

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 Mario Merlo Director of Artsana s.p.a.
Name of a Company Director Company name

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

PiC Indolor Classic Check
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

PiC Indolor My Check
Existing validated blood pressure measuring device

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

Giuseppe Germano; Angelos Psimenos; Francesco Sarullo; Alessandro Venditti
Authors(s)
Valerio Pecchioli; Roland Asmar

Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol: The Pic Indolor Personal Check, Comfort Check, My Check and Travel Check

Title
Blood Pressure 2009 - 18:1,15 — 23
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 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 type="checkbox"/>	No <input checked="" 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"/>
	16	Communication Facilities	Yes <input checked="" 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 checked="" type="checkbox"/>

Brief explanations of differences and further relevant details:

The PiC Indolor Classic Check model is very basic and it has only the same algorithm and cone cuff of the PiC Indolor My Check model for performing the measurement. No other features.

The PiC Indolor My Check has the opportunity to download the data to the connected PC. This feature is not available for the PiC Indolor Classic Check



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 Merlo Mario
Name Mario Merlo
Date 16 October 2009



Company Stamp/Seal



Signature of Witness [Signature]
Name Francesco Lo Piccolo

Address Artsana S.p.A., Via Saldarini Catelli 1, 22070 Grandate (CO), Italy

Comparison of the Artsana Pic Indolor Classic Check with the Artsana Pic Indolor My Check

Devices	Artsana Pic Indolor Classic Check	Artsana Pic Indolor My Check
Pictures		
Validation		ESH
Device 1 Criteria		
Same Criteria	<p>Measurement</p> <p>Accuracy ± 3 mmHg 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>Pressure sensor: semi conductor 5</p> <p>Cuff: (Arm circ. 24 to 36 cm) 6</p> <p>Optional small (AC 18-26 cm) and large (AC 34-46 cm) cuffs 6</p> <p>Automatic Inflation and Deflation 7, 8</p> <p>Deflation: Automatic release valve 8</p> <p>Buttons/Switches</p> <p>O/I Start 10</p> <p>Display/Symbols/Indicators</p> <p>Low battery 11, 17</p> <p>Recalibrate 11, 18</p> <p>Pulse 11</p> <p>Case</p> <p>Single screen display 10</p> <p>Power: 4 “AA” batteries 17</p> <p>Power: Optional AC adapter 17</p>	<p>Measurement</p> <p>Accuracy ± 3 mmHg 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>Pressure sensor: semi conductor 5</p> <p>Cuff: (Arm circ. 24 to 36 cm) 6</p> <p>Optional small (AC 18-26 cm) and large (AC 34-46 cm) cuffs 6</p> <p>Automatic Inflation and Deflation 7, 8</p> <p>Deflation: Automatic release valve 8</p> <p>Buttons/Switches</p> <p>O/I Start 10</p> <p>Display/Symbols/Indicators</p> <p>Low battery 11, 17</p> <p>Recalibrate 11, 18</p> <p>Pulse 11</p> <p>Case</p> <p>Single screen display 10</p> <p>Power: 4 “AA” batteries 17</p> <p>Power: Optional AC adapter 17</p>
Comparable Criteria	<p>Measurement</p> <p>BP 40 mmHg to 250 mmHg, Pulse 40-199 bpm 1, 5, 7, 8</p> <p>Case</p> <p>Power: Automatic switch-off when not used for 1 min 17</p>	<p>Measurement</p> <p>BP 30 mmHg to 240 mmHg, Pulse 40-199 bpm 1, 5, 7, 8</p> <p>Case</p> <p>Power: Automatic switch-off when not used for 4 min 17</p>

Devices	Artsana Pic Indolor Classic Check	Artsana Pic Indolor My Check
Device 2 Criteria		<p>Measurement</p> <p>Memory: 120 measurements 11, 14</p> <p>Buttons/Switches</p> <p>Date/Time set 10</p> <p>Memory 10</p> <p>Display/Symbols/Indicators</p> <p>Date and Time 11</p> <p>Memory 11</p> <p>Hypertension 11, 13</p> <p>Charged battery 11, 17</p> <p>Algorithms</p> <p>Last 3 measurements mean 13</p> <p>Case</p> <p>Lid 10</p> <p>Data port (Optional USB cable and PC software) 16, 18</p> <p>Sound</p> <p>Beeps before and after measurements 18</p>
Web link	http://www.picindolor.com/Prodotti/tabid/65/language/en-GB/IdItem/1711/language/en-GB/Default.aspx	http://www.picindolor.com/Prodotti/tabid/65/language/en-GB/IdItem/1709/language/en-GB/Default.aspx

Comments	<p>Page 20 of the My Check manual appears to have an erroneous reference to “the irregular heartbeat icon”. This is not mentioned elsewhere in the manual.</p> <p>The item “Casing”, in the form should, strictly speaking, have been ticked as “Yes” due to the presence of the lid on the My Check.</p> <p>Despite the memory capacity being declared in the specifications to be “n/a”, and there being no reference to recalling previous messages, on page 19 of the Classic Check manual, it state that “The measurement is then automatically stored into the pre-designated memory zone.” This may be an inadvertent oversight in copying sections of another manual.</p> <p>However, these are minor and have nothing to do with the BP measurement. The Classic Check is essentially a much stripped down version of the My Check.</p>
Recommendation	Equivalence recommended
Date	11/12/2009