

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 **Mr. Thomas Neubeck**, a Director of **Uebe Medical GmbH**,  
Name of a Company Director Company name

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

Maker <sup>a</sup>	Uebe Medical GmbH	Address	Zum Ottersberg 9, 97877 Wertheim / Germany
Manufacturer <sup>b</sup>	Uebe Medical GmbH	Address	Zum Ottersberg 9, 97877 Wertheim / Germany
Brand <sup>c</sup>	visomat®	Model <sup>d</sup>	comfort E, REF 24016

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 <sup>a</sup>	Uebe Medical GmbH	Address	Zum Ottersberg 9, 97877 Wertheim / Germany
Manufacturer <sup>b</sup>	Uebe Medical GmbH	Address	Zum Ottersberg 9, 97877 Wertheim / Germany
Brand <sup>c</sup>	visomat®	Model <sup>d</sup>	double comfort

Existing validated blood pressure measuring device.

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

Masiero S, Fania C, Palatini P. Validation of the UEBE Visomat Double Comfort upper arm blood pressure monitor, in oscillometry mode, for clinic use and self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010 [Internet]. Dublin: dablEducational Trust; 2011 Apr 27. 4 p. Available at: [http://www.dableducational.org/Publications/2011/ESH-IP\\_2010\\_Validation\\_of\\_UEBE\\_Visomat\\_Double\\_Comfort\\_\(Oscillometric\\_Mode\).pdf](http://www.dableducational.org/Publications/2011/ESH-IP_2010_Validation_of_UEBE_Visomat_Double_Comfort_(Oscillometric_Mode).pdf).

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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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 <sup>f</sup> <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	7	Inflation Mechanism	Yes <input checked="" type="checkbox"/>	No <input 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 checked="" type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input 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.

Part I

6) The microphone is the only difference between #2405001 and #2401601. Both cuffs use the same bladder size inside which is crucial for the same functionality in oscillometric mode.

7) Comfort E pumps up to 190~200mmHg and re-pumps if necessary to find a pressure from about 30-40mmHg above the systolic blood pressure. Double comfort pumps up with a fuzzy inflation until 40 mmHg above the systolic BP.

**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 \_\_\_\_\_

Name Thomas Neubeck

Date 22.08.2013



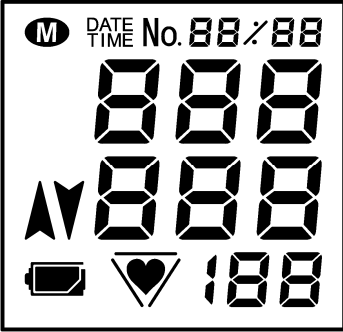
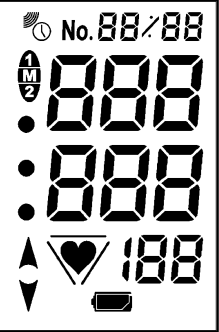
Signature of Witness \_\_\_\_\_

Name Felix Uebe

Address Zum Ottersberg 9, 97877 Wertheim / Germany




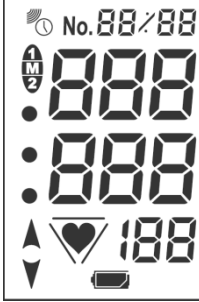

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Comparison of the visomat comfort E with the visomat double comfort

Devices	visomat® comfort E	visomat® double comfort
Reference Numbers	24016 (not comparable with the former visomat comfort E which was manufactured until the year 2007, it's reference number was 24020)	24050
Image		
Display		

Validation	ESH-IP 2010			
Device 1 Criteria				
Same Criteria	Measurement algorithm, Oscillometric	1,5	Measurement algorithm, Oscillometric	1,5
	Wide-range cuff 23-43cm	6	Wide-range cuff 23-43cm	6
	Pressure accuracy	11,13	Pressure accuracy	11,13
	Deflation with electronic control valve	8	Deflation with electronic control valve	8
	Pulse accuracy	11,13	Pulse accuracy	11,13
	Pressure indication range	11,13	Pressure indication range	11,13
	BP (SYS, DIA) range	11,13	BP (SYS, DIA) range	11,13
	Pulse range	11,13	Pulse range	11,13
	Irregular pulse rhythm detection	11,13	Irregular pulse rhythm detection	11,13
	Low battery indication	11,13	Low battery indication	11,13
	Automatic switch off function	11,13	Automatic switch off function	11,13
	Err indication (Err-1, 2, 3, 300)	3,11,13	Err indication (Err-1, 2, 3, 300)	3,11,13
	All memory average	13,14	All memory average	13,14
	4 x AA battery or AC adaptor	17	4 x AA battery or AC adaptor	17
	Buzzer	18	Buzzer	18
Comparable Criteria	60 x 1 memory	13,14	60 x 2 memory	13,14
	Automatic inflation	7	Automatic inflation	7
	LCD size (51.2 x 53.5mm)	11	LCD size (60 x 40mm)	11
	Design of main unit	10	Design of main unit	10
	1 x Start/Stop button, 1 x memory button	10	2 x Start/Stop button, 1 x memory button	10
	Design for air circuit	18	Design for air circuit	18
	Design for electrical circuit	18	Design for electrical circuit	18
Device 2 Criteria			Auscultatory Measurement	2
			Err-4 (microphone Err)	2,18
			Pulse pressure indication	11,13
			PC connection with USB interface kit	13,16
			Radio clock	18

Comparison of the UEBE Visomat Comfort E (Ref 24016) with the UEBE Visomat Double Comfort

Devices	UEBE Visomat Comfort E (Ref 24016)	UEBE Visomat Double Comfort
Pictures		
Display		
Validation		ESH-IP 2010
Device 1 Criteria		
Same Criteria	<p><b>Measurement</b></p> <p><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>SBP 50 mmHg – 250 mmHg, DBP 40 mmHg – 150 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm – 160 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>Inflation 0 mmHg – 300 mmHg 1, 5, 7</p> <p>Zero pressure check before inflation 7</p>	<p><b>Measurement</b></p> <p><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>SBP 50 mmHg – 250 mmHg, DBP 40 mmHg – 150 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm – 160 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>Inflation 0 mmHg – 300 mmHg 1, 5, 7</p> <p>Zero pressure check before inflation 7</p>







Devices	UEBE Visomat Comfort E (Ref 24016)	UEBE Visomat Double Comfort
Same Criteria (continued)	<b>Measurement (continued)</b>	<b>Measurement (continued)</b>
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation 8	Automatic Deflation 8
	<b>Buttons/Switches</b>	<b>Buttons/Switches</b>
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory 10	Memory 10
	<i>Settings</i>	<i>Settings</i>
	Date/Time set using Start/Stop and Memory buttons 10	Date/Time set using Start/Stop and Memory buttons 10
	<b>Display/Symbols/Indicators</b>	<b>Display/Symbols/Indicators</b>
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	Inflation symbol 11	Inflation symbol 11
	Deflation symbol 11	Deflation symbol 11
	During Measurement: BP Level & Heartbeat 11	During Measurement: BP Level & Heartbeat 11
	Beep after measurement 18	Beep after measurement 18
	<i>Post Measurement</i>	<i>Post Measurement</i>
	SBP, DBP and Pulse 11	SBP, DBP and Pulse 11
	Measurement error <i>Err 300, Err -1, Err -2, Err -3</i> 11	Measurement error <i>Err 300, Err -1, Err -2, Err -3</i> 11
	Average <i>R</i> symbol 11, 13, 14	Average <i>R</i> symbol 11, 13, 14
	Irregular heartbeat/Body movement 11, 13, 18	Irregular heartbeat/Body movement 11, 13, 18
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory “M” symbol 11	Memory “M” symbol 11
	Memory recall number 11	Memory recall number 11
	<i>Date and Time</i>	<i>Date and Time</i>
	Date and Time 11	Date and Time 11
	Date and Time (During memory recall) 11	Date and Time (During memory recall) 11
	<i>Power</i>	<i>Power</i>
	Low battery 11, 17	Low battery 11, 17
	<b>Algorithms</b>	<b>Algorithms</b>
<i>Diagnostic</i>	<i>Diagnostic</i>	
Irregular heartbeat/ Body movement detection 13	Irregular heartbeat/ Body movement detection 13	
<b>Case</b>	<b>Case</b>	
<i>Display</i>	<i>Display</i>	
Single screen display 10	Single screen display 10	
Segment LCD 10	Segment LCD 10	
<i>Power</i>	<i>Power</i>	
4 “AA” batteries > 800 measurements 17	4 “AA” batteries > 800 measurements 17	
AC adapter (Optional – Part #2401020) 17	AC adapter (Optional – Part #2401020) 17	

Devices	UEBE Visomat Comfort E (Ref 24016)	UEBE Visomat Double Comfort
Same Criteria (continued)	<p><b>Case (continued)</b> <i>Power (continued)</i></p> <p>Automatic switch-off when not used for 3 min 17</p> <p>Rechargeable batteries not permitted 17</p>	<p><b>Case (continued)</b> <i>Power (continued)</i></p> <p>Automatic switch-off when not used for 3 min 17</p> <p>Rechargeable batteries not permitted 17</p>
Comparable Criteria	<p><b>Measurement</b></p> <p><i>Inflation</i></p> <p>Automatic Inflation<sup>Query 2</sup> 7</p> <p><i>Cuffs</i></p> <p>Universal (Arm circ. 23 to 43 cm) #2401601<sup>Query 1</sup> 6</p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements 14</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On with Start/Stop (Start/Stop Label) 10</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>All measurements mean 13</p>	<p><b>Measurement</b></p> <p><i>Inflation</i></p> <p>Automatic Inflation<sup>Query 2</sup> 7</p> <p><i>Cuffs</i></p> <p>Universal (Arm circ. 23 to 43 cm) inc. Microphone #2405001<sup>Query 1</sup> 6</p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements × 2 zones 14</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On with Start/Stop × 2 (Start/Stop 1 and Start/Stop 2 Labels) 10</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Memory zone means 13</p>
Device 2 Criteria		<p><b>Measurement</b></p> <p><i>Method</i></p> <p>Auscultatory measurement method 1, 5</p> <p><i>Cuffs</i></p> <p>Small (Arm circ. 14 to 23 cm) optional, inc. Mic. #2405005<sup>Query 1</sup> 6</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Post Measurement</i></p> <p>PP 11</p> <p>Measurement error <math>E_{rr} -4</math> (Microphone fault) 11</p> <p>BP classification (WHO) 10, 11, 13</p> <p><i>Measurement Records</i></p> <p>Memory zone 11</p> <p><i>Settings</i></p> <p>Radio Clock 11, 16</p> <p><b>Algorithms</b></p> <p><i>Diagnostic</i></p> <p>WHO Guidelines 13</p> <p><i>Parameter Settings</i></p> <p>Automatic DCF77 time synchronisation (CET &amp; CEST only) 5, 18</p>

Devices	UEBE Visomat Comfort E (Ref 24016)	UEBE Visomat Double Comfort
Device 2 Criteria (continued)		<p><i>Case Ports</i> USB port, cable and PC software</p> <p style="text-align: right;">16, 18</p>

Queries	
1	<p>Query The universal cuff for the Visomat Double Comfort is #2405001, whereas that for the Visomat Comfort E is #2401601. In addition, a small cuff, #2405005, is available for the Visomat Double Comfort.</p> <p style="padding-left: 40px;">a) Is the presence of the microphone the only difference between #2405001 and #2401601?</p> <p style="padding-left: 40px;">b) In theory, could #2405005 be used with the Visomat Comfort E with the microphone left unattached?</p> <p>Response a) Yes, the microphone is the only difference between #2405001 and #2401601. Both cuffs use the same bladder size inside which is crucial for the same functionality in oscillometric mode.</p> <p style="padding-left: 40px;">b) Yes, it is possible to remove the tube from #2405005 and use the one from #2401601. #2405005 was not tested at the clinical trial of ESH, this is why we do not mention it in the device equivalence report.</p> <p>Comment The explanation is accepted.</p>
2	<p>Query The “Automatic Inflation” is declared as “Comparable” for both devices, rather than “Same”. Please explain.</p> <p>Response Both devices have automatic inflation.</p> <p style="padding-left: 40px;">The Comfort E pumps up to 190~200mmHg and re-pumps if necessary to find a pressure from about 30-40mmHg above the systolic blood pressure.</p> <p style="padding-left: 40px;">The Double Comfort pumps up with a fuzzy inflation until 40 mmHg above the systolic BP. For example - it pumps with a blood pressure from about 120 Sys only up to 160 mmHg, which is more comfortable for the user.</p> <p>Comment The explanation is accepted.</p>



<p><b>Queries (continued)</b></p>	<p>3</p>	<p><b>Query</b> A device, that is clearly different but also named the Visomat Comfort E, as shown below, is available currently. Please explain how these devices are distinguished in such a manner that an equivalence validation for the applicant device will not be mistakenly assumed to apply to the other device of the same name.</p> <table border="1" data-bbox="698 284 1859 627"> <thead> <tr> <th data-bbox="698 284 1279 323">Applicant Visomat Comfort E</th> <th data-bbox="1279 284 1859 323">Currently Available Visomat Comfort E</th> </tr> </thead> <tbody> <tr> <td data-bbox="698 323 1279 627">  </td> <td data-bbox="1279 323 1859 627">  </td> </tr> </tbody> </table> <p><b>Response</b> The picture of the Visomat Comfort E (white with light blue) show the former Comfort E, last production was in June 2007. The reference number of the old one was 24020 and was written on the label on the bottom of the housing.</p> <p>The picture of the Visomat Comfort E (white with dark blue) shows the new Visomat Comfort E, which will be launched into the market in September 2013. The reference number of it will be 24016 and it will be written on the label on the bottom of the housing.</p> <p>It is unlikely that there are still #24020 available for sale, as its production stopped 6 years ago.</p> <p><b>Comment</b> The reference numbers are sufficient to distinguish the devices.</p>	Applicant Visomat Comfort E	Currently Available Visomat Comfort E		
Applicant Visomat Comfort E	Currently Available Visomat Comfort E					
						
<p><b>Note</b></p>	<p>1</p>	<p>The UEBE Visomat Comfort E (Ref 24016) is essentially a scaled back version of the UEBE Visomat Double Comfort. The main difference is that latter can record measurements in both auscultatory and oscillometric modes (It was validated separately in each of these modes), whereas the former only uses oscillometry.</p> <p>As a consequence, the cuff for the Comfort E does not require a microphone. In the oscillometric validation for the Double Comfort, the standard cuff was used for all measurements and this is the same cuff, without the microphone, supplied with the Comfort E. (Query 1)</p> <p>There is a small difference between the inflation mechanisms of both devices whereby the Double Comfort does not inflate as high for those with SBP up to about 150 mmHg. (Query 2)</p>				
<p><b>Recommendation</b></p>	<p>Equivalence is recommended</p>					
<p><b>Date</b></p>	<p>27 August 2013</p>					