

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE www.dablededucational.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^a **Uebe Medical GmbH** Address **Zum Ottersberg 9, 97877 Wertheim / Germany**
 Manufacturer^b **Uebe Medical GmbH** Address **Zum Ottersberg 9, 97877 Wertheim / Germany**
 Brand^c **visomat®** Model^d **comfort eco, REF 24026**

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 **Uebe Medical GmbH** Address **Zum Ottersberg 9, 97877 Wertheim / Germany**
 Manufacturer^b **Uebe Medical GmbH** Address **Zum Ottersberg 9, 97877 Wertheim / Germany**
 Brand^c **visomat®** Model^d **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 oscillometric mode for clinical use and self measurement in a general population, according to the European Society of Hypertension *

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 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 ^g <input 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 checked="" type="checkbox"/>	No <input 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.

- 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.

6) The microphone is the only difference between the cuff of double comfort #24050001 and the cuff of visomat comfort eco #2401601. Both cuffs use the same bladder size which is crucial for the same functionality in oscillometric mode.

7) Comfort Eco pumps up to 180 mmHg and repumps if necessary to find a pressure from about 30-40 mmHg 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@dablededucational.org.

Signature of Director _____

Name Thomas Neubeck

Date 10 Apr. 2015

Signature of Witness _____




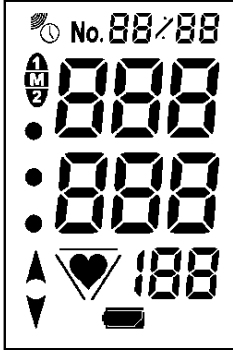
Name Felix Uebe

Address Zum Ottersberg 9, 97877 Wertheim / Germany

Company Stamp/Seal







UEBE Medical GmbH
Zum Ottersberg 9
D 97877 Wertheim
Tel. 093 42 - 9240 0
Fax 093 42 - 9240 60

Comparison of the Visomat comfort eco with the Visomat double comfort

Devices	visomat® comfort eco 24026	visomat® double comfort 24050										
Pictures												
Display												
Validation		ESH 2010										
Device 1 Criteria		<table border="0"> <tr> <td>Auscultatory Measurement</td> <td style="text-align: right;">2</td> </tr> <tr> <td>Err-4 (microphone Err)</td> <td style="text-align: right;">2,18</td> </tr> <tr> <td>Pulse pressure indication</td> <td style="text-align: right;">11,13</td> </tr> <tr> <td>PC connection with USB interface kit</td> <td style="text-align: right;">13,16</td> </tr> <tr> <td>Radio clock</td> <td style="text-align: right;">18</td> </tr> </table>	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
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											
Device 2 Criteria	None											
Same Criteria	<table border="0"> <tr> <td>Measurement algorithm</td> <td style="text-align: right;">1,5</td> </tr> <tr> <td>Wide-range cuff 23-43cm</td> <td style="text-align: right;">6</td> </tr> </table>	Measurement algorithm	1,5	Wide-range cuff 23-43cm	6	<table border="0"> <tr> <td>Measurement algorithm</td> <td style="text-align: right;">1,5</td> </tr> <tr> <td>Wide-range cuff 23-43cm</td> <td style="text-align: right;">6</td> </tr> </table>	Measurement algorithm	1,5	Wide-range cuff 23-43cm	6		
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	Pressure accuracy Deflation with electronic control valve Pressure indication range BP (SYS, DIA) range Pulse range Irregular pulse rhythm detection Low battery indicator Automatic switch off function Err indication (Err- 1,2,3, 300) All memory average 4 x AA Battery or AC adaptor Buzzer	11,13 8 11,13 11,13 11,13 11,13 11,13 11,13 3,11,13 13,14 17 18	Pressure accuracy Deflation with electronic control valve Pressure indication range BP (SYS, DIA) range Pulse range Irregular pulse rhythm detection Low battery indicator Automatic switch off function Err indication (Err- 1,2,3, 300) All memory average 4 x AA Battery or AC adaptor Buzzer	11,13 8 11,13 11,13 11,13 11,13 11,13 11,13 3,11,13 13,14 17 18
Comparable Criteria	60 x 1 Memory Automatic inflation LCD size (49.5 x 51mm) Design of main unit 1 x Start/stop button, 1 x memory button Design for air circuit Design for electrical circuit	13,14 7 11 10 10 18 18	60 x 2 Memory Automatic inflation LCD size (60 x 40mm) Design of main unit 2 x Start/stop button, 1 x memory button Design for air circuit Design for electrical circuit	13,14 7 11 10 10 18 18

Comments	1	<p>Query The universal cuff for the visomat double comfort is #2405001, whereas that for the visomat comfort eco is #2401601. In addition, small cuff, #2405005, is available for the visomat double comfort.</p> <p>a) Is the presence of the microphone the only difference between #2405001 and #2401601?</p> <p>b) In theory, could #2405005 be used with the visomat comfort eco 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>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 Accepted</p>
	2	<p>Query The “Automatic Inflation” is declared a “comparable” for both devices, rather than “same”; please explain.</p>

	<p>Response Both devices have automatic inflation. The Comfort Eco pumps up to ~180 mmHg and re-pumps if necessary to find the systolic blood pressure from about 30-40 mmHg above the systolic blood pressure. The Double Comfort pumps up with a fuzzy inflation until 40 mmHg above the systolic blood pressure. For example it pumps with a blood pressure from about 120Sys only up to 160 mmHg, which is more comfortable for the user.</p> <p>Comment Accepted</p>				
<p>3</p>	<p>Query A device, that is clearly different but also named the visomat comfort eco, as show 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 other device of the same name.</p> <table border="1" data-bbox="689 715 1877 1066"> <thead> <tr> <th data-bbox="689 715 1267 785">applicant visomat comfort eco #24026</th> <th data-bbox="1267 715 1877 785">currently available visomat comfort eco #24025</th> </tr> </thead> <tbody> <tr> <td data-bbox="689 785 1267 1066">  </td> <td data-bbox="1267 785 1877 1066">  </td> </tr> </tbody> </table> <p>Response The picture of the visomat comfort eco #24025 shows the “old” visomat comfort eco whose production is running out in 2015. The reference number of this device is 24025. The comfort eco #24025 need two different cuffs, one for arm circumferences 22-32 cm and one for 32-42 cm.</p> <p>The picture of the visomat comfort eco #24026 shows the new one, which will be launched into the market in September 2015. The reference number of it will be 24026 and it will be written on the bottom of the housing. The comfort eco #24026 needs one single cuff for arm circumferences 23-43 cm</p>	applicant visomat comfort eco #24026	currently available visomat comfort eco #24025		
applicant visomat comfort eco #24026	currently available visomat comfort eco #24025				
					

		Comment	Accepted
Recommendation	Recommended		
Date	13 April 2015		