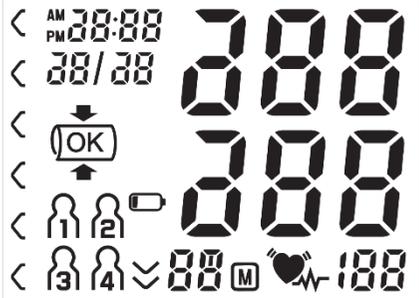
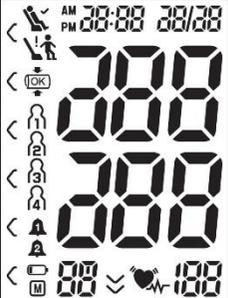


Comparison of the BEURER BM27 with the BEURER BM28

Devices – Item 9	BEURER BM27	BEURER BM28
Pictures		
Display Image		
Validation		ESH 2010 ESH 2002 BHS AAMI
Category	Blood Pressure Monitor Device	Blood Pressure Monitor Device
Casing – Item 10	<p><i>Dimensions</i> L 112mm x W 110mm x H 53mm</p> <p><i>Ports</i> Cuff Port (left side)</p> <p><i>Features</i> Systolic and diastolic blood pressure measurement 4x30 memory, cuff tightness indicator, IHB (irregular heartbeat) detection, Pulse rate measurement, risk indicator according WHO guidelines</p>	<p><i>Dimensions</i> L 134mm x W 103mm x H 60mm</p> <p><i>Ports</i> Cuff Port (left side)</p> <p><i>Features</i> Systolic and diastolic blood pressure measurement 4x30 memory, cuff tightness indicator, IHB (irregular heartbeat) detection, Pulse rate measurement, risk indicator according WHO guidelines</p>
Display – Item 11	<p><i>Type</i> LCD</p>	<p><i>Type</i> LCD</p>

	Segment LCD	Segment LCD
Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	4 User, date and time, 2 Alarm Average Memory zone 7- day morning average memory-zone 7- day evening average memory-zone Risk indicator WHO Guidelines 1999	4 User, date and time, 2 Alarm Average Memory zone 7- day morning average memory-zone 7- day evening average memory-zone Risk indicator WHO Guidelines 1999
Memory Capacity Item 14	<i>Number of stored measurements</i> 30 memories x 4 users	<i>Number of stored measurements</i> 30 memories x 4 users
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	Alkaline Battery (DC 6V 600mA, LR6 (AA) 1.5V x 4 pcs) Battery Life ~ 300 measurements	Alkaline Battery (DC 6V 600mA, LR6 (AA) 1.5V x 4 pcs) Battery Life ~ 300 measurements Optional: Power Adapter Connection 6V-600mA
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i>	<i>Other Details on Validated device that are different to Equivalent device</i> HSD (Hämodynamic stability) Indikator
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy \pm 3mmHg Pulse accuracy \pm 5%</p> <p><i>Method</i></p> <p>Oscillometric method made during cuff deflation</p> <p><i>Ranges</i></p> <p>Cuff pressure 0-300mmHg Systolic pressure: 50 – 280 mmHg Diastolic pressure: 30 – 200 mmHg Pulse rate: 40 – 199 pulse/minute</p> <p><i>Inflation</i></p> <p>Inflation 0mmHg – 300mmHg</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy \pm 3mmHg Pulse accuracy \pm 5%</p> <p><i>Method</i></p> <p>Oscillometric method made during cuff deflation</p> <p><i>Ranges</i></p> <p>Cuff pressure 0-300mmHg Systolic pressure: 50 – 280 mmHg Diastolic pressure: 30 – 200 mmHg Pulse rate: 40 – 199 pulse/minute</p> <p><i>Inflation</i></p> <p>Inflation 0mmHg – 300mmHg</p>

	<p>Automatic Inflation by internal Pump Zero pressure check before inflation</p> <p><i>Deflation</i> Automatic Deflation System</p> <p><i>Cuffs (Please state sizes and materials used)</i> Polyester Material Standard Type: 22 – 42 cm (Original) Bladder dimension: 140 x 250mm</p> <p><i>Sensors</i> MSP40-GSF</p> <p><i>Measurement Records</i> Memory Capacity: 30 memories x 4 users</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches <i>Power</i> Start/Stop ( Symbol)</p> <p><i>Measurement Records</i> Memory ( Symbol)</p> <p>Forward ( Symbol)</p> <p>Backward ( Symbol)</p> <p><i>Function</i> Start/Stop ( Symbol) Start/Stop Measurement</p> <p>Memory ( Symbol) Enter Memory Mode</p> <p>Forward ( Symbol) Increase value or go forward</p> <p>Backward ( Symbol) decrease value or go backward</p>	<p>Automatic Inflation by internal Pump Zero pressure check before inflation</p> <p><i>Deflation</i> Automatic Deflation System</p> <p><i>Cuffs(Please state sizes and materials used)</i> Polyester Material Standard Type: 22 – 42 cm (Original) Bladder dimension: 140 x 250mm</p> <p><i>Sensors</i> MSP40-GSF</p> <p><i>Measurement Records</i> Memory Capacity: 30 memories x 4 users</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches <i>Power</i> Start/Stop ( Symbol)</p> <p><i>Measurement Records</i> Memory ( Symbol)</p> <p>Forward ( Symbol)</p> <p>Backward ( Symbol)</p> <p><i>Function</i> Start/Stop ( Symbol) Start/Stop Measurement</p> <p>Memory ( Symbol) Enter Memory Mode</p> <p>Forward ( Symbol) Increase value or go forward</p> <p>Backward ( Symbol) decrease value or go backward</p>
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	<p>Setting (SET Symbol) Enter Setting mode (Date, Time)</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators <i>Preparation</i></p> <p> Zero pressure check used</p> <p><i>Measurement Procedure</i> Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol</p> <p><i>Post Measurement</i> SBP, DBP and Pulse Measurement Error's: E1, E2, E3, E4, E5, E6, Battery Low Memory-Zone mean (A symbol) 7- day morning memory-zone mean (AM symbol) 7- day evening memory-zone mean (PM symbol) WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection and indication</p> <p><i>Measurement Records</i> Memory Capacity: 30 memories x 4 users</p> <p><i>Date and Time</i> Date and Time Date and Time (During memory recall and measuring)</p>	<p>Setting (SET Symbol) Enter Setting mode (Date, Time)</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators <i>Preparation</i></p> <p> Zero pressure check used</p> <p><i>Measurement Procedure</i> Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol</p> <p><i>Post Measurement</i> SBP, DBP and Pulse Measurement Error's: E1, E2, E3, E4, E5, E6, Battery Low Memory-Zone mean (A symbol) 7- day morning memory-zone mean (AM symbol) 7- day evening memory-zone mean (PM symbol) WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection and indication HSD Indicator</p> <p><i>Measurement Records</i> Memory Capacity: 30 memories x 4 users</p> <p><i>Date and Time</i> Date and Time Date and Time (During memory recall and measuring)</p>
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	<p><i>Power</i> Alkaline Battery (DC 6V 600mA, LR6 (AA) 1.5V x 4 pcs) Battery Life ~ 300 measurements</p> <p><i>Function</i> Measurement during deflation</p> <p><i>Communication</i> N/A</p> <p><i>Features</i></p> <p><i>Not described</i></p> <p>Algorithms <i>Averages and Differences</i> A (Average of all measurements); AM (Average morning 5:00AM-9:00AM), PM (Average Evening 6:00PM- 8:00PM)</p> <p><i>Diagnostic</i> WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection</p> <p><i>Functions</i></p> <p><i>Communication</i> N/A</p>	<p><i>Power</i> Alkaline Battery (DC 6V 600mA, LR6 (AA) 1.5V x 4 pcs) Battery Life ~ 300 measurements Optional: Power Adapter Connection 6V-600mA</p> <p><i>Function</i> Measurement during deflation</p> <p><i>Communication</i> N/A</p> <p><i>Features</i></p> <p><i>Not described</i></p> <p>Algorithms <i>Averages and Differences</i> A (Average of all measurements); AM (Average morning 5:00AM-9:00AM), PM (Average Evening 6:00PM- 8:00PM)</p> <p><i>Diagnostic</i> WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection</p> <p><i>Functions</i></p> <p><i>Communication</i> N/A</p>
Comparable Criteria		

Comments	
Recommendation	RECOMMENDED
Date	April 2022

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

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

SECTION A - Please complete all items.

I **Marco Bühler,** a Director of **Beurer 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	Beurer GmbH	Address	BEURER GmbH * Söflinger Straße 218 * 89077 Ulm / Germany
Manufacturer^b	Beurer GmbH	Address	BEURER GmbH * Söflinger Straße 218 * 89077 Ulm / Germany
Brand^c	Beurer	Model^d	BM27

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	Beurer GmbH	Address	BEURER GmbH * Söflinger Straße 218 * 89077 Ulm / Germany
Manufacturer^b	Beurer GmbH	Address	BEURER GmbH * Söflinger Straße 218 * 89077 Ulm / Germany
Brand^c	Beurer	Model^d	BM28

Existing validated blood pressure measuring device.

which has previously passed the ESH-2010 protocol, the results of which were published as follows:

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 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 checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" 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.

- 9. Modelname has been changed, it is a device with a different design and slightly changed functions beside the algorithm.
10. Casing has been changed with no change of the algorithm
11. Display has been changed so that it fits to the new design of the housing.
12. Mounting facilities have been change because of the new design.
13. Software beside the algorithm has beend changed. There is an additional HSD (hemodynamic stability diagnostic) function, which helps the user to make sure that he is in rest before doing a measurement. This function is only available for BM28, the validated device.
17. BM28 can be used with a power adapter optionally, BM27 only with batteries.

SECTION C Please check that the following are included with the application

- A manual for the validated device [X]
A manual for the device for which equivalence is being sought [X]
Completed DET9 Form [X]
An image of the device for which equivalence is being sought [X]
An image of the screen layout of validated device* [X]
An image of the screen layout of the device for which equivalence is being sought* [X]

* 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 [Signature]
Name MARCO BÜHLER
Date 5.4.2022
Signature of Witness [Signature]
Name DR. DIRK FREUND
Address 12.4.2022

Company Stamp/Seal Beurer GmbH
Söflinger Straße 218 • 89077 Ulm