

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, **Liu Zhiqing**,
Name of a Company Director

a Director of **Andon Health Co.,Ltd.**,
Company name

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

Maker^a **Peroxfarma, S.A.** Address **Carrer Provença 328. 08037 Barcelona (Spain)**
 Manufacturer^b **Andon** Address **No.3 JinPing Street, YaAn Road, Nankai District, Tianjin 300190, China.**
 Brand^c **ICO** Model^d **MT-30**

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 **Andon** Address **No.3 JinPing Street, YaAn Road, Nankai District, Tianjin 300190, China.**
 Manufacturer^b **Andon** Address **No.3 JinPing Street, YaAn Road, Nankai District, Tianjin 300190, China.**
 Brand^c **Andon** Model^d **KD-5851**

Existing validated blood pressure measuring device.

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

Validation of the **Andon KD-5851** upper arm blood pressure monitor, for self-measurement according to the **European Society of Hypertension International Protocol revision 2010**

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 checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" 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) The Model Name is changed to ICO MT-30 from Andon KD-5851;
- (10) The new device has a different industrial design.
- (11) increase "bodymove symbol" ~~in KD-5812~~ *SHH 2022.5.12*
- (13) increase "bodymove" and bluetooth software code
- (14) Stores 2*120 readings instead of 60 readings.
- (16) increase bluetooth function ~~in KD-5812~~ *SHH 2022.5.12*

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@dableducational.org.

Signature of Director *Liu Zhiqing*
Name Liu Zhiqing
Date May 12, 2022
Signature of Witness *Sun Guimei*
Name Sun Guimei
Address No.3 JinPing Street, YaAn Road, Nankai District, Tianjin 300190, China.



Comparison of the ICO MT-30 with the Andon KD-5851

Devices – Item 9	ICO MT-30	Andon KD-5851
Pictures		
Display Image		
Validation	N/A	ESH 2010
Category	SBPM	SBPM
Casing – Item 10	<p><i>Dimensions</i></p> <p>118*97*175cm</p> <p><i>Ports</i></p> <p>Cuff port and Adapter port</p>	<p><i>Dimensions</i></p> <p>137*87*177</p> <p><i>Ports</i></p> <p>Cuff port and Adapter port</p>

	<i>Features</i> N/A	<i>Features</i> N/A
Display – Item 11	<i>Type</i> Segment LCD	<i>Type</i> Segment LCD
Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	Just changing the way of the code written, not the software scheme	N/A
Memory Capacity Item 14	2*120	60
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	bluetooth	<i>No communication facilities</i>
Power Supply Item 17	4*size AA	4*size AA
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i> <i>Body move detection function</i>	<i>Other Details on Validated device that are different to Equivalent device</i> No body move detection function
Same Criteria	<i>Measurement</i> <i>Accuracy</i> Pressure: ±3mmHg Pulse rate: Less than 60: ±3bpm More than 60 (incl.) : ±5%	<i>Measurement</i> <i>Accuracy</i> Pressure: ±3mmHg Pulse rate: Less than 60: ±3bpm More than 60 (incl.) : ±5%

	<p><i>Method</i></p> <p>Oscillometric</p> <p><i>Ranges</i></p> <p>Cuff pressure: 0-300mmHg</p> <p>Systolic: 60-260mmHg</p> <p>Diastolic: 40-199mmHg</p> <p>Pulse rate: 40-180 beats/minute</p> <p><i>Inflation</i></p> <p>Automatic inflation by internal pump</p> <p><i>Deflation</i></p> <p>Automatic speed deflation system</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>22-30cm (identical to 20-34cm,only silk mark is different)</p> <p>30-42cm (identical to 30-44cm,only silk mark is different)</p> <p>42-48cm (identical to 40-48cm,only silk mark is different)</p> <p>Materials are Nylon and polyester</p> <p><i>Sensors</i></p> <p>KD-2107-006GA</p> <p><i>Measurement Records</i></p> <p>2*120 readings</p>	<p><i>Method</i></p> <p>Oscillometric</p> <p><i>Ranges</i></p> <p>Cuff pressure: 0-300mmHg</p> <p>Systolic: 60-260mmHg</p> <p>Diastolic: 40-199mmHg</p> <p>Pulse rate: 40-180 beats/minute</p> <p><i>Inflation</i></p> <p>Automatic inflation by internal pump</p> <p><i>Deflation</i></p> <p>Automatic speed deflation system</p> <p><i>Cuffs(Please state sizes and materials used)</i></p> <p>15-24cm</p> <p>20-34cm</p> <p>30-44cm</p> <p>40-48cm</p> <p>Materials are Nylon and polyester</p> <p><i>Sensors</i></p> <p>KD-2107-006GA</p> <p><i>Measurement Records</i></p> <p>60 readings</p>
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	<p><i>Measurements other than Blood Pressure</i></p> <p>Pulse rate and IHB</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>Start/Stop button</p> <p><i>Measurement Records</i></p> <p>Memory button M1,M2</p> <p><i>Function</i></p> <p>Date and Time setting</p> <p><i>Analysis</i></p> <p>N/A</p> <p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>N/A</p> <p><i>Measurement Procedure</i></p> <p>Measuring during inflation</p> <p><i>Post Measurement</i></p> <p>Upper arm</p>	<p><i>Measurements other than Blood Pressure</i></p> <p>Pulse rate and IHB</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>Start/Stop button</p> <p><i>Measurement Records</i></p> <p>Memory button M</p> <p><i>Function</i></p> <p>Date and Time setting</p> <p><i>Analysis</i></p> <p>N/A</p> <p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>N/A</p> <p><i>Measurement Procedure</i></p> <p>Measuring during inflation</p> <p><i>Post Measurement</i></p> <p>Upper arm</p>
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	<p><i>Measurement Records</i></p> <p>2*120 readings</p> <p><i>Date and Time</i></p> <p>Displayed on LCD</p> <p><i>Power</i></p> <p>4*size AA</p> <p><i>Function</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p><i>Features</i></p> <p>N/A</p> <p><i>Not described</i></p> <p>N/A</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Average value of the last three measurements</p> <p>the average value of all results in am or pm in last 7 day</p> <p><i>Diagnostic</i></p> <p>N/A</p> <p><i>Functions</i></p> <p>N/A</p>	<p><i>Measurement Records</i></p> <p>60 readings</p> <p><i>Date and Time</i></p> <p>Displayed on LCD</p> <p><i>Power</i></p> <p>4*size AA</p> <p><i>Function</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p><i>Features</i></p> <p>N/A</p> <p><i>Not described</i></p> <p>N/A</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>No such function</p> <p><i>Diagnostic</i></p> <p>N/A</p> <p><i>Functions</i></p> <p>N/A</p>
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	<p><i>Communication</i></p> <p>Bluetooth connect symbol</p>	<p><i>Communication</i></p> <p>N/A</p> <p>No bluetooth function</p>
Comparable Criteria		

Comments		
Recommendation	RECOMMENDED	
Date	May 2022	