Medical Device Assessment

Medaval Certified Accuracy

Medaval Accreditation Assessment Full Report

Volume 2024 Report 2401FR 06 February 2024

Full report on the assessment of the blood pressure measurement technology used in the SELVAS ACCUNIQ BP500 upper arm blood pressure monitor, as validated in adults according to the ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 standard.

Investigators Neil Atkins, Medaval Ltd., Dublin, IRELAND.

Derek O'Sullivan, Medaval Ltd., Dublin, IRELAND.

Analysis Neil Atkins, Medaval Ltd., Dublin, IRELAND.

Administration Con Creedon Medaval Ltd., Dublin, IRELAND.

Reference Medaval Ltd. Full report on the assessment of the blood pressure measurement technology used in the SELVAS ACCUNIQ BP500 upper arm blood pressure monitor, as validated according to the ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 standard. *Medical Device Assessment*. 2024 Feb 06;**2024**(2401FR) 27 p.

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MEDICAL DEVICE ASSESSMENT 2401FR:2024

Full report on the assessment of the blood pressure measurement technology used in the SELVAS ACCUNIQ BP500 upper arm blood pressure monitor, as validated according to the ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 standard

Medaval Accreditation Assessment Full Report – 06 February 2024

Contents

Glossary

Abbreviations

%RH	relative humidity percent
°C	degrees Celsius
ABPM	Ambulatory blood pressure measurement
BP	Blood pressure
bpm	beats per minute
cm	centimetre(s)
DBP	Diastolic blood pressure
ECG	Electrocardiogram
ESH	European Society of Hypertension
EU	European Union
g	gram(s)
hPa	hectopascals
IRL	Republic of Ireland
ISO	International Organization for Standardization/International Standards Organization
KOR	Republic of Korea
m	metre(s)
MAP	Mean arterial pressure
meas.	Measurement
min	minute(s)
mmHg	millimetre(s) of mercury
PC	Personal computer (any external system do which data can be downloaded)
PP	Pulse Pressure (SBP – DBP)
PR	Pulse rate
req.	requirement
SBP	Systolic blood pressure
SD	standard deviation

Plot Legend

●	Single point, area one unit
●	Two superimposed points, area two units
●	Three superimposed points, area three units

Summary

Objective

The objective of this study was to determine the accuracy of the oscillometric blood pressure measurement technology of the SELVAS ACCUNIQ BP500 blood pressure monitor, intended for office and waiting-room blood pressure measurement and to determine if the BP501, BP503, BP600, BP650, BP651 and BP653 devices were equivalent to the BP500, according to MEDDEV 2.7/1 rev 4 requirements.

Methodology

The SELVAS ACCUNIQ BP500 was evaluated according to the requirements of the ISO 81060-2:2018/Amd 1:2020 standard. The BP501, BP503, BP600, BP650, BP651 and BP653 devices and cuffs were compared to the BP500, according to MEDDEV 2.7/1 rev 4 requirements using a checklists of 320 items for the devices and 16 items for the cuffs.

Results

The SELVAS ACCUNIQ BP500 fulfilled all of the requirements for a pass in the ISO 81060-2:2018/Amd 1:2020 study. The Criterion 1 errors were +1.1 mmHg ± 7.6 mmHg for SBP and +0.1 ± 7.3 mmHg for DBP and the Criterion 2 errors were +1.0 mmHg ± 6.3 mmHg for SBP and +0.1 ± 6.5 mmHg for DBP. The BP501, BP503, BP600, BP650, BP651 and BP653 devices and cuffs all fulfilled the MEDDEV 2.7/1 rev 4 requirements for equivalence to the BP500.

Conclusion

The SELVAS ACCUNIQ BP500, BP501, BP503, BP600, BP650, BP651 and BP653, when used according to the text and pictorial instructions provided, can be recommended for blood pressure measurement in the adult population.

Organisational Details

Medaval Ltd.

Incorporated in 1989 as Medical Device Assessment Ltd, the company abbreviated its name to Medaval Ltd. in 2015. Medaval provides several services including comprehensive cardiovascular device listings according to peer-reviewed validations, certification for devices that have been proven to have been validated strictly according to a current standard protocol, validation of devices and comparative-equivalence according to MEDDEV 2.7/1 rev 4 standards[8]. Both validation and comparative-equivalence services are in accordance with Regulation (EU) 2017/745[4].

The passing criteria in validation protocols are based on specific sample distributions and on other criteria and can only be applied if all of the requirements are followed correctly. Therefore, in any validation study, Medaval, first tests the hypothesis that the study was not carried out in accordance with the requirements and it is only if that hypothesis is rejected can the results be considered reliable.

All procedures were developed and reviewed by a panel of experts. The Medaval Accreditation Procedure is designed to check that every aspect of a validation protocol is fulfilled. Modifications, that may be necessary for particular populations or circumstances not defined specifically in a protocol must be supported by relevant peer-reviewed scientific publications.

Validation is considered to apply to the specific measurement technology being tested, as distinct from the device itself. No inference should be made about the validity of any other aspect of the device, unless it is also tested according to a regulatory or peer-reviewed protocol. Validation also only applies to the population from which the sample is taken and under the circumstances in which it was carried out, as defined in the protocol. No inference should be made about the validity of the device in a different population or under different circumstances.

The results must apply equally to any device that uses the same measurement technology, as proven under MEDDEV 2.7/1 rev 4 standards irrespective of whether that equivalence is proven prior to or subsequent to the validation. Medaval has developed as comparative-equivalence procedure to test the null hypothesis that two devices are not equivalent, according to this standard. Should that hypothesis be rejected, the devices must be regarded as equivalent for that measurement technology.

For more information, please refer to www.medaval.ie.

SELVAS Healthcare Inc.

SELVAS Healthcare Inc. (formerly Jawon Medical), established in 1993, is a digital healthcare company based on technology for medical devices and assistive rehabilitation technology devices.

The company has won several awards including the Presidential Award in the National Venture Awards and selected as a World Top-class Company (1999), Top Prize in the Leaders' Venture Awards (2000), the Prime Minister's Award by the Korean Good Manufacturing Practice Trade Day (2001), the Director's Award by the Korea Food and Drug Administration (2003), Bronze Prize in the Republic of Korea Technical Awards, Silver Prize in the Venture Design Awards and Bronze Medal of Industrial Effort in the Precision Technology Promotion Contest (2005), the Director's Award by the Korea Food and Drug Administration (2006), the Advanced Venture Company Award (2010), Grand Prize in the 1st People's Happiness Premium IT and the Popularity Award, Analysis and Diagnosis System Segment in the Korean Medical Device Awards (2014).

Its brand ACCUNIQ derives from its mission to provide accurate diagnosis and unique technology.

SELVAS Headquarters are in Daejeon, Republic of Korea and it has major offices in Beijing, Peoples Republic of China and in Austin, Texas, USA. It also has offices in Venlo, Netherlands, Taipei City, Taiwan and Tokyo, Japan.

The company has, among several others, ISO 13485, ISO 9001 and GMP certification. See https://www.ACCUNIQ.com/en/company/certification.php for a complete list.

For more information, please refer to www.ACCUNIQ.com.

Full Report

Introduction

The SELVAS ACCUNIQ BP500 is a blood pressure monitor intended for waiting room use or for availability in, for instance, a staff common area in a business. A visual aid shows how to place the, usually right, arm and a sensor prevents it from working until at least the elbow is placed correctly Measurement is initiated by pressing a Start/Stop button and the results are displayed with an optional printout with three levels of details. It is intended for adults (18+) with arm circumferences in the range 20 cm to 40 cm only but not for those with arrhythmias and some other stated conditions.

An additional rear monitor, allowing anthropometric data to be entered is available and the device has a USB port and two RS-232C ports. None of these were used in this study.

Methodology

The SELVAS ACCUNIQ BP500 was validated according to the requirements of the ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 standard [1-3]. This is the current universal standard required to satisfy blood pressure monitor validation according to Regulation (EU) 2017/745[4]. This standard requires a study in a sample of at least 85 subjects from a general population, in accordance with specified recruitment requirements.

This protocol has several requirements regarding gender distribution, blood pressure distribution and arm circumference distribution, as it has a single cuff. Furthermore sequential SBP reference measurements cannot differ by more than 12 mmHg and DBP measurements by more than 8 mmHg.

A system based on the sphygmocorder was set up[5-7]. The stethoscope was linked via Bluetooth to an Apple® iPad Air MD792B-B. The earpiece section of the stethoscope was removed and the gap was plugged. The iPad displayed the sound waves from the stethoscope. This was placed beside the mercury sphygmomanometer. A visual indication of the participant's reference number and the measurement number was also placed in the scene. This was recorded on a Sony ZV1F camera. A lead from the iPad transmitted the sound from the stethoscope to the camera while the image captured the mercury column, the iPad and the measurement ID. The cuff was inflated using a custom built pump mechanism and was deflated manually using a bulb. The video recordings were reviewed independently by the two observers using both the sounds and the visual cues on the iPad, along with the playback video control bar to determine the values of SBP and DBP on the mercury column. If these differed by more than 2 mmHg the were later reviewed together to resolve the discrepancy..

Procedure

The ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 standard and European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely[1-3]. No adjustments were required or made. The supervisor explained the procedure to each participant and obtained signed consent. Participant date of birth, sex and whether or not they were on antihypertensive medication was obtained. An interpreter facilitated this on measurements recorded in the Republic of Korea. Arm circumference was measured midway between the olecranon process and the acromion process. The brachial artery was located and marked. The narrow bell of the stethoscope was used for participants with arm circumferences less than 22 cm, the wide bell was used for all others.

Five mercury measurements were recorded and printouts were made of the four test-device recordings and fixed to the Supervisor Form.

Afterwards the recordings were reviewed by two observers blinded from both each other's readings and from the device readings. These values were entered into a spreadsheet. A facility to highlight discrepancies over 2 mmHg was included. These were re-reviewed by both observers to agree on the correct value. Due to the recording of measurements, there were no repeat measurements due to observer differences.

As the device has one inbuilt cuff recruitment had to satisfy the single-cuff requirements of the protocol.

Sequential same-arm measurements were recorded on video showing a falling mercury column and audio pulses with a separate audio connection. In most cases, the right warm was used. In some cases, only the left arm was within the specifications for the device or the participant

could only have measurements recorded from the left arm.

Results

All of the requirements of each of the protocols were satisfied without any adjustments or violations.

In order to fulfil all requirements, it was necessary to include 90 subjects. Due changes in sequential observer SBP measurements over 12 mmHg, eight subjects (8.9%) did not contribute three SBP measurements. Similarly, due changes in sequential observer DBP measurements over 8 mmHg, eight subjects (8.9%) did not contribute three DBP measurements. For the 90 subjects, there were 273 SBP measurements and

The ISO 81060-2:2018 Criterion 1 errors were +1.1 mmHg ± 7.6 mmHg for SBP and +0.1 mmHg ± 7.3 mmHg for DBP and both sets were within the ±5.0 mmHg ± 8.0 mmHg requirements. The Criterion 2 errors were also +1.0 mmHg ± 6.4 mmHg for SBP (within the ±5.0 mmHg ± 6.87 mmHg requirements – the standard deviation requirement being based on the mean value) and +0.1 mmHg ± 6.5 mmHg for DBP (within the ±5.0 mmHg ± 6.95 mmHg requirement).

Conclusion

The protocol is designed to test the null hypothesis that the device is inaccurate and that this hypothesis must be rejected if the passing criteria are met.

As the protocol was followed strictly, any hypothesis that the reliability of the results may be compromised due to protocol adjustment or violation must also be rejected.

Therefore, as the passing criteria have been met, there is no option but to reject the null hypothesis and conclude that the oscillometric blood pressure measurement technology used in SELVAS ACCUNIQ BP500 is accurate, when used correctly, as per the manufacturer's instructions, within the criteria set out in ISO 81060-2:2018/Amd 1:2020.

It is, therefore, recommended for use in clinical blood pressure measurement.

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Device Details

Test Device

		Assessment
Full Name	SELVAS ACCUNIQ BP500	Requirement satisfactory
Model	BP500	Requirement satisfactory
Measurement Site	Upper Arm	Requirement satisfactory
Client Use	Suitable for waiting room and communal space use.	Requirement satisfactory
Operation Method	Oscillometry, automatic during deflation	Requirement satisfactory
Measurement Occurrence	Single Measurements Only	Requirement satisfactory
Device Photograph		Requirement satisfactory
Manufacturer(s)	SELVAS Healthcare Inc. 155 Sinseong-ro, Yuseong-gu, Daejeon 34109, REPUBLIC of KOREA	Requirement satisfactory
Cuffs	Integrated 20 cm to 40 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

Reference Sphygmomanometers

		Assessment
Full Name	Riester Diplomat-Presameter	Information requirement
Model	1009-108	Information requirement
Manufacturer(s)	Rudolf Riester GmbH, Jungingen, GERMANY.	Desirable information
Full Name	Jericho JE-710	Information requirement
Model	JE-710	Information requirement
Manufacturer(s)	Jericho International Enterprise Co. Ltd., Taipei, TAIWAN.	Desirable information

Reference Cuff(s)

		Assessment
Name and Model	Comfort Fit (HEM-FM31) 17 cm to 36 cm	Cuffs Listed: Desirable requirement Arm Circumferences: Desirable requirement
Manufacturer	Omron Corporation, Shiokoji Horikawa, Shimogyo-ku, Kyoto 600-8530, Japan	Desirable information
Name(s) and Model	Riester 2-tube XXL (153) 32 cm to 41 cm	Cuffs Listed: Desirable requirement Arm Circumferences: Desirable requirement
Manufacturer	Rudolf Riester GmbH, P.O. Box 35, Bruckstr. 3, D - 72417 Jungingen, Germany	Desirable information

Reference Stethoscope

		Assessment
Full Name	3M™ Littmann® CORE Digital Stethoscope	Desirable information
Model	8490	Desirable information
Manufacturer(s)	3M Health Care, 3M Medical Solutions Division, 2510 Conway Ave., St. Paul, MN 55144 USA	Desirable information

Device Details Assessment		
	Checks	14
	Permitted Modifications	0
	Violations	0

ISO 81060-2:2018/Amd 1:2020 Study

Study Details

		Assessment
Protocol	The ISO 81060-2:2018 & ISO 81060-2:2018/Amd 1:2020 standard for a general study in adults[1-3]	
Reference Determination	Sequential same-arm	Information requirement satisfactory
Adherence	Followed Precisely	Information requirement satisfactory
Adjustments	None	Information requirement satisfactory
Study Meas. Method	Oscillometric	Information requirement satisfactory
Study Measurement Site	Upper Arm	Information requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes – Measurements video-recorded by supervisor, later reviewed by two observers	Information requirement satisfactory
Observer Training	By expert in BP measurement	Information requirement satisfactory
Observer Familiarisation	40 test measurements	Supplementary Information
Observers Blinded	From device and each other	Information requirement satisfactory
Sample		
Population	A general population	Information requirement satisfactory
Circumstances	None	Information requirement satisfactory
HBP Subjects Selection	General public, nursing home and day care residents, staff, recommendations.	Supplementary Information
NBP Subjects Selection	General public, staff	Supplementary Information
Subject Preparation		
Back, elbow and arm supported	Yes	Information requirement
Legs uncrossed	Yes	Information requirement
Cuff centre at right atrium level	Yes	Information requirement
Comfortable	Yes	Information requirement
5-min rest at start	Yes	Information requirement

Study Details Assessment	**Checks**	15
	Permitted Modifications	0
	Violations	0

Procedure

Screening and Recruitment Details

Screening and Recruitment	Total	IRL	KOR	Assessment
Total Screened	**175**	**105**	**70**	Information requirement satisfactory
Total Excluded	**85**	**71**	**14**	Information requirement satisfactory
Arrhythmias	**4**	**4**	**0**	Information requirement satisfactory
Other BP Abnormalities	**4**	**3**	**1**	Information requirement satisfactory
Arm positioning Difficulties	**5**	**4**	**1**	Information requirement satisfactory
Technical Reasons	**21**	**19**	**2**	Information requirement satisfactory
Arm Circ. Outside Device Range	**1**	**1**	**0**	Information requirement satisfactory
Participant Left	**18**	**18**	**0**	Information requirement satisfactory
Recruitment Requirements	**32**	**22**	**10**	Information requirement satisfactory
Total Recruited *(85 Required)*	**90**	**34**	**56**	Value within requirements

Subject Details Assessment	**Checks**	10
	Permitted Modifications	0
	Violations	0

Subject Details

	Requirement	**Value**	**Assessment**	
Sex				
Male:Female	27..63 (≥ 30%)	**61:29 (68%:32%)**	Value within requirements	Value within requirements
Age *(years)*				
Range *(Low:High)*	≥ 13	**19:91**	Value within requirements	Value within requirements
Mean (SD)		**52.0 (21.3)**	Desirable Information	Desirable Information
Adults:Children	90:0	**90:0**	Value within requirements	Value within requirements
Arm Circumference *(cm)*				
Range *(Low:High)*		**20:40**	Desirable Information	Desirable Information
Mean (SD)		**29.7 (6.2)**	Desirable Information	Desirable Information
Cuff for Test Device (*cm)*				
Lower Octal *(20 – 22.5)*	9..54 (≥ 10%)	**11 (12.2%)**	Value within requirements	
Lower Quarter *(20 – 25)*	18..54 (≥ 20%)	**18 (20.0%)**	Value within requirements	
Lower Half *(20 – 30)*	36..54 (≥ 40%)	**46 (51.1%)**	Value within requirements	
Upper Half *(30 – 40)*	36..54 (≥ 40%)	**47 (52.2%)**	Value within requirements	
Upper Quarter *(35 – 40)*	18..54 (≥ 20%)	**18 (20.0%)**	Value within requirements	
Upper Octal *(37.5– 405)*	9..54 (≥ 10%)	**13 (14.4%)**	Value within requirements	
Total	Based on 90	**90**		
Recruitment SBP *(mmHg)*				
Range (Low:High)		**78:194**	Supplementary Information	Supplementary Information
Mean (SD)		**127.9 (23.8)**	Supplementary Information	Supplementary Information
Recruitment DBP *(mmHg)*				
Range (Low:High)		**32:114**	Supplementary Information	Supplementary Information
Mean (SD)		**73.0 (15.6)**	Supplementary Information	Supplementary Information

Subject Details Assessment		
	Checks	12
	Permitted Modifications	0
	Violations	0

Observer Measurements Range-Requirements

	Requirement	**Value**	**Assessment**
SBP (mmHg)			
≤ 100	13 to 207 (≥ 5%, < 80%)	**35 (13.5%)**	Percentage within requirements
101 to 139	0 to 194 (< 75%)	**162 (62.5%)**	Percentage within requirements
≥ 140	52 to 246 (≥ 20%, < 95%)	**62 (23.9%)**	Percentage within requirements
≥ 160	13 to 246 (≥ 5%, < 95%)	**13 (5.0%)**	Percentage within requirements
Total		**272**	
DBP *(mmHg)*			
≤ 60	13 to 207 (≥ 5%, < 80%)	**60 (23.3%)**	Percentage within requirements
61 to 84	0 to 194 (< 75%)	**138 (53.5%)**	Percentage within requirements
≥ 85	52 to 246 (≥ 20%, < 95%)	**60 (23.3%)**	Percentage within requirements
≥ 100	13 to 246 (≥ 5%, < 95%)	**16 (6.2%)**	Percentage within requirements
Total		**274**	
DBP sounds used			
K4:K5	Based on 90	**0:90**	Information req. satisfactory	Information req. satisfactory

Observer Measurements Range Assessment		
	Checks	10
	Permitted Modifications	0
	Violations	0

Study Results

Observer Differences

			Assessment	
Observer 2 – Observer 1				
SBP *(mmHg)*	Range *(Low:High)*	**-2:2**	Supplementary Information	Supplementary Information
	Mean (SD)	**-0.7 (1.0)**	Supplementary Information	Supplementary Information
DBP *(mmHg)*	Range *(Low:High)*	**-2:2**	Supplementary Information	Supplementary Information
	Mean (SD)	**-0.1 (1.1)**	Supplementary Information	Supplementary Information
Repeated Measurements		**N/A**	Information requirement satisfactory	

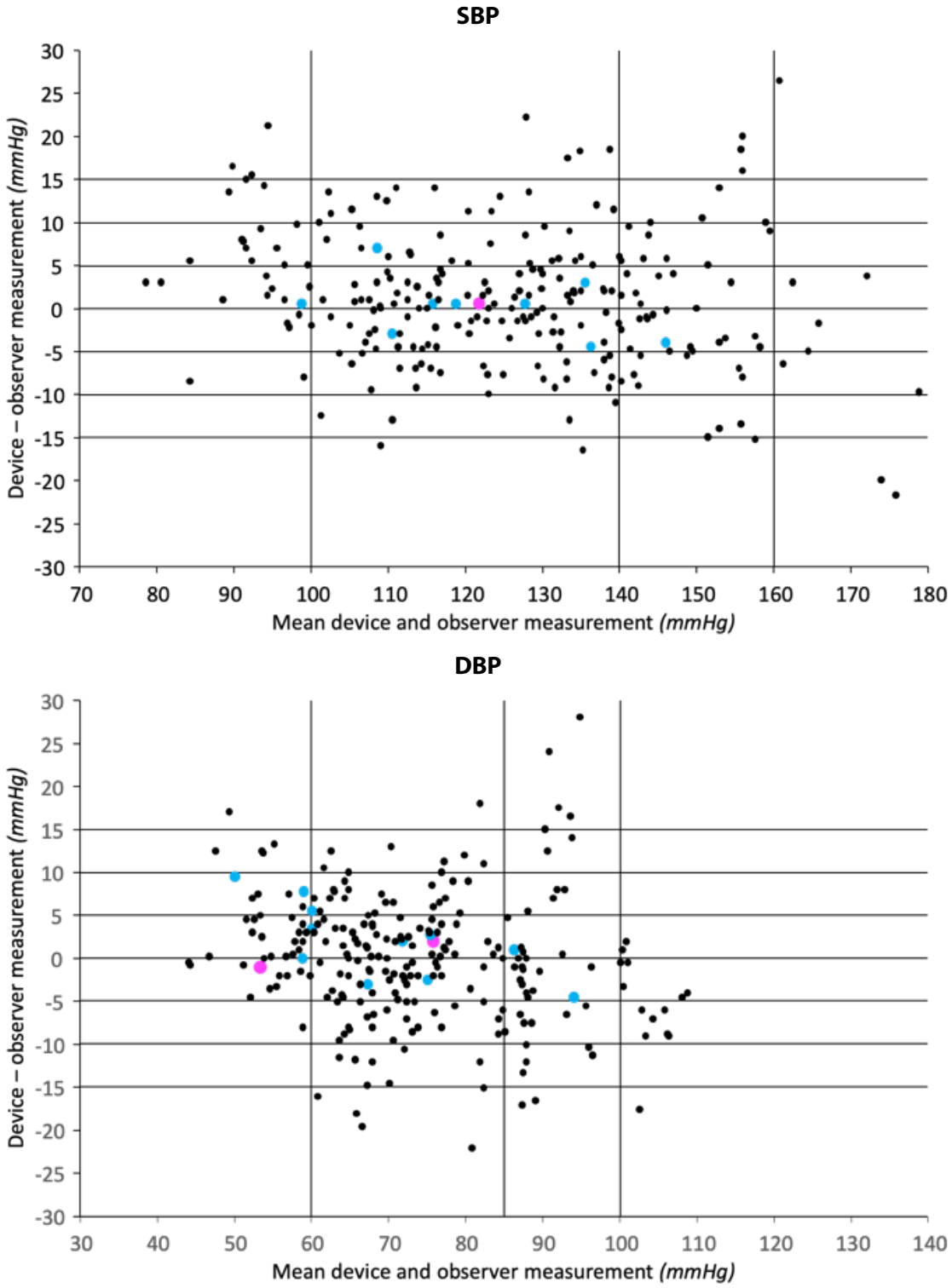
Observer Differences Assessment		
	Checks	1
	Permitted Modifications	0
	Violations	0

Validation Results

	Pass Req.	Achieved SBP	Achieved DBP	Assessment	
Criterion 1					
Measurement pairs		**272**	**274**	Value within requirements	Value within requirements
Mean *mmHg*	≤ 5	**+1.1**	**+0.1**	Value within passing criteria	Value within passing criteria
SD *mmHg*	≤ 8	**7.6**	**7.3**	Value within passing criteria	Value within passing criteria
Criterion 1 Result		**Pass**	**Pass**	Passing criterion satisfied	Passing criterion satisfied
Criterion 2					
Number of subjects		**90**		Value within requirements	
Mean *mmHg*		**+1.0**	**+0.1**	Value within passing criteria	Value within passing criteria
SD *mmHg*	≤ 6.87/6.95	**6.3**	**6.5**	Value within passing criteria	Value within passing criteria
Criterion 2 Result		**Pass**	**Pass**	Passing criterion satisfied	Passing criterion satisfied
Result		**Pass**		All Passing criterion satisfied	
Supplementary Information					
≤ 5 *mmHg*		**56%**	**59%**	Supplementary Information	Supplementary Information
≤ 10 *mmHg*		**84%**	**85%**	Supplementary Information	Supplementary Information
≤ 15 *mmHg*		**94%**	**95%**	Supplementary Information	Supplementary Information

Validation Results Assessment		
	Checks	16
	Permitted Modifications	0
	Violations	0

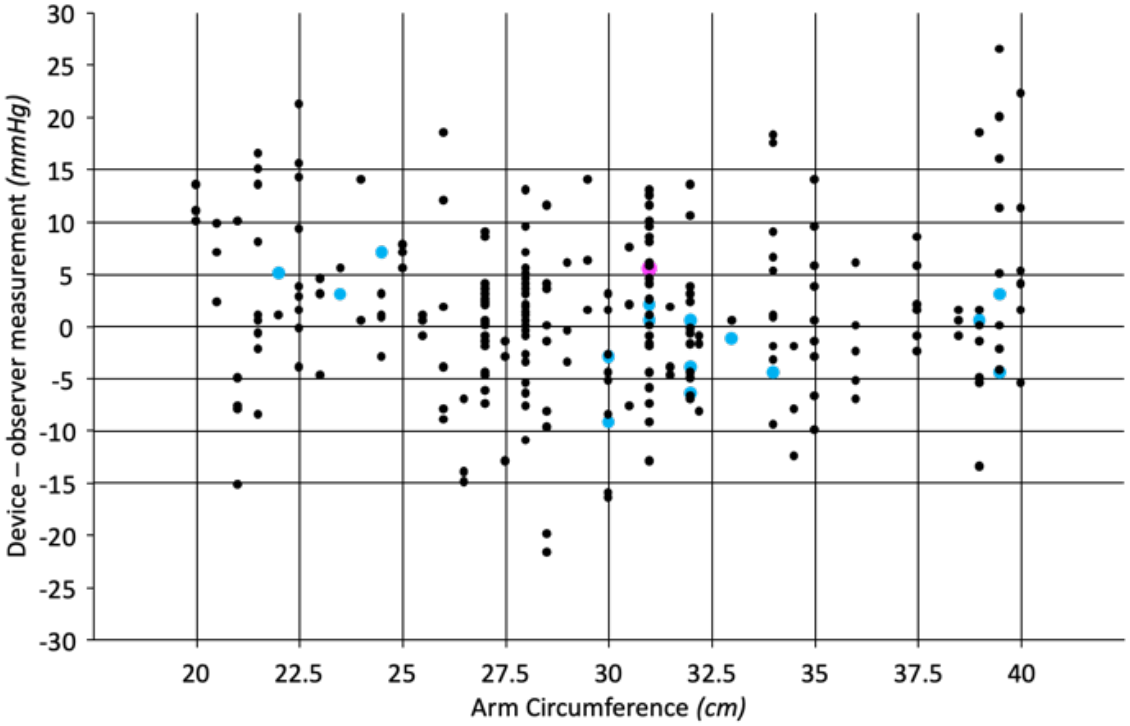
Difference against Mean Plots



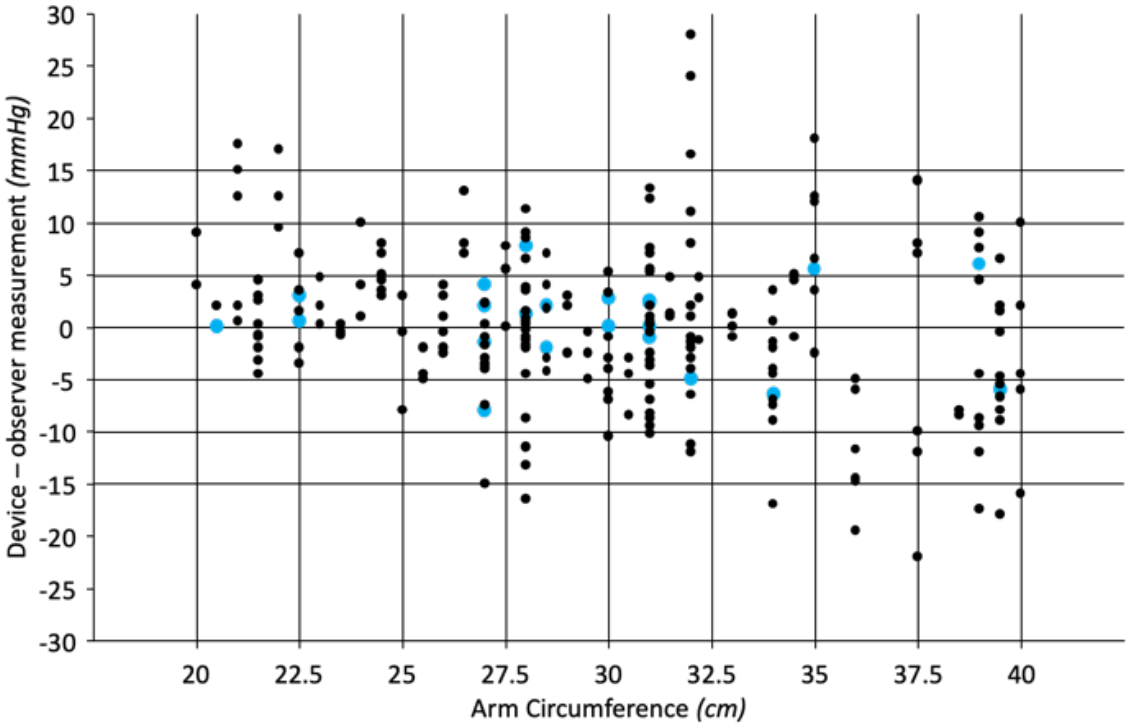
See Page 6 for Plot Legend

Difference against Arm Circumference Plots

SBP



DBP



See Page 6 for Plot Legend

		Assessment
SBP Difference against Mean Plot Provided	**Yes**	Information requirement satisfactory
DBP Difference against Mean Plot Provided	**Yes**	Information requirement satisfactory
SBP Difference against AC Plot Provided	**Yes**	Information requirement satisfactory
DBP Difference against AC Plot Provided	**Yes**	Information requirement satisfactory

Plots Assessment	**Checks**	4
	Permitted Modifications	0
	Violations	0

Limitations

		Assessment
Effect of Problems	No problems	Information requirement satisfactory
Justification of Adjustments	No adjustments to protocol	Information requirement satisfactory
Effect of K4 use	K4 not used	Information requirement satisfactory
Previous Validation Studies	None	Information requirement satisfactory
Comparisons	Not applicable	Information requirement satisfactory
Contrasts	Not applicable	Information requirement satisfactory
Cautions for correct use	Arm must be placed according to instructions. It is unsuitable for those who are unable to do so in a relaxed manner.	Information requirement satisfactory

Limitations Assessment	**Checks**	7
	Permitted Modifications	0
	Violations	0

ISO 81060-2:2018/Amd 1:2020 Study Assessment	**Checks**	82
	Permitted Modifications	0
	Violations	0

Recommendations

Assessment Summary

The validation has been checked and are verified as having been conducted in accordance with the ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 protocol requirements. Therefore, any hypothesis that the reliability of the results may be compromised due to protocol adjustment or violation must be rejected and each of the results must be considered to be valid. According to the protocol, these results require that the null hypothesis, that the tested technology in the device is inaccurate in measuring blood pressure, is rejected. Therefore, it must be concluded, that the oscillometric blood pressure measurement technology used in the SELVAS ACCUNIQ BP500 monitor is accurate for blood pressure measurement in adults, when the device is used according to manufacturer instructions.

Certification Decision

The SELVAS ACCUNIQ BP500, is certified by Medaval Ltd., for blood pressure measurement, in adults, as the technology fulfilled the conditions required for a pass in a validation study carried out in accordance with the requirements of the ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 standard.

Date of Approval: 08 January 2024.

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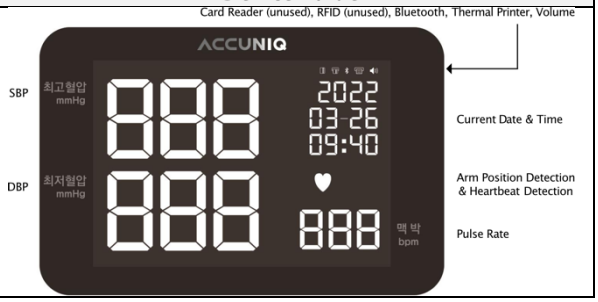
Appendix 1 – Device Registration and Audit Details

Primary Details

Item Category	Item	Device Value
Device Identification		
Identity	Primary Device Name	ACCUNIQ BP500
Identity	All device identities	BP500
Identity	All Measurement Modes	Oscillometric
Identity	Defined Measurement Mode	Oscillometric
Manufacturers		
Identity	Brand	ACCUNIQ
Identity	Distributer	SELVAS Healthcare, Inc. 155 Sinseong-ro, Yuseong-gu, Daejeon, Republic of Korea
Identity	Own Brand Labeller	Not applicable
Identity	Original Equipment Manufacturer	Not applicable
Identity	Regulation Manufacturer	Not applicable
Identity	Sole Manufacturer	SELVAS Healthcare, Inc. 155 Sinseong-ro, Yuseong-gu, Daejeon, Republic of Korea
Identity	Other role	Not applicable
Documentation	Contact	elliott.k.kim@SELVAShc.com, 82-42-879-3026
Primary Descriptors		
Feature	Measuring Functions	Blood Pressure
Feature	Primary Client Use	Use as a public facility
Documentation	Validation Publications	None
Core (Clinical)	Measurement Site	Upper Arm
Feature	Measurement Occurrence	Single measurement
Documentation	Availability	Available Currently
Feature	Accessibility	Optional voiced instructions and results
	Voiced Languages	Korean / English
Documentation	Warranty	
Files Supplied		
Essential Documentation	User Manual Supplied	Yes
Documentation	Service Manual Supplied	Yes
Documentation	Specifications Supplied	Yes
Essential Documentation	Device Image Supplied	

Item Category	Item	Device Value
Essential Documentation	Display Image Supplied	

Standard Device Details

Item Category	Item	Device Value

Standard Device Hardware

Casing

Accessory	Length	502 mm
Accessory	Width	450 mm
Accessory	Height	279 mm
Accessory	Weight (with batteries)	4800 g
Accessory	Number of Screens	1
Accessory	Screen Type	Segment LCD
Accessory	Screen Width	130 mm
Accessory	Screen Height	90 mm
Accessory	Screen Backlight	Yes
Accessory	Adjustable Font Size	Not applicable

Climate

Core (Technical)	Minimum Storage Temperature	-10 °C
Core (Technical)	Maximum Storage Temperature	60 °C
Core (Technical)	Minimum Operating Temperature	10 °C
Core (Technical)	Maximum Operating Temperature	40 °C
Core (Technical)	Minimum Storage Humidity	0%
Core (Technical)	Maximum Storage Humidity	94%
Core (Technical)	Non-condensing Storage Humidity	Yes
Core (Technical)	Minimum Operating Humidity	15%
Core (Technical)	Maximum Operating Humidity	85%
Core (Technical)	Non-condensing Operating Humidity	Yes
Core (Technical)	Minimum Storage Atmospheric Pressure	700 hPa
Core (Technical)	Maximum Storage Atmospheric Pressure	1060 hPa
Core (Technical)	Minimum Operating Atmospheric Pressure	700 hPa
Core (Technical)	Maximum Operating Atmospheric Pressure	1060 hPa
Core (Technical)	Approximate Maximum Altitude	3000 m

Power

Accessory	Battery Type	No batteries used
Accessory	Battery Size	Not applicable
Accessory	Battery Details	Not applicable
Accessory	Battery Quantity	0

Item Category	Item	Device Value
Accessory	Battery Life (# measurements)	Not applicable
Accessory	Rechargeable battery use	Rechargeable batteries not permitted
Accessory	AC Adapter Provision	Required – Device only operates from mains
Core (Technical)	AC Adapter Number(s)	BRIDGEPOWER BPM060S12F14
Accessory	Automatic Power On	No automatic power on
Accessory	Automatic Power Off	No automatic power off
Communication		
Accessory	Communication Port	USB and RS232
Accessory	Cable Provided	Yes
Audio		
Feature	Voice Memo Recorder	Not provided
Accessories		
Accessory	Storage/Carrying Case	Not applicable – not intended to be portable
Accessory	Lid	Not applicable – not intended to be closed
Accessory	Desk mount facilities	Not applicable
Accessory	Wall mount facilities	Not applicable
Accessory	Mobile mount facilities	Not applicable
Accessory	Pouch	Not applicable
Accessory	Belt	Not applicable
Accessory	Belt Clip	Not applicable
Accessory	Shoulder Straps	Not applicable
Accessory	Printer	Integrated as part of device
Accessory	Card Holder	Not applicable
Appearance		
Accessory	Case Description	White/Grey, Available in English and/or Korean
Accessory	Button Description(s)	Start/Stop: Indigo Acrylonitrile Butadiene Styrene (ABS) Emergency Stop: Red ABS Available in English or Korean
Accessory	Other Description(s)	Not applicable

Standard Device Firmware

Algorithm		
Core (Technical)	Firmware Name and Version	BP500.EN.1.0.00 (Only to distinguish model number)

Standard Device Software

Memory		
Feature	Number of Memory Locations per User/Zone	0
Feature	Number of Users/Zones	0
Feature	Non-memory use (Guest mode)	Not applicable (No memory facility)
Feature	Method of Clearing Memory	Not applicable (No memory facility)
Accessory	Memory card slot	Not provided
Feature	Date Stored	Not applicable (No memory facility)
Feature	Time Stored	Not applicable (No memory facility)
Feature	Error Code Stored	Not applicable (No memory facility)
Feature	Facility to mark unique results	Not applicable (No memory facility)
Procedure		
Feature	Value shown before measurement	Not applicable (No memory facility)
Feature	Average displayed on measurement completion	Not applicable (No memory facility)
Measurement		
Core (Technical)	Error Codes	M01 M02 M09 M15 M16 M18 D01 D06 D12 D23 D24
Analysis		
Feature	Software Use	No proprietary software provided
Feature	Proprietary Software Name	Not applicable

Item Category	Item	Device Value
Non-Medical Extra Features		
Accessory	Clock	Not provided
Accessory	Alarm	Not provided
Accessory	Radio	Not provided
Accessory	Ambient Temperature	Not provided

Standard Device Features

Summary

Documentation	Features Summary	This device is an electronic device used to measure blood pressure in a non-invasive way outside the body. The cuff is automatically pressurized and systolic and diastolic blood pressure and heart rate are measured and displayed as results.
Feature or Accessory	Items not listed	None

Standard Screen and Audio Indicators

Measurement

After Measurement

Feature	Measurement Unit(s)	Shown
Feature	Average – Overall	Function not provided
Feature	Plot	No plot provided

Error Indicators

Feature	Measurement Error	"Error" text with code or number

Timestamp

Feature	Date and Time	Date and Time shown
Feature	Time Format	24-hour and 12-hour clocks

Markers

Feature	Event – Medication	Function not provided

Memory

Feature	Value from Memory	Not applicable (No memory facility)
Feature	Recorded Measurement Timestamp	Not applicable (No memory facility)
Feature	Memory Location Number	Not applicable (No memory facility)
Feature	Memory Locations Used	Not applicable (No memory facility)
Feature	Memory Full	Not applicable (No memory facility)
Feature	Memory Zone Name	Not applicable (No memory facility)
Feature	Delete memory	Not applicable (No memory facility)

Non-Measurement

Power

Feature	Battery Symbol	Not applicable (No battery)
Feature	Battery Charging Indicator	Not applicable (No charging)
Feature	Voltage Check	Function not provided
Feature	AC Adapter Symbol	Function not provided
Feature	Power Error Symbol	Error code
Feature	Start	Function not provided
Feature	Stop	Function not provided

Communication

Feature	Reminder to Transfer Data	Function not provided
Feature	Device Connected	Special Icon 
Feature	Transmitting Data	Function not provided
Feature	Transmission Successful	Function not provided
Feature	Transmission Unsuccessful	Function not provided
Feature	Signal out-of-range	Function not provided
Feature	PC Link	Reuse of 7-segment characters

Settings

Feature	Settings	Function not provided

Item Category	Item	Device Value
Feature	Initialisation	Function not provided
Feature	Hide measurement display option	Not provided

Audio Indicators

Feature	Sound Volume	Seven levels
Feature	Measurement Value	Optional Voiced Indicator
Feature	Memory Value	None
Feature	Statistics Value	None
Feature	Measurement Reminder	None
Feature	Measurement Complete	Optional Voiced Indicator
Feature	Measurement Error	Optional Voiced Indicator
Feature	Voice Recorder	Function not provided

Display

Feature	Screen Background Colour(s)	Black
Feature	Screen Font Colour(s)	White
Feature	Screen Language(s)	None

Standard Buttons and Switches

Power

Feature	Power On	Power
Feature	Power Off	Power
Feature	Start	Start/Stop
Feature	Stop	Start/Stop

Up/Down

Feature	Increase value	Up
Feature	Decrease value	Down
Feature	Previous value	Not applicable
Feature	Next value	Not applicable
Feature	Increase volume	Set and Up
Feature	Decrease volume	Down and Set

Memory

Feature	Memory mode	Not applicable
Feature	Memory bank selection	Not applicable
Feature	Delete memory	Not applicable
Feature	Delete last measurement	Not applicable

Date and Time

Feature	Date and Time settings	Down, Set and Up
Feature	Alarm settings	Not applicable
Feature	Date and Time announcement	Not applicable

Statistics

Feature	Show Average	Not applicable
Feature	Show Alternative Average	Not applicable
Feature	Show Plot	Not applicable

Settings

Feature	Settings	Set
Feature	Confirm	Not applicable
Feature	Measurement unit settings	Not applicable
Feature	Change language	User

BPM-Specific Details

Item Category	Item	Device Value

BPM Device Hardware

Cuffs

Core (Clinical)	Cuff List	Style 1 

Sensors

Core (Technical)	Number of pressure sensors	1
Core (Technical)	Pressure sensor type	Strain gauge
Core (Technical)	Pressure sensor model number(s)/code(s)	ADP1131
Core (Technical)	Pressure sensor cross-check	Not provided
Documentation	Pressure sensor details supplied	Yes
Core (Technical)	Positioning sensor type	Capacitive position sensor
Core (Technical)	Positioning sensor model number(s)/code(s)	BS812A-1
Documentation	Positioning sensor details supplied	Yes
Core (Technical)	Cuff-Wrapping Sensor	Not provided
Core (Technical) or Feature	ECG sensor	No sensor
Documentation	ECG sensor details supplied	Not applicable
Core (Technical) or Feature	Korotkoff-sound sensor	No sensor
Documentation	Korotkoff-sound sensor details supplied	Not applicable
Core (Technical)	Activity sensor	Not provided
Documentation	Activity sensor details supplied	Not applicable

Signal Processing

Core (Technical)	Amplifier model number(s)/code(s)	LM324DR
Core (Technical)	Analogue filter model number(s)/code(s)	Not applicable
Core (Technical)	Analogue-to-digital convertor model number(s)/code(s)	ADC within Micom (ATSAM4S16CA)
Core (Technical)	Pressure Sampling Rate	1000 Hz

Pneumatic Hardware

Core (Technical)	Pneumatic pump model number/code	P54A-0001R (abr P54A01R) or RFP45J-0002R (abr RFP45J02R)
Documentation	Pneumatic pump details	Pump P54A-0001R Details.pdf, Pump RFP45J-0002R Details.pdf
Core (Technical)	Exhaust valve model number/code	KSV15C-6I
Documentation	Exhaust valve details	Exhaust-Valve KSV15C-6I Details.pdf
Core (Technical)	Safety Release Valve	Not provided

Accessories

Accessory	Cuff Holder	Cuff integrated into device

BPM Device Software

Memory

Feature	SBP Stored	Not applicable (No memory facility)
Feature	DBP Stored	Not applicable (No memory facility)
Feature	PR Stored	Not applicable (No memory facility)
Feature	MAP Stored	Not applicable (No memory facility)
Feature	Generic Event Code Stored	Not applicable (No memory facility)
Feature	Medication Code Stored	Not applicable (No memory facility)
Feature	Atrial Fibrillation	Not applicable (No memory facility)
Feature	Arrhythmia/IHB Code Stored	Not applicable (No memory facility)
Feature	BP Grade Stored	Not applicable (No memory facility)
Feature	Body Movement Code Stored	Not applicable (No memory facility)
Feature	Bed and Rising Times Stored	Not applicable (No memory facility)

Ranges

Core (Technical)	Maximum Pressure (Upper Limit of Upper Technical Alarm Condition Range)	300 mmHg
Core (Technical)	Upper Limit of Rated Range	280 mmHg
Core (Technical)	Lower Limit of Rated Range	30 mmHg
Core (Technical)	Minimum Pressure (Lower Limit of Low Technical Alarm Condition Range)	0 mmHg
Core (Technical)	Maximum SBP	280 mmHg

Item Category	Item	Device Value
Core (Technical)	Minimum SBP	60 mmHg
Core (Technical)	Maximum DBP	200 mmHg
Core (Technical)	Minimum DBP	30 mmHg
Core (Technical)	Maximum PP	250 mmHg
Core (Technical)	Minimum PP	15 mmHg
Core (Technical)	Maximum PR	240 bpm
Core (Technical)	Minimum PR	30 bpm
Specified Accuracy		
Core (Technical)	Specified BP Accuracy (±)	2 mmHg
Core (Technical)	Specified PR Accuracy (±)	1.5%

BPM Device Firmware

Analysis

Feature	Overall arithmetic mean	Not applicable (No memory facility)
Feature	Last overall 3-meas arithmetic mean	Not applicable (No memory facility)
Feature	Last overall 7-day arithmetic mean	Not applicable (No memory facility)
Feature	Last overall ESH arithmetic mean	Not applicable (No memory facility)
Feature	Overall median	Not applicable (No memory facility)
Feature	Overall morning arithmetic mean	Not applicable (No memory facility)
Feature	Last morning 3-meas arithmetic mean	Not applicable (No memory facility)
Feature	Last morning 7-day arithmetic mean	Not applicable (No memory facility)
Feature	Overall evening arithmetic mean	Not applicable (No memory facility)
Feature	Last evening 3-meas arithmetic mean	Not applicable (No memory facility)
Feature	Last evening 7-day arithmetic mean	Not applicable (No memory facility)
Feature	BP Classification	Not provided
Feature	Pulse Classification	Not provided
Feature	Measurement-Target BP difference	Not provided

BPM Device Features

Technical

Core (Technical)	Operation Method	Oscillometry: automatic during deflation
Feature	Single Measurements	Yes
Feature	Double Measurement	Not provided
Feature	Triple Measurement	Not provided
Feature	Measurements at ESH-recommended times	Not provided
Feature	ABPM Measurement Occurrences	Device does not support ABPM
Feature	ABPM duration	Not applicable (Not ABPM)
Core (Technical)	Continuous Measurements	Not provided
Feature	Continuous mode frequency	Not applicable (No continuous mode)
Core (Technical)	ECG triggered measurements (ECG used to confirm Korotkoff sounds)	Not provided
Feature	Measurement Interval Set	Not applicable
Feature	Measurement Times Set	Not applicable
Core (Clinical)	Repeat measurement	No automatic repeat provided
Feature	Suspend Multiple/ABPM measurements	Not applicable (No multiple measurements)

Calibration

Feature	Calibration Mode	Not provided
Core (Technical)	Recommended Calibration Intervals	Not applicable
Feature	Recalibrate Reminder	Not provided

Special Measurements

Core (Technical)	Test Measurements	None
Core (Clinical)	Measurements triggered by ECG event	Not provided
Feature	Measurements triggered by posture	Not provided
Feature	Measurements triggered by activity	Not provided
Feature	Manually triggered measurements (ABPM only)	Not provided

Procedure

Core (Technical)	Positioning Check	Yes
Core (Technical)	Zero Pressure Check	Not provided
Core (Technical)	Inflation Method	Automatic after manual-initiated start
Core (Technical)	Inflation Rate	Depends on upper arm thickness and expected SBP value
Core (Technical)	Inflation Target	Measurement during inflation – SBP dependent
Core (Technical)	Inflation Target Value(s)	Not applicable
Core (Technical)	Deflation Method	Logical control (drop after SBP)

Item Category	Item	Device Value
Core (Technical)	Deflation Rate	4 mmHg/s
Measurement		
Feature	Measurement Units	mmHg only
Core (Clinical)	Systolic Blood Pressure (SBP)	On Screen and Report
Core (Clinical)	Diastolic Blood Pressure (DBP)	On Screen and Report
Core (Clinical)	Pulse Rate (PR)	On Screen and Report
Core (Clinical)	Measured Mean Arterial Pressure (MAP)	Not provided
Feature	Estimated Mean Arterial Pressure (MAP)	Optionally on Report only
Feature	Pulse Pressure (PP)	Optionally on Report only
Feature	Pressure Rate Product (PRP)	Optionally on Report only
Feature	Left and right arm pressures	Not provided
Core (Clinical) or Feature	Central Aortic Pressures	Not provided
Feature	Ankle-Brachial Index	Not provided
Core (Technical)	Technical Alarm Condition	Included in standard out-of-range error
Feature	Arterial Stiffness Index	Not provided
Feature	Posture	Not provided
Feature	Activity Level	Not provided
ISO Certification - Manual Devices		
Documentation	ISO-81060-1 Certification (Manual devices only)	Not applicable (automatic)
Documentation	Date of ISO Certification (Manual devices only)	Not applicable

BPM Screen and Audio Indicators

Measurement

Before Measurement

Feature	Measurement Mode	Function not provided
Feature	Arm positioning indicator	Special Icon 
Feature	Wrist positioning indicator	Function not provided
Feature	Posture indicator	Function not provided
Feature	Cuff wrapping indicator	Function not provided
Feature	Left/Right Limb Selection	Function not provided
Feature	Inflation Target Selection	Not applicable for intended device use
Feature	Threshold Selection	Function not provided
Feature	Memory zone	Function not provided

During Measurement

Feature	Inflation	Reuse of 7-segment characters
Feature	Deflation	Reuse of 7-segment characters
Feature	Heartbeat Indicator	Special Icon 
Feature	Pressure	Digital value

After Measurement

Feature	SBP	Always shown
Feature	DBP	Always shown
Feature	Measured MAP	Not provided
Feature	PR	Always shown
Feature	Posture	Function not provided
Feature	Activity Level	Function not provided
Feature	Pulse Wave Pattern	Available on printout

Derived Values

Feature	PP	Available on printout
Feature	Estimated MAP ((SBP + 2 × DBP) / 3)	Available on printout
Feature	Pressure Rate Product (PRP = SBP × PR)	Available on printout
Feature	Average – Morning	Function not provided
Feature	Average – Evening	Function not provided
Feature	BP Classification	Classification not indicated
Feature	Pulse Classification	Function not provided
Feature	Arrhythmias	Function not provided
Feature	Haemodynamic Stability	Function not provided

Item Category	Item	Device Value
Feature	Inter-Arm Difference	Function not provided
Feature	Arterial Stiffness	Function not provided
Feature	Visit doctor	Function not provided
Error Indicators		
Feature	Body-Movement Error	Function not provided
Feature	Air leak/Cuff Connection Error	Function not provided
Feature	Ambient temperature Error	Function not provided
Feature	Measurement Reliability Error	Function not provided
Feature	Measurement being repeated	Function not provided
Markers		
Feature	Event – Generic	Function not provided
Feature	Event – Bed Time & Rising Time	Function not provided
Memory		
Feature	Pulse Rate from Memory	Not provided
Special Measurements		
Feature	Test Measurements	Function not provided
Feature	Test Successful	Function not provided
Non-Measurement		
Settings		
Feature	Button Lock	Function not provided
Audio Indicators		
Feature	Measurement imminent	None
Feature	Pulse signal detected	Not applicable (No sound)

BPM Buttons and Switches

Safety		
Feature	Immediate Exhaust	Emergency
Mode		
Feature	Mode: Single Measurement	Start/Stop
Feature	Mode: Double Measurement	Not applicable
Feature	Mode: Triple Measurement	Not applicable
Feature	Mode: Home Measurement	Not applicable
Feature	Mode: ABPM	Not applicable
Feature	Mode: Nocturnal repeated measurements	Not applicable
Feature	Mode: Diagnostic	Not applicable
Feature	Mode: ESH controlled	Not applicable
Feature	Mode: Auscultation/Manual	Not applicable
Feature	Mode: Automatic	Not applicable
Settings		
Feature	Manual Threshold Selection	Not applicable
Feature	Left/Right Limb Selection	Not applicable
Feature	Inflation Target Selection	Not applicable
Event		
Feature	Event: Generic	Not applicable
Feature	Event: Medication	Not applicable
Feature	Event: Bed Time	Not applicable
Feature	Event: Rising Time	Not applicable

Cuffs

Item Category	Item	Cuff Value
Cuff Identification		
Identity	Primary Cuff Name	SELVAS Style 1
Identity	All cuff identities	Integrated
Identity	Generic Name	Universal
Identity	Manufacturer	As Device
Descriptors		
Size		
Core (Technical)	Minimum Circumference	200 mm
Core (Technical)	Maximum Circumference	400 mm
Core (Technical)	Bladder Length	146 mm
Core (Technical)	Bladder Width	158 mm
Cuff Details		
Core (Technical)	Cuff Style	Rigid cylindrical upper-arm cuff
Core (Technical)	Bladder Style	Integrated cuff and bladder
Core (Technical)	Cuff Fastenings	Integrated cuff without fastenings
Core (Biological)	Outer Material	Spandex
Feature	Connector	Not applicable – Integrated cuff
Other Details	Connector	Indigo deco cover
Microphone Details		
Core (Technical) or Accessory	Microphones	No microphone
Core (Technical) or Accessory	Microphone model number(s)/code(s)	Not applicable
Provision		
Documentation	Default Provision	Integrated as part of the device
Documentation	Availability	Integrated
Validation and Certification		
Documentation	ISO-81060-1 Certification (Cuffs for manual devices only)	Not applicable (automatic)
Documentation	Date of ISO Certification (Cuffs for manual devices only)	Not applicable
Files Supplied		
Documentation	Cuff Image Supplied	
Documentation	Microphone details	Not applicable