

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 Self Check
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

PiC Indolor Travel 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 type="checkbox"/>	No <input checked="" 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 Self Check model is the basic model for the PiC Indolor wrist line. It has the same algorithm and cuff, but no memory zones (just 1 instead of 2) and different number of memories (90 instead of 60+60) compared to the PiC Indolor Travel Check. Some other features are not activated compared to the PiC Indolor Travel Check like IHB Indicator and date/time.

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

Company Stamp/Seal

Name Mario Merlo

Date 16 October 2009





Signature of Witness [Signature]

Name Francesco Lo Piccolo

Address Artisana S.p.A. Via Saldarini Catelli 1, 22070 Grandate (co), Italy

OK
[Signature]
[Signature]

Comparison of the Artsana Pic Indolor Self Check with the Artsana Pic Indolor Travel Check

Devices	Artsana Pic Indolor Self Check	Pic Indolor Travel Check
Pictures		
Validation	<i>Image height 2.25 cm</i>	
Device 1 Criteria		
Same Criteria	<p>Measurement</p> <p>Accuracy ± 3 mmHg 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg to 260 mmHg, Pulse 40-199 bpm 1, 5, 7, 8</p> <p>Pressure sensor: semi conductor 5</p> <p>Cuff: (Wrist circ. 13.5 to 22 cm) 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>Algorithms</p> <p>Last 3 measurements mean 13</p> <p>Case</p> <p>Single screen display 10</p> <p>Power: 2 “AAA” batteries 17</p> <p>Power: Automatic switch-off when not used for 1 min 17</p>	<p>Measurement</p> <p>Accuracy ± 3 mmHg 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg to 260 mmHg, Pulse 40-199 bpm 1, 5, 7, 8</p> <p>Pressure sensor: semi conductor 5</p> <p>Cuff: (Wrist circ. 13.5 to 22 cm) 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>Algorithms</p> <p>Last 3 measurements mean 13</p> <p>Case</p> <p>Single screen display 10</p> <p>Power: 2 “AAA” batteries 17</p> <p>Power: Automatic switch-off when not used for 1 min 17</p>
Comparable Criteria	<p>Measurement</p> <p>Memory: 90 measurements 11, 14</p> <p>Buttons/Switches</p> <p>Memory 10</p>	<p>Measurement</p> <p>Memory: 60 measurements \times 2 zones 11, 14</p> <p>Buttons/Switches</p> <p>Memory 10</p>

Device 2 Criteria		<p>Buttons/Switches</p> <p>Date/Time set 10</p> <p>Memory zone (e.g. user, time of day) 10</p> <p>Display/Symbols/Indicators</p> <p>Date and Time 11</p> <p>Memory 11</p> <p>Memory zone 11</p> <p>Irregular heartbeat 11, 13</p> <p>Average 11</p> <p>Case</p> <p>Data port (Optional USB cable and PC software) 16, 18</p>
Web link	http://www.picindolor.com/Prodotti/tabid/65/language/en-GB/IdItem/1713/language/en-GB/Default.aspx	http://www.picindolor.com/Prodotti/tabid/65/language/en-GB/IdItem/1792/language/en-GB/Default.aspx

Comments	<p>The “data link socket” appears in the main diagram on page 22 of the Self Check manual but it is not mentioned elsewhere and neither is the optional “Datalink” package for linking the device to the PC. This appearance may be inadvertent. Either way it has no effect on the equivalence.</p> <p>The Self Check is essentially a stripped down version of the Travel Check.</p>
Recommendation	Equivalence recommended
Date	11/12/2009