SECTION A - Please complete all items.

I, Mr. Thomas Neubeck, a Director of Uebe Medical GmbH, hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker: Uebe Medical GmbH  
Address: Zum Ottersberg 9, 97877 Wertheim / Germany

Manufacturer: Uebe Medical GmbH  
Address: Zum Ottersberg 9, 97877 Wertheim / Germany

Brand: visomat®
Model: 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: Uebe Medical GmbH  
Address: Zum Ottersberg 9, 97877 Wertheim / Germany

Manufacturer: Uebe Medical GmbH  
Address: Zum Ottersberg 9, 97877 Wertheim / Germany

Brand: visomat®
Model: 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:

<table>
<thead>
<tr>
<th>Part I</th>
<th>1 Algorithm for Oscillometric Measurements</th>
<th>Yes ☑</th>
<th>No ☐</th>
<th>N/A ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 Algorithm for Auscultatory Measurements</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>3 Artefact/Error Detection</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>4 Microphone(s)</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>5 Pressure Transducer</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>6 Cuffs or Bladders</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>7 Inflation Mechanism</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>8 Deflation Mechanism</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part II</th>
<th>9 Model Name or Number</th>
<th>Yes ☑</th>
<th>No ☐</th>
<th>N/A ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 Casing</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>11 Display</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>12 Carrying/Mounting Facilities</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>13 Software other than Algorithm</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>14 Memory Capacity/Number of stored measurements</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>15 Printing Facilities</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>16 Communication Facilities</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>17 Power Supply</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
<tr>
<td></td>
<td>18 Other Facilities</td>
<td>Yes ☑</td>
<td>No ☐</td>
<td>N/A ☐</td>
</tr>
</tbody>
</table>

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.
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@dableducational.org.

Signature of Director ___________________________ Company Stamp/Seal

Name Thomas Neuleck
Date 10 Apr. 2019

Signature of Witness ___________________________

Name Felix Uebe
Address Zum Ottersberg 9, 97877 Wertheim / Germany
## Comparison of the Visomat comfort eco with the Visomat double comfort

<table>
<thead>
<tr>
<th>Devices</th>
<th>visomat® comfort eco 24026</th>
<th>visomat® double comfort 24050</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pictures</strong></td>
<td><img src="image1" alt="Visomat comfort eco" /></td>
<td><img src="image2" alt="Visomat double comfort" /></td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td><img src="image3" alt="Display comfort eco" /></td>
<td><img src="image4" alt="Display double comfort" /></td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>ESH 2010</td>
<td></td>
</tr>
<tr>
<td><strong>Device 1 Criteria</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auscultatory Measurement</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Err-4 (microphone Err)</td>
<td>2,18</td>
<td></td>
</tr>
<tr>
<td>Pulse pressure indication</td>
<td>11,13</td>
<td></td>
</tr>
<tr>
<td>PC connection with USB interface kit</td>
<td>13,16</td>
<td></td>
</tr>
<tr>
<td>Radio clock</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td><strong>Device 2 Criteria</strong></td>
<td>None</td>
<td></td>
</tr>
<tr>
<td><strong>Same Criteria</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurement algorithm</td>
<td>1,5</td>
<td>Measurement algorithm</td>
</tr>
<tr>
<td>Wide-range cuff 23-43cm</td>
<td>6</td>
<td>Wide-range cuff 23-43cm</td>
</tr>
</tbody>
</table>
Pressure accuracy | 11,13 | Deflation with electronic control valve | 8
Deflation with electronic control valve | 8 | 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 indicator | 11,13
Low battery indicator | 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 | 4 | 60 x 1 Memory | 13,14
60 x 1 Memory | 13,14 | Automatic inflation | 7
Automatic inflation | 7 | LCD size (49.5 x 51mm) | 11
LCD size (49.5 x 51mm) | 11 | Design of main unit | 10
Design of main unit | 10 | 1 x Start/stop button, 1 x memory button | 10
1 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 | 60 x 2 Memory | 13,14
60 x 2 Memory | 13,14 | Automatic inflation | 7
Automatic inflation | 7 | LCD size (60 x 40mm) | 11
LCD size (60 x 40mm) | 11 | Design of main unit | 10
Design of main unit | 10 | 2 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

**Comments**

1. **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.  
a) Is the presence of the microphone the only difference between #2405001 and #2401601?  
b) In theory, could #2405005 be used with the visomat comfort eco with the microphone left unattached?

1. **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.  
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.

1. **Comment**  
Accepted

2. **Query**  
The “Automatic Inflation” is declared a “comparable” for both devices, rather than “same”; please explain.
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.

Comment

Accepted

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.

<table>
<thead>
<tr>
<th>applicant visomat comfort eco #24026</th>
<th>currently available visomat comfort eco #24025</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Applicant Visomat Comfort Eco" /></td>
<td><img src="image2.png" alt="Currently Available Visomat Comfort Eco" /></td>
</tr>
</tbody>
</table>

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.

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
<table>
<thead>
<tr>
<th>Comment</th>
<th>Accepted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendation</strong></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td>13 April 2015</td>
</tr>
</tbody>
</table>