered for KD-5915 (no order number available, because no plans to order)</p> <p>Query The following table summarises the information provided:</p> <table border="1"> <thead> <tr> <th></th> <th>Arm Circ.</th> <th>Bladder Size</th> <th>Cover</th> <th>Order No.</th> <th>BM47</th> <th>KD-5915</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>22 cm – 30 cm</td> <td>120 mm x 240 mm</td> <td>109% – 80%</td> <td>None</td> <td>No</td> <td>Yes, Included</td> </tr> <tr> <td>2</td> <td>22 cm – 35 cm</td> <td>120 mm x 340 mm</td> <td>155% – 97%</td> <td>None</td> <td>Yes, Included</td> <td>No</td> </tr> <tr> <td>3</td> <td>30 cm – 42 cm</td> <td>120 mm x 340 mm</td> <td>113% – 81%</td> <td>162.795</td> <td>Yes, by order</td> <td>Yes, by order</td> </tr> <tr> <td>4</td> <td>42 cm – 48 cm</td> <td>120 mm x 390 mm</td> <td>93% – 81%</td> <td>None</td> <td>Can be used</td> <td>Yes, by order</td> </tr> </tbody> </table>		Arm Circ.	Bladder Size	Cover	Order No.	BM47	KD-5915	1	22 cm – 30 cm	120 mm x 240 mm	109% – 80%	None	No	Yes, Included	2	22 cm – 35 cm	120 mm x 340 mm	155% – 97%	None	Yes, Included	No	3	30 cm – 42 cm	120 mm x 340 mm	113% – 81%	162.795	Yes, by order	Yes, by order	4	42 cm – 48 cm	120 mm x 390 mm	93% – 81%	None	Can be used	Yes, by order
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	<p>Please check the bladder size provided for the 22 cm – 35 cm cuff. However, assuming it is 120 mm x 280 mm (350 mm x 80% = 280 mm), there is a difference in the cuffs supplied. The cuffs are listed in Part 1 of the list of components, as they are critical to device equivalence. Different cuffs can result in different blood pressure values.</p> <p>Reply After long, internal discussion, we will use the 22-30 cm cuff for BM47. This is the original cuff also used with the KD-5915. Please find attached the equivalence letter. And we will use the larger cuff 30 – 42 cm as an extra part by order</p> <p>Comment The cuffs are now</p> <table border="1"> <thead> <tr> <th></th> <th>Arm Circ.</th> <th>Bladder Size</th> <th>Cover</th> <th>Order No.</th> <th>BM47</th> <th>KD-5915</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>22 cm – 30 cm</td> <td>120 mm x 240 mm</td> <td>109% – 80%</td> <td>None</td> <td>Yes, Included</td> <td>Yes, Included</td> </tr> <tr> <td>2</td> <td>30 cm – 42 cm</td> <td>120 mm x 340 mm</td> <td>113% – 81%</td> <td>162.795</td> <td>Yes, by order</td> <td>Yes, by order</td> </tr> </tbody> </table> <p>This is accepted.</p>		Arm Circ.	Bladder Size	Cover	Order No.	BM47	KD-5915	1	22 cm – 30 cm	120 mm x 240 mm	109% – 80%	None	Yes, Included	Yes, Included	2	30 cm – 42 cm	120 mm x 340 mm	113% – 81%	162.795	Yes, by order	Yes, by order
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4	<p>Query The pressure sensor for the KD-5915 is described as KD-2107-006G or KD-2107-006GR. No information is provided for the BM47. Are the same sensors used?</p> <p>Reply The answer is yes.</p> <p>Comment The explanation is accepted.</p>																					
Notes	<p>Previous queries, relating to the AndonKD-5915 are relevant. The replies were accepted.</p>																					
1	<p>Query No information on pulse accuracy is provided for the KD-5915. What is the pulse accuracy for the KD-5915?</p> <p>Reply The pulse accuracy of KD-5915 is +/- 5%</p>																					
2	<p>Query On the display screen of the KD-5915, there are units for mmHg and kPa that seem to indicate a conversion facility. No such ability is described. Can you please confirm this facility either way?</p> <p>Reply When the "START" button is pressed, all display characters are shown for self-test. The kPa is only displayed at the moment. It's a reserved function that the result is displayed for kPa. The function doesn't open, so the Operation Guide of the KD-5915 doesn't mention it. The displayed "kPa" is just a reserved functionality.</p>																					
Recommendation	Equivalence is recommended																					
Date	08/11/2013																					