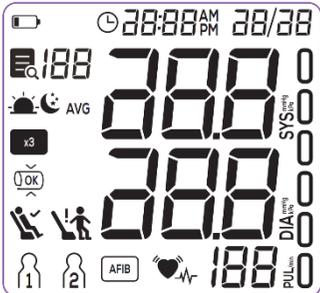
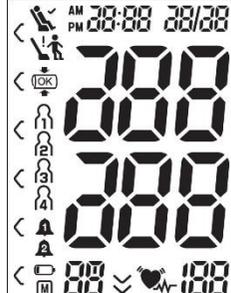


Comparison of the BEURER BM 53 with the BEURER BM 28

Devices – Item 9	BEURER BM 53	BEURER BM 28
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 140 mm x 94 mm x 46 mm</p> <p><i>Ports</i> Cuff Port (left side) USB-C Port (left side)</p> <p><i>Features</i> Systolic and diastolic blood pressure measurement 2x100 memory, cuff tightness indicator, IHB (irregular heartbeat) detection, AFIB 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>Type LCD Segment LCD</p>	<p>Type LCD Segment LCD</p>

Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	2 User, date and time, 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> 100 memories x 2 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 Optional: Power Adapter Connection 5V-1A	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> AFIB detection, USB-C for Power supply	<i>Other Details on Validated device that are different to Equivalent device</i>
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i> BP accuracy \pm 3mmHg Pulse accuracy \pm 5%</p> <p><i>Method</i> Oscillometric method made during cuff deflation</p> <p><i>Ranges</i> 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> Inflation 0mmHg – 300mmHg Automatic Inflation by internal Pump Zero pressure check before inflation</p> <p><i>Deflation</i> Automatic Deflation System</p>	<p>Measurement</p> <p><i>Accuracy</i> BP accuracy \pm 3mmHg Pulse accuracy \pm 5%</p> <p><i>Method</i> Oscillometric method made during cuff deflation</p> <p><i>Ranges</i> 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> Inflation 0mmHg – 300mmHg 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: 100 memories x 2 users</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches</p> <p><i>Power</i> Start/Stop ( Symbol)</p> <p><i>Measurement Records</i> Memory ( Symbol) Forward ( Symbol) Backward ( Symbol)</p> <p><i>Function</i> Start/Stop ( Symbol) Start/Stop Measurement Memory ( Symbol) Enter Memory Mode Forward ( Symbol) Increase value or go forward Backward ( Symbol) decrease value or go backward Setting ( Symbol) Enter Setting mode (Date, Time)</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</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</p> <p><i>Power</i> Start/Stop ( mbol)</p> <p><i>Measurement Records</i> Memory ( Mymbol) Forward (+ Symbol) Backward (- Symbol)</p> <p><i>Function</i> Start/Stop ( mbol) Start/Stop Measurement Memory ( Mymbol) Enter Memory Mode Forward (+ Symbol) Increase value or go forward Backward (- Symbol) decrease value or go backward 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>
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	<p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i> Cuff tightness indicator 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 (AVG symbol) 7- day morning memory-zone mean (☀️ symbol) 7- day evening memory-zone mean (🌙 symbol) WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection and indication HSD Indicator AFIB Indicator</p> <p><i>Measurement Records</i> Memory Capacity: 100 memories x 2 users</p> <p><i>Date and Time</i> Date and Time Date and Time (During memory recall and measuring)</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 5V-1A</p> <p><i>Function</i> Measurement during deflation</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> Not described</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 AFIB 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> <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> Not described</p>
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	<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>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	March 2023

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

A SIGNED COPY WILL BE POSTED ON THE www.dablededucational.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	BM 53

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	BM 28

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 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 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.

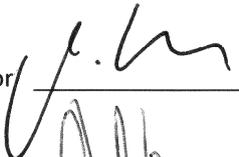
- 9. Modelname has been changed, it is a device with a different design and slightly changed functions beside the algorithm.
- 10. Casing has been changed with no change of the allgorithm
- 11. Display has been changed so that it fits to the new design of the housing.
- 12. Mounting facilities have been change because of the new design.
- 13. Software beside the algorithm has beend changed. There is an additional AFIB Feature, which is just a calculation with no change to the algorithm
- 14. Memory capacity has been changed to 2x100
- 17. BM28 uses 6V 600 mA power adapter, BM53 uses 5V 1A power adapter

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
- Completed DET9 Form
- 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.

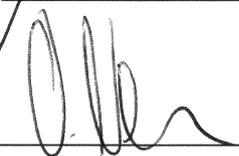
SECTION D Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dablededucational.org.

Signature of Director  _____

Company Stamp/Seal

Name

Date

Signature of Witness  _____

Name

Address