SECTION A - Please complete all items.

Kevin Tan, a Director of Guangdong Transtek Medical Electronics Co., Ltd hereby state that there are no differences that will affect blood pressure measuring accuracy between the blood pressure measuring device and the validated blood pressure measuring device

Maker: Kaz Europe Sàrl
Address: Place Chauderon 18, 1003 Lausanne, Switzerland

Manufacturer: Transtek
Address: 

Brand: Braun
Model: BUA6150

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

Maker: Guangdong Transtek Medical Electronics Co., Ltd
Address: Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China

Manufacturer: Guangdong Transtek Medical Electronics Co., Ltd
Address: Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China

Brand: TRANSTEK
Model: TMB-986

Existing validated blood pressure measuring device.

which has previously passed the 2002 protocol, the results of which were published as follows:

Title: Validation of the TRANSTEK blood pressure monitor TMB-986 for home blood pressure monitoring according to the International Protocol

Authors: Wen Jun Liu; Su Gang Li; Zhe Song; Wei Gong

Publication: Blood Pressure Monitoring. 15(5):278-280, OCT 2010

Full reference

The only differences between the devices involve the following components:

Tick one box for each item 1–18.

<table>
<thead>
<tr>
<th>Part</th>
<th>Item</th>
<th>Device 1</th>
<th>Device 2</th>
<th>Device 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Algorithm for Oscillometric Measurements</td>
<td>Yes</td>
<td>No</td>
<td>N/A*</td>
</tr>
<tr>
<td>2</td>
<td>Algorithm for Auscultatory Measurements</td>
<td>Yes</td>
<td>No</td>
<td>N/A*</td>
</tr>
<tr>
<td>3</td>
<td>Artefact/Error Detection</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Microphone(s)</td>
<td>Yes</td>
<td>No</td>
<td>N/A*</td>
</tr>
<tr>
<td>5</td>
<td>Pressure Transducer</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Cuffs or Bladders</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Inflation Mechanism</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Deflation Mechanism</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Model Name or Number</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Casing</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Display</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Carrying/Mounting Facilities</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Software other than Algorithm</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Memory Capacity/Number of stored measurements</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Printing Facilities</td>
<td>Yes</td>
<td>No</td>
<td>N/A*</td>
</tr>
<tr>
<td>16</td>
<td>Communication Facilities</td>
<td>Yes</td>
<td>No</td>
<td>N/A*</td>
</tr>
<tr>
<td>17</td>
<td>Power Supply</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>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.
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.

See attached document

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

Kevin Tan

Date

September 6, 2018

Signature of Witness

Wan Hu

Name

Wan Hu

Address

Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China
# Comparison of the BRAUN BUA6150 with the TRANSTEK TMB-986

<table>
<thead>
<tr>
<th>Devices – Item 9</th>
<th>BRAUN BUA6150</th>
<th>TRANSTEK TMB-986</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pictures</strong></td>
<td><img src="image1" alt="BRAUN BUA6150 Picture" /></td>
<td><img src="image2" alt="TRANSTEK TMB-986 Picture" /></td>
</tr>
<tr>
<td><strong>Display Image</strong></td>
<td><img src="image3" alt="BRAUN BUA6150 Display" /></td>
<td><img src="image4" alt="TRANSTEK TMB-986 Display" /></td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>ESH 2010 ESH 2002 BHS AAMI</td>
<td>Upper arm device for self-measurement of blood pressure</td>
</tr>
<tr>
<td><strong>Category</strong></td>
<td>Upper arm device for self-measurement of blood pressure</td>
<td>Upper arm device for self-measurement of blood pressure</td>
</tr>
<tr>
<td><strong>Casing – Item 10</strong></td>
<td><strong>Dimensions</strong> 110mm<em>124mm</em>113mm</td>
<td><strong>Dimensions</strong> 182mm<em>100mm</em>39mm</td>
</tr>
<tr>
<td></td>
<td><strong>Ports</strong> Cuff port</td>
<td><strong>Ports</strong> Cuff port and DC power port</td>
</tr>
<tr>
<td></td>
<td><strong>Features</strong></td>
<td><strong>Features</strong></td>
</tr>
<tr>
<td>Display – Item 11</td>
<td>Type</td>
<td>LCD (negative type – white on black background)</td>
</tr>
<tr>
<td>------------------</td>
<td>------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Carrying/Mounting Facilities – Item 12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Software other than Algorithm – Item 13</td>
<td>40 sets memories/per user (2*40) 4 grade indicator mmHg unit</td>
<td>40 sets memories/per user (2*60) 6 grade indicator mmHg unit</td>
</tr>
<tr>
<td>Memory Capacity Item 14</td>
<td>40 sets memories/per user</td>
<td>60 sets memories/per user</td>
</tr>
<tr>
<td>Printing Facilities Item 15</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Communication Facilities – Item 16</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Power Supply Item 17</td>
<td>4*AA batteries</td>
<td>4*AAA batteries DC power socket (6V)</td>
</tr>
<tr>
<td>Other differences</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Same Criteria</td>
<td><strong>Measurement</strong></td>
<td><strong>Measurement</strong></td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>Pulse accuracy ± 5%</td>
<td>Pulse accuracy ± 5%</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>Oscillometric measurement method Manually initiated measurement Measurements are from single inflations</td>
<td>Oscillometric measurement method Manually initiated measurement Measurements are from single inflations</td>
</tr>
<tr>
<td><strong>Rated cuff pressure:</strong> 0 mmHg – 300 mmHg</td>
<td><strong>Rated cuff pressure:</strong> 0 mmHg – 300 mmHg</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Pulse 40 bpm – 199 bpm</strong></td>
<td><strong>Pulse 40 bpm – 199 bpm</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Inflation**
- Automatic inflation by internal pump
- Zero pressure check before inflation

**Deflation**
- Automatic Deflation
- Automatic safety release

**Cuffs (Please state sizes and materials used)**
- **Nylon**
  - Small/Medium (Arm circ. 22 cm to 32 cm) # TMB-1250-02
  - Large/XLarge (Arm circ. 32-42 cm) # TMB-1250-03

**Sensors**
- Piezoelectric (semiconductor) pressure sensor

**Measurement Records**
- YES: SYS, DIA, Pulse, IHB, Date & time

**Measurements other than Blood Pressure**
- Pulse (heart rate)
- Irregular heartbeat
- Date & time

**Buttons/Switches**
- **Power**
  - On/Off with Start/Stop (Start Label)

**Measurement Records**
- Memory
- User ID (A or B)

**Display/Symbols/Indicators**
- Preparation
  - Zero pressure adjust - arrow down symbol

**Sensors**
- Piezoelectric (semiconductor) pressure sensor

**Measurement Records**
- YES: SYS, DIA, Pulse, IHB, Date & time

**Measurements other than Blood Pressure**
- Pulse (heart rate)
- Irregular heartbeat
- Date & time

**Buttons/Switches**
- **Power**
  - On/Off with Start/Stop (Start/Stop Label)

**Measurement Records**
- Memory
- User ID (A or B)

**Display/Symbols/Indicators**
- Preparation
  - Zero pressure adjust - arrow down symbol
## Measurement Procedure

### During Measurement:
- Cuff pressure level & heartbeat symbol

### Post Measurement:
- SBP, DBP and Pulse
- BP classification (WHO)

### Measurement Records:
- Memory recall number
- User (A or B)
- Date and Time
- Date and Time (During memory recall)

### Power:
- Low battery indicator

### Function:
- N/A

### Communication:
- N/A

### Features:
- Average of last 3 records

---

## Comparable Criteria

### Measurement

#### Accuracy
- BP accuracy ± 3 mmHg (10°C-40°C)

#### Measurement Records
- Memory: 40 measurements × 2 users

### Buttons/Switches

#### Settings
- Date/Time set

---

### Measurement

#### Accuracy
- BP accuracy ± 3 mmHg (15°C-25°C) ± 6 mmHg otherwise

#### Measurement Records
- Memory: 60 measurements × 2 users

### Buttons/Switches

#### Settings
- Set
### Display/Symbols/Indicators

**Post Measurement**
- Measurement error E1, E2, E3, E4, Eexx
- Hypertension (Indicator strip)
- Average (Icon)

**Measurement Records**
- Memory “M” symbol

**Date and Time**
- Date and Time

**Casing**
- Power
- 4 “AA” batteries ~ 300 measurements

### Display/Symbols/Indicators

**Post Measurement**
- Measurement error E1, E2, E3, (E10, E11) → E4, E20, E21, Eexx
- Hypertension (Grading strip)
- Average (AVG)

**Measurement Records**
- Memory icon (Magnifying glass)

**Date and Time**
- Setting of Date and Time set but only display of Time

**Casing**
- Power
- 4 “AAA” batteries

### Comments

Braun BUA6150 is similar to previous Braun BP6000 series (BP600, BP6100, BP6200)

Braun BP6000 is already ESH approved by equivalence to Transtek TMB-986

### Recommendation

Recommended

### Date

15 November 2018