

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items online.

I HAN, JEA WOO Director of Genexel Medical Instruments, Inc
Name of a Company Director Company name

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

BP1700 (Braun BP VitalScan Plus 1700)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

BP1650 (Braun BP VitalScan Plus 1650)
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the ESH protocol, the results of which were published as follows

Nolly H, Osso P, Nolly A, Silva M and Romero M.
Authors(s)

Self-measurement of blood pressure: validation of the Braun BP VitalScan Plus 1650 monitor

According to the European Society of Hypertension International Protocol
Title

Blood Pressure Monitoring 2008, 13 : 101-106
Publication Year Volume Pages


The only differences between the devices involve the following components:

(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences below.)

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <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"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" 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 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 type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Brief explanation of differences and further relevant details:

SECTION B - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director 

Company Stamp/Seal

Name HAN, JEA WOO

Date 2009. 5. 19

Genexel Medical, Inc.



Signature of Witness 

Name Seo, Jongwon



Address 111, Yangjae-dong, Seocho-gu, Seoul, Korea



An accepted equivalence application **Additional information supplied by applicant**

	Submitted device (1)	Validated device (2)
Devices	BP1700	BP1650
Images		
Validation		BHS Wrist Blood Pressure Devices (Incorrect – ESH)
Device 1 criteria	Memory preservation	
Same criteria	Oscillometric measuring method	Oscillometric measuring method
	Error code (ERR and ----)	Error code (ERR and ----)
	Cuffs (device attached type)	Cuffs (device attached type)
	LR03(AAA) 1.5V × 2 batteries	LR03(AAA) 1.5V × 2 batteries
Comparable criteria	Memory : 60 measurements	Memory : 20 measurements
Comments	The BP1700 has memory preservation. As far as accuracy is concerned, these are clearly equivalent. Not for applicant to decide	
Recommendation	Accept	Not for applicant to decide

Comparison of the Braun BP VitalScan Plus 1700 with the Braun BP VitalScan Plus 1650

Devices	Braun BP VitalScan Plus 1700	Braun BP VitalScan Plus 1650
Pictures		
Validation		ESH
Device 1 Criteria		
Same Criteria^{1z}	<p>Accuracy ± 3 mmHg (AAMI ± 5 (8) mmHg) 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>Measurement ≤ 300 mmHg SBP, ≥ 20 mmHg DBP 1, 5</p> <p>BP 0 mmHg to 320 mmHg, Pulse 40-199 bpm 1, 5, 7, 8</p> <p>Sensor not described 5</p> <p>Cuff: (Wrist circ. 13 to 21 cm) 6</p> <p>Inflation: "Automatic" 7</p> <p>Deflation: Step valve 8</p> <p>Date/Time Set button 10</p> <p>I/O button 10</p> <p>Single screen LCD display 10</p> <p>Memory button, memory symbol 10, 11</p> <p>Date/Time Display 11</p> <p>Low battery symbol 11, 17</p> <p>Power: 2 "AAA" batteries ~ 200 measurements 17</p> <p>Power: Automatic switch-off when not used for 1 min 17</p>	<p>Accuracy ± 3 mmHg (AAMI ± 5 (8) mmHg) 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>Measurement ≤ 300 mmHg SBP, ≥ 20 mmHg DBP 1, 5</p> <p>BP 0 mmHg to 3200 mmHg, Pulse 40-199 bpm 1, 5, 7, 8</p> <p>Sensor not described 5</p> <p>Cuff: (Wrist circ. 13 to 21 cm) 6</p> <p>Inflation: "Automatic" 7</p> <p>Deflation: Step valve 8</p> <p>Date/Time Set button 10</p> <p>Start/Stop button 10</p> <p>Single screen LCD display 10</p> <p>Memory button, memory symbol 10, 11</p> <p>Date/Time Display 11</p> <p>Low battery symbol 11, 17</p> <p>Power: 2 "AAA" batteries ~ 200 measurements 17</p> <p>Power: Automatic switch-off when not used for 1 min 17</p>
Comparable Criteria	Memory: 60 measurements (Non volatile) 11, 14	Memory: 20 measurements (Remove batteries for 15s to erase) 11, 14
Device 2 Criteria		
Web link		http://www.braun.com/global/products/healthwellness/bloodpressure/vitalscanplus/models/bp1650.html

<p>Comments</p>	<p>The only difference between these models is in the memory functions. In the 1650, memory is erased if the batteries are removed for 15s – effectively when changing the batteries. In the 1700, the measurements cannot be erased. After 60 measurements, the oldest ones are overwritten.</p> <p>Query The manual claims accuracy according to the AAMI standard. This claim is also made on your website and on several independent vendor sites. Unfortunately no reference to a publication is given.</p> <p>Response Regarding the AAMI concern, AAMI SP10 test protocol is a prerequisite for FDA approval. This device has already been approved by FDA.</p>
<p>Recommendation</p>	<p>Equivalence is Recommended</p>
<p>Date</p>	<p>17/07/2009</p>