

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 GLORY CLUE HOLDINGS INC. Director of SENSACARE LTD
Name of a Company Director Company name

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

MEDEL IDEA (MODEL # 91913 IDEA)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

ARM BLOOD PRESSURE MONITOR (MODEL #SAA-102)
Existing validated blood pressure measuring device

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

Vania Zaetta, Longo Daniele, Davor Perkovic, Francesco Pratico, Marlena Barisa,
Authors(s)
Paola Perfetti, Alberto Gabrieli, Francesco Buonocore and Mikolaj Winnicki

Validation of the SAA-102 home blood pressure monitor according to the protocols of the European Society of Hypertension, the Association for the advancement of Medical Instrumentation and the British Society of Hypertension

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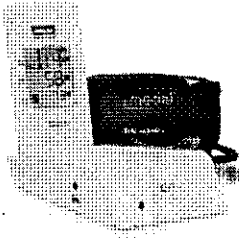
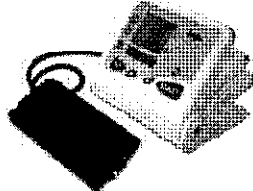
The only differences between the devices involve the following components:

(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 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 checked="" 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 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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input 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"/>

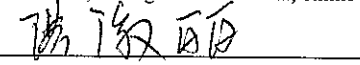

Brief explanation of differences and further relevant details:

Comparison of the Medel Idea (91913 IDEA) with the SensaCare SAA - 102 (Standard Model)

Devices	Medel Idea (91913 IDEA)	SensaCare SAA - 102 (Standard)
Pictures		 <i>Standard model</i>
Device 1 Criteria	Case Lid 10	
Same Criteria	<p>Measurement</p> <p>Accuracy ± 3 mmHg 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 - 280 mmHg / 20 - 255 mmHg, Pulse 20 - 255 bpm 1, 5, 7, 8</p> <p>Cuff: (Arm circ. 22 to 32 cm) 6</p> <p>Optional small (AC 18 - 24 cm) and large (AC 32 - 42 cm) cuffs 6</p> <p>Automatic Inflation and Deflation 7, 8</p> <p>Measurements are from single inflations 13</p> <p>Buttons/Switches</p> <p>Start/Stop (Buttons print "O/I ") 10</p> <p>Display/Symbols/Indicators</p> <p>During Measurement: Inflation, Deflation & Heartbeat 11</p> <p>Measurement error 11</p> <p>Memory 11</p> <p>Delete memory 11</p> <p>Irregular heartbeat 11, 13</p> <p>Charged battery 11, 17</p> <p>Low battery 11, 17</p> <p>SBP, DBP & Pulse 11</p> <p>Algorithms</p> <p>Atrial fibrillation detection 13</p> <p>Case</p> <p>Power: 4 "AA" 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 - 280 mmHg / 20 - 255 mmHg, Pulse 20 - 255 bpm 1, 5, 7, 8</p> <p>Cuff: (Arm circ. 22 to 32 cm)* 6</p> <p>Optional small (AC 16 - 24 cm) and large (AC 32 - 42 cm) cuffs 6</p> <p>Automatic Inflation and Deflation 7, 8</p> <p>Measurements are from single inflations 13</p> <p>Buttons/Switches</p> <p>Start/Stop (Buttons print "Start") 10</p> <p>Display/Symbols/Indicators</p> <p>During Measurement: Inflation, Deflation & Heartbeat 11</p> <p>Measurement error 11</p> <p>Memory 11</p> <p>Delete memory 11</p> <p>Irregular heartbeat 11, 13</p> <p>Charged battery 11, 17</p> <p>Low battery 11, 17</p> <p>SBP, DBP & Pulse 11</p> <p>Algorithms</p> <p>Atrial fibrillation detection 13</p> <p>Case</p> <p>Power: 4 "AA" batteries 17</p> <p>Power: Automatic switch - off when not used for 1 min 17</p>

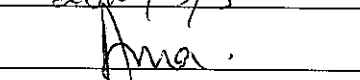
Comparable Criteria	Measurement Memory: 30 measurements Buttons/Switches Memory Display/Symbols/Indicators User (A) Case Single screen display	11, 14 10 11 10	Measurement Memory: 120 measurements or 60 measurements × 2 users Buttons/Switches Memory × 2 Display/Symbols/Indicators User (A or B) Case Dual screen display	11, 14 10 11 10
	Device 2 Criteria	No	Buttons/Switches Set Forward Backward Display/Symbols/Indicators Date and Time set/Time display BP classification (WHO) PC connection Alarm Case Cuff Compartment USB port, cable and PC software Power: Optional AC adapter Power: Automatic switch - off when case is closed Other Audible pulse indicator during deflation (optional) Beeps before and after measurements (optional) Alarm reminder (3 alarms/day)	10 10 10 11 11, 13 11, 16 11, 13 12 16, 18 17 17 11, 13 18 18

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  Company Stamp/Seal 

Name GLORY CLUE HOLDINGS INC.

Date 2010/3/5

Signature of Witness 

Name MS ANNA LAI

Address 11/F, AXA CENTRE, 151 GLOUCESTER ROAD, WANCHAI, HONG KONG



CUFF'S Information of 91914REPLAY and SAW - 102

Medel Replay (91914REPLAY)	SensaCare SAW - 102 (Standard Model)
Cuff: (Wrist circ. 13.5 to 19.5 cm)	Cuff: (Wrist circ. 13.5 to 19.5 cm)

CUFF'S Information of 91913 IDEA and SAA - 102

Medel Idea (91913 IDEA)	SensaCare SAA - 102 (Standard)
Arm circ. 22 to 32 cm	Arm circ. 22 to 32 cm
Optional small CUFF (Arm circ. 18 - 24 cm)	Optional small CUFF (Arm circ. 16 - 24 cm)
Optional large CUFF (Arm circ. 32 - 42 cm)	Optional large CUFF (Arm circ. 32 - 42 cm)

Comparison of the Medel Idea (#91913 IDEA) with the SensaCare SAA-102 (Standard Model)

Devices	Medel Idea (#91913 IDEA)	SensaCare SAA-102 (Standard)
Pictures		
Validation		ESH, BHS and AAMI
Device 1 Criteria	<p>Case</p> <p>Features</p> <p>Lid 10</p>	
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>SBP 30 mmHg - 280 mmHg, DBP 20 mmHg -255 mmHg 1, 5, 7, 8</p> <p>Pulse 20 bpm -255 bpm 1, 5</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Automatic inflation 7, 8</p> <p><i>Deflation</i></p> <p>Automatic deflation 7, 8</p> <p><i>Cuffs</i></p> <p>Medium cuff (Arm circ. 22 to 32 cm) 6</p> <p>Large cuff (Arm circ. 32-42 cm) (Optional) 6</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Inflation symbol 11</p> <p>Deflation symbol 11</p> <p>Heartbeat symbol during deflation 11</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>SBP 30 mmHg - 280 mmHg, DBP 20 mmHg -255 mmHg 1, 5, 7, 8</p> <p>Pulse 20 bpm -255 bpm 1, 5</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Automatic inflation 7, 8</p> <p><i>Deflation</i></p> <p>Automatic deflation 7, 8</p> <p><i>Cuffs</i></p> <p>Medium cuff (Arm circ. 22 to 32 cm) 6</p> <p>Large cuff (Arm circ. 32-42 cm) (Optional) 6</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Inflation symbol 11</p> <p>Deflation symbol 11</p> <p>Heartbeat symbol during deflation 11</p>

Devices	Medel Idea (#91913 IDEA)	SensaCare SAA-102 (Standard)
Same Criteria (Continued)	<p>Display/Symbols/Indicators (Continued)</p> <p><i>Post Measurement</i></p> <p>SBP, DBP & Pulse 11</p> <p>Measurement error (Err1, Err 2, Err 3, Err 4, Err 5) 11</p> <p>Irregular heartbeat 11, 13</p> <p><i>Measurement Records</i></p> <p>Memory 11</p> <p>Delete memory 11</p> <p><i>Power</i></p> <p>Charged battery 11, 17</p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Atrial fibrillation detection 13</p> <p>Case</p> <p><i>Power</i></p> <p>4 “AA” batteries 17</p> <p>Automatic switch-off when not used for 1 min 17</p>	<p>Display/Symbols/Indicators (Continued)</p> <p><i>Post Measurement</i></p> <p>SBP, DBP & Pulse 11</p> <p>Measurement error (Err1, Err 2, Err 3, Err 4, Err 5) 11</p> <p>Irregular heartbeat 11, 13</p> <p><i>Measurement Records</i></p> <p>Memory 11</p> <p>Delete memory 11</p> <p><i>Power</i></p> <p>Charged battery 11, 17</p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Atrial fibrillation detection 13</p> <p>Case</p> <p><i>Power</i></p> <p>4 “AA” batteries 17</p> <p>Automatic switch-off when not used for 1 min 17</p>
Comparable Criteria	<p>Measurement</p> <p><i>Cuffs</i></p> <p>Small cuff (Arm circ. 18-24 cm) (Optional) 6</p> <p><i>Measurement Records</i></p> <p>Memory: 30 measurements 11, 14</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>Display/Symbols/Indicators</p> <p><i>Memory</i></p> <p>User (A) 11</p> <p>Case</p> <p><i>Display</i></p> <p>Single screen display 10</p>	<p>Measurement</p> <p><i>Cuffs</i></p> <p>Small cuff (Arm circ. 16-24 cm) (Optional) 6</p> <p><i>Measurement Records</i></p> <p>Memory: 120 measurements or 60 measurements × 2 users 11, 14</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>Start/Stop (Start Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory × 2 10</p> <p>Display/Symbols/Indicators</p> <p><i>Memory</i></p> <p>User (A or B) 11</p> <p>Case</p> <p><i>Display</i></p> <p>Dual screen display 10</p>

Devices	Medel Idea (#91913 IDEA)	SensaCare SAA-102 (Standard)
Device 2 Criteria		<p>Buttons/Switches</p> <p><i>Settings</i></p> <p>Set 10</p> <p>Forward 10</p> <p>Backward 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurements (optional) 18</p> <p>Audible pulse indicator during deflation (optional) 11, 13</p> <p>Beeps after measurements (optional) 18</p> <p><i>Post Measurement</i></p> <p>BP classification (WHO) 11, 13</p> <p><i>Date and Time</i></p> <p>Date and Time set and Time display 11</p> <p>Alarm 11, 13</p> <p>Alarm reminder (3 alarms/day) 18</p> <p><i>Communication</i></p> <p>PC connection 11, 16</p> <p>Case</p> <p><i>Ports</i></p> <p>USB port, cable and PC software 16, 18</p> <p><i>Power</i></p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-on when case is opened 17</p> <p>Automatic switch-off when case is closed 17</p> <p><i>Features</i></p> <p>Cuff Compartment 10</p>
Web link		http://sensacare.com/products2.php

Comments	<p>A simple version of the SAA-102 is also presented on the SensaCare website. ESH, BHS (A/A) and AAMI validation is claimed but no paper equivalence is known to dabl® Educational. However, according to the SensaCare website, it has a single screen display, it is single user, it has 30 memories and it does not have a USB port.</p> <p>The manuals are very similar in style and for common areas, have identical wording. General operations of both devices are the same with the same symbols being used during inflation and deflation. Error codes are identical. Even though the Medel Idea is a single user device, an “A” appears during memory recall. In the SAA-102 in dual user mode, this can be “A” or “B” to distinguish between the users. There is a dot on the display of the SAA-102 that is positioned beside a green/yellow/red strip to indicate WHO classification. There is a similar unexplained dot at the top of the Medel Idea screen but no WHO strip.</p> <p>No cuff information is provided in the SAA-102 manual. The details are provided in the declaration and in the SAA-102 validation paper¹. This information is provided in the Medel Idea manual. There is a discrepancy in the size of the small cuff.</p> <p>Reference</p> <p>1 Zaetta V, Daniele L, Perkovic D, Prattico F, Barisa M, Perfetti P, Gabrieli A, Buonocore F, Winnicki M. Validation of the SAA-102 home blood pressure monitor according to the protocols of the European Society of Hypertension, the Association for the Advancement of Medical Instrumentation and the British Society of Hypertension <i>Blood Press Monit</i> 2007;12:363-368</p>
Recommendation	The Medel Idea is essentially the same as the SAA-102 without many of its extra features. Equivalence is recommended.
Date	05/03/2010