

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 REPLY (MODEL # 91914REPLAY)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

WRIST BLOOD PRESSURE MONITOR (MODEL # SAW-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, Daniele Longo, Davor Perkovic, Paola Perfetti, Alberto Gabrieli,
Authors(s)
Francesco Pratico, and Mikolaj Winnicki

Validation of the SAW-102 wrist home blood pressure monitor according to the
Protocols of the British Hypertension Society, the Association for the Advancement of
Medical Instrumentation, and the European Society of Hypertension

Title
Blood Pressure Monitoring 2009, Vol 14, Page 32-36
Publication Year Volume Pages

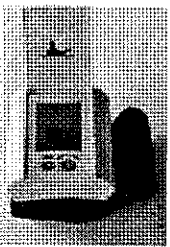
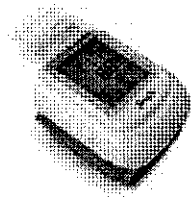
The only differences between the devices involve the following components:

(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 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 type="checkbox"/>	No <input checked="" 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 Replay (91914REPLAY) with the SensaCare SAW - 102 (Standard Model)

Devices	Medel Replay (91914REPLAY)	SensaCare SAW - 102 (Standard Model)
Pictures		 <i>Standard model</i>
Device 1 Criteria	Case Lid 10	
Same Criteria	Measurement Accuracy ± 3 mmHg 1, 5 Oscillometric measurement method 1, 5 BP 30 - 280 mmHg / 20 - 255 mmHg, Pulse 20 - 255 bpm 1, 5, 7, 8 Automatic Inflation and Deflation 7, 8 Measurements are from single inflations 13 Cuff: (Wrist circ. 13.5 to 19.5 cm) 6 Buttons/Switches Start/Stop 10 Display/Symbols/Indicators During Measurement: Inflation, Deflation & Heartbeat 11 Measurement error 11 Memory 11 Delete memory 11 Irregular heartbeat 11, 13 Charged battery 11, 17 Low battery 11, 17 SBP, DBP & Pulse 11 Algorithms Atrial fibrillation detection 13 Case Single screen display 10 Power: 2 "AAA" batteries 17	Measurement Accuracy ± 3 mmHg 1, 5 Oscillometric measurement method 1, 5 BP 30 - 280 mmHg / 20 - 255 mmHg, Pulse 20 - 255 bpm 1, 5, 7, 8 Automatic Inflation and Deflation 7, 8 Measurements are from single inflations 13 Cuff: (Wrist circ. 13.5 to 19.5 cm) 6 Buttons/Switches Start/Stop 10 Display/Symbols/Indicators During Measurement: Inflation, Deflation & Heartbeat 11 Measurement error 11 Memory 11 Delete memory 11 Irregular heartbeat 11, 13 Charged battery 11, 17 Low battery 11, 17 SBP, DBP & Pulse 11 Algorithms Atrial fibrillation detection 13 Case Single screen display 10 Power: 2 "AAA" batteries 17
Comparable Criteria	Measurement Memory: 30 measurements 11, 14 Buttons/Switches Memory 10 Display/Symbols/Indicators User (A) 11	Measurement Memory: 120 measurements or 60 measurements × 2 users 11, 14 Buttons/Switches Memory × 2 10 Display/Symbols/Indicators User (A or B) 11

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Device 2 Criteria	No	Measurement	
		Buttons/Switches	
		Set	10
		Forward (= Memory A)	10
		Backward (= Memory B)	10
		Display/Symbols/Indicators	
		Date and Time set/Time display	11
		BP classification (WHO)	11, 13
		PC connection	11, 16
		Alarm	11, 13
		Case	
		Slider to reveal buttons and for power off	10, 17
		USB port, cable and PC software	16, 18
		Other	
		Audible pulse indicator during deflation (optional)	11, 13
		Beeps before and after measurements (optional)	18
		Alarm reminder (3 alarms/day)	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 張淑麗

Company Stamp/Seal



Name GLORY CLUE HOLDINGS INC.

Date 2010/3/5

Signature of Witness Anna Lai

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 Replay (#91914REPLAY) with the SensaCare SAW-102 (Standard Model)

Devices	Medel Replay (#91914REPLAY)	SensaCare SAW-102 (Standard Model)
Pictures		
Validation		ESH, BHS and AAMI
Device 1 Criteria	<p>Case</p> <p>Features</p> <p>Lid</p> <p style="text-align: right;">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>Wrist circ. 13.5-19.5 cm 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>Wrist circ. 13.5-19.5 cm 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 Replay (#91914REPLAY)	SensaCare SAW-102 (Standard Model)
Same Criteria (Continued)	Display/Symbols/Indicators (Continued) <i>Post Measurement</i> SBP, DBP & Pulse 11 Measurement error (Err1, Err 2, Err 3, Err 4, Err 5) 11 Irregular heartbeat 11, 13 <i>Measurement Records</i> Memory 11 Delete memory 11 <i>Power</i> Charged battery 11, 17 Low battery 11, 17 Algorithms <i>Diagnostic</i> Atrial fibrillation detection 13 Case <i>Display</i> Single screen display 10 <i>Power</i> 2 “AAA” batteries 17	Display/Symbols/Indicators (Continued) <i>Post Measurement</i> SBP, DBP & Pulse 11 Measurement error (Err1, Err 2, Err 3, Err 4, Err 5) 11 Irregular heartbeat 11, 13 <i>Measurement Records</i> Memory 11 Delete memory 11 <i>Power</i> Charged battery 11, 17 Low battery 11, 17 Algorithms <i>Diagnostic</i> Atrial fibrillation detection 13 Case <i>Display</i> Single screen display 10 <i>Power</i> 2 “AAA” batteries 17
Comparable Criteria	Measurement <i>Measurement Records</i> Memory: 30 measurements 11, 14 Buttons/Switches <i>Power</i> On/Off with Start/Stop (Start/Stop Label) 10 <i>Measurement Records</i> Memory 10 Display/Symbols/Indicators <i>Measurement Records</i> User (A) 11	Measurement <i>Measurement Records</i> Memory: 120 measurements or 60 measurements × 2 users 11, 14 Buttons/Switches <i>Power</i> Start/Stop/On (Start Label) 10 <i>Measurement Records</i> Memory × 2 10 Display/Symbols/Indicators <i>Measurement Records</i> User (A or B) 11
Device 2 Criteria		Buttons/Switches <i>Settings</i> Set 10 Forward (= Memory A) 10 Backward (= Memory B) 10

Devices	Medel Replay (#91914REPLAY)	SensaCare SAW-102 (Standard Model)
Device 2 Criteria (Continued)		<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>Setting of Date and Time set but only display of Time 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>Automatic switch-on when slider is opened 17</p> <p>Automatic switch-off when slider is closed 17</p> <p><i>Features</i></p> <p>Slider to reveal buttons and for power off 10, 17</p>
Web link		http://sensacare.com/products2.php

Comments	<p>A simple version of the SAW-102 is also presented on the website. According to the SensaCare website, it, like the Medel Replay, 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 Replay is a single user device, an “A” appears during memory recall. In the SAW-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 SAW-102 that is positioned under a green/yellow/red strip to indicate WHO classification. There is a similar unexplained dot in the same position on the Medel Replay screen but no WHO strip.</p> <p>No cuff information is provided in either manual. The details are provided in the declaration and the SAW-102 validation paper¹.</p> <p>Reference</p> <p>1 Zaetta V, Longo D, Perkovic D, Perfetti P, Gabrieli A, Praticò F, Winnicki M. Validation of the SAW-102 wrist home blood pressure monitor according to the protocols of the British Hypertension Society, the Association for the Advancement of Medical Instrumentation, and the European Society of Hypertension <i>Blood Press Monit</i> 2009;14:32-36</p>
Recommendation	The Medel Replay is essentially the same as the SAW-102 without many of its extra features. Equivalence is recommended.
Date	05/03/2010