dabl® Educational Trust

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. (Name of a Company Director) Director of SENSACARE LTD (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 Prattico, Marlena Barisa, Paola Perfetti, Alberto Gabrieli, Francesco Buonocore and Mikolaj Winnicki
Authors(s)

Validation off 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
Title

Blood Pressure Monitoring (Publication) 2007 Vol 12, Page 363-368 (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 ☐	No ☒
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☒
	3	Artefact/Error Detection	Yes ☐	No ☒
	4	Microphone(s)	Yes ☐	No ☒
	5	Pressure Transducer	Yes ☐	No ☒
	6	Cuff or Bladder	Yes ☐	No ☒
	7	Inflation Mechanism	Yes ☐	No ☒
	8	Deflation Mechanism	Yes ☐	No ☒
Part II	9	Model Name or Number	Yes ☒	No ☐
	10	Casing	Yes ☒	No ☐
	11	Display	Yes ☒	No ☐
	12	Carrying/Mounting Facilities	Yes ☒	No ☐
	13	Software other than Algorithm	Yes ☒	No ☐
	14	Memory Capacity/Number of stored measurements	Yes ☒	No ☐
	15	Printing Facilities	Yes ☐	No ☒
	16	Communication Facilities	Yes ☒	No ☐
	17	Power Supply	Yes ☒	No ☐
	18	Other Facilities	Yes ☐	No ☒

Brief explanation of differences and further relevant details:

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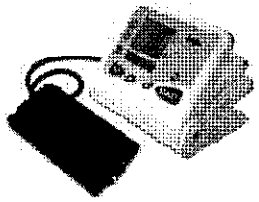
Comparison of the Medel Idea (91913 IDEA) with the SensaCare SAA - 102 (Standard Model)

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

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

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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	***Case***			
	Features			
	Lid	10		
Same Criteria	***Measurement***		***Measurement***	
	Accuracy		*Accuracy*	
	BP accuracy ± 3 mmHg	1, 5	BP accuracy ± 3 mmHg	1, 5
	Pulse accuracy ± 5%	1, 5	Pulse accuracy ± 5%	1, 5
	Method		*Method*	
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	SBP 30 mmHg - 280 mmHg, DBP 20 mmHg -255 mmHg	1, 5, 7, 8	SBP 30 mmHg - 280 mmHg, DBP 20 mmHg -255 mmHg	1, 5, 7, 8
	Pulse 20 bpm -255 bpm	1, 5	Pulse 20 bpm -255 bpm	1, 5
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Inflation		*Inflation*	
	Automatic inflation	7, 8	Automatic inflation	7, 8
	Deflation		*Deflation*	
	Automatic deflation	7, 8	Automatic deflation	7, 8
	Cuffs		*Cuffs*	
	Medium cuff (Arm circ. 22 to 32 cm)	6	Medium cuff (Arm circ. 22 to 32 cm)	6
	Large cuff (Arm circ. 32-42 cm) (Optional)	6	Large cuff (Arm circ. 32-42 cm) (Optional)	6
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Inflation symbol	11	Inflation symbol	11
	Deflation symbol	11	Deflation symbol	11
	Heartbeat symbol during deflation	11	Heartbeat symbol during deflation	11

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

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

Comments	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. 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. No cuff information is provided in the SAA-102 manual. The details are provided in the declaration and in the SAA-102 validation paper[1]. This information is provided in the Medel Idea manual. There is a discrepancy in the size of the small cuff. **Reference** 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 *Blood Press Monit* 2007;**12**:363-368
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