Medical Device Assessment

Medaval Accreditation Assessment

Volume 2019 Report 1901AR 05 March 2019

Accreditation assessment of the blood pressure measurement technology used in the Novacor Diasys 3 (DIS-0001-00) upper arm ABPM monitor, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard both for a general study in adults and for an additional ABPM-device study and according to the European Society of Hypertension International Protocol revision 2010

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Reference Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the Novacor Diasys 3 (DIS-0001-00) upper arm ABPM monitor, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard both for a general study in adults and for an additional ABPM-device study and according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2019 Mar 05;**2019**(1901AR) 23 p. Available from: https://www.medaval.ie/MDA/2019/MDA1901AR.pdf.

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MEDICAL DEVICE ASSESSMENT 1901AR:2019

Accreditation assessment of the blood pressure measurement technology used in the Novacor Diasys 3 (DIS-0001-00) upper arm ABPM monitor, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard both for a general study in adults and for an additional ABPM-device study and according to the European Society of Hypertension International Protocol revision 2010

Medaval Accreditation Assessment – 05 March 2019

Summary

Introduction

The Novacor Diasys 3 (model number DIS-0001-00) is a blood pressure monitor intended for ambulatory blood pressure measurement. Oscillometric measurements are recorded automatically at timed intervals with additional measurements by manual initiation or on indication of postural hypotension.

Methodology

The Novacor Diasys 3 was validated according to the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard[1]. This standard requires two validations for ABPM devices: The first is a primary study in a sample of at least 85 subjects from a general population, in accordance with specified recruitment requirements. The second, an additional requirements for ABPM devices, is a study in a sample of at least 35 subjects who's pulse rate is increased by between 10% and 20% by exercising on bicycle ergometer in order to achieve this change. The Novacor Diasys 3 was also validated according to the requirements of the European Society of Hypertension International Protocol revision 2010 (ESH-IP)[2]. This is a study in a sample of 33 subjects from a general population, in accordance with very strict recruitment requirements.

A total of 85 subjects were included. Thirty-three of the first 35 subjects comprised the sample required for the ESH-IP study. Thirty six of the remaining 50 subjects also comprised the sample required for the additional requirements study. No subject who participated in the ESH-IP study also participated in the additional requirements study.

Three cuffs were used in accordance with the requirements of the protocols. These were the Paediatric 18 cm to 24 cm cuff (model number ACC-0215-00), the Standard 24 cm to 32 cm cuff (model number ACC-0213-00) and the Large 32 cm to 40 cm cuff (model number ACC-0214-00).

Results

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

In the primary AAMI/ANSI/ISO 81060-2:2013 study, the Criterion 1 errors were +3.9 mmHg ± 2.9 mmHg for SBP and +3.4 ± 2.5 mmHg for DBP and all values were within the ±5.0 mmHg ± 8.0 mmHg requirements. The Criterion 2 errors were also +3.9 mmHg ± 2.9 mmHg for SBP (within the ±5.0 mmHg ± 5.70 mmHg requirements) and +3.4 ± 2.5 mmHg for DBP (within the ±5.0 mmHg ± 6.03 mmHg requirements).

In the additional requirements AAMI/ANSI/ISO 81060-2:2013 study, the Criterion 1 errors were +4.1 mmHg ± 2.2 mmHg for SBP and +3.8 ± 2.1 mmHg for DBP and all values were within the ±5.0 mmHg ± 8.0 mmHg requirements. The Criterion 2 errors were +4.1 mmHg ± 2.0 mmHg for SBP (within the ±5.0 mmHg ± 5.56 mmHg requirements) and +3.8 ± 1.9 mmHg for DBP (within the ±5.0 mmHg ± 5.77 mmHg requirements).

The ESH-IP protocol has two set of passing requirements. Part 1 sets out ideal and minimal accuracy levels for the 99 individual pairs of measurements each with three criteria. At least two of the ideal criteria and all three of the minimal criteria must be met. The ideal criteria are at least 73 differences (between test and reference measurement) are within 5 mmHg, at least 87 differences are within 10 mmHg and at least 96

differences are within 15 mmHg. For the Novacor Diasys 3, those differences were 75, 99 and 99 respectively for SBP and were 95, 99 and 99 respectively for DBP. Part 1 criteria were, therefore, met for both SBP and DBP. Part 2 sets out accuracy levels for the sets of three measurements from the 33 subjects. At least 24 subjects must have at least two measurements within 5 mmHg of the reference measurements and at most 3 subjects can have no measurements within 5 mmHg of the reference measurements. For the Novacor Diasys 3, those counts were 26 and 3 subjects respectively for SBP and were 32 and 0 subjects respectively for DBP. Part 2 criteria were, therefore, met for both SBP and DBP.

Conclusion

Each of the protocols are designed to test the null hypothesis that the device is inaccurate and that this hypothesis must be rejected if the respective passing criteria are met.

As the protocols were 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 in each case has been met, there is no option but to reject the null hypothesis and conclude that the oscillometric blood pressure measurement technology used in Novacor Diasys 3 is accurate, when used with the appropriate cuff, as described herein, within the criteria set out in AAMI/ANSI/ISO 81060-2:2013 for both a primary study in adults and an additional requirements for ABPM study and also within the criteria set out in the European Society of Hypertension International Protocol revision 2010 for a study in a general population.

Due to dual recruitment, neither the ESH-IP or AAMI/ANSI/ISO 81060-2:2013 additional requirements study can be considered as being entirely independent of the AAMI/ANSI/ISO 81060-2:2013 primary study. However, the ESH-IP and AAMI/ANSI/ISO 81060-2:2013 additional requirements studies are mutually independent.

Contents

Glossary

Abbreviations

%RH	relative humidity percent
°C	degrees Celsius
AAMI	Association for the Advancement of Medical Instrumentation (USA)
ABPM	Ambulatory blood pressure measurement
AMP	Associazione Medica Patavina (Medical Association Patavina – Italy)
ANSI	American National Standards Institute
BP	Blood pressure
bpm	beats per minute
CE	Conformité Européene (European Conformity)
CEE	Communauté Economique Européenne (European Economic Community – former name for EU)
cm	centimetre(s)
DBP	Diastolic blood pressure
DIMED	Dipartimento di Medicina (Department of Medicine)
ECG	Electrocardiogram
ESH	European Society of Hypertension
ESH-IP	European Society of Hypertension International Protocol
EU	European Union
g	gram(s)
hPa	hectopascals
ISO	International Organization for Standardization/International Standards Organization
m	metre(s)
mAh	milliamp hours
MAP	Mean arterial pressure
meas.	Measurement
min	minute(s)
mmHg	millimetre(s) of mercury
NiMH	Nickel–metal hydride (battery)
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
SIIA	Società Italiana per l'Ipertensione Arteriosa (Italian Society for Arterial Hypertension)
SRL	Società a responsabilità limitata (Italian equivalent to a limited liability company)
VR	Verona (Italy)

Plot Legend

●	Single point, area one unit
●	Two superimposed points, area two units
●	Three superimposed points, area two units
●	Four superimposed points, area four units
●	Five superimposed points, area five units

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[3]. Both validation and comparative-equivalence services are in accordance with Regulation (EU) 2017/745.

Validations are performed by members of a Validation Panel. They are assigned blind to the manufacturer. Validation reports are peer reviewed by members from a corresponding Reviewer Panel. Once reviewed, investigators are free to prepare a scientific paper for publication, should they so wish.

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 are developed and reviewed by members of our Scientific Procedures Panel. 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 an equivalent 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. The Medaval Scientific Procedures Panel 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.

Casa di Cura Villa Maria SRL

The study investigators were

> Prof. Paolo Palatini, Department of Medicine, University of Padova, ITALY
>
> Dr. Claudio Fania, Reparto di Medicina, Casa di Cura Villa Maria SRL., Padova, ITALY.

Casa di Cura Villa Maria is one of the most important hospitals, accredited within the Italian National Health System, in Padua.

It has departments in Orthopaedic rehabilitation, Neurological rehabilitation, Rehabilitative long-term care, Plastic surgery and General medicine as well as extensive and intensive outpatient services.

Dr. Claudio Fania is a researcher and an expert in hypertension, on early diagnosis, in the study of possible secondary causes, in the study and prevention of organ damage, in appropriate therapy and in the validation of blood pressure monitors. He worked for years, alongside Prof. Paolo Palatini, at the SIIA-certified hypertension centre at the DIMED Department (Department of Medicine) of the University of Padua and now works in the General Medicine Department at Casa di Cura Villa Maria.

He is the author of 40 international publications in the fields of hypertension, cardiovascular diseases and blood pressure monitor validation. He is a member of the SIIA (Italian Society for Arterial Hypertension), the ESH (European Society of Hypertension) and the AMP (Medical Association Patavina).

For more information, please refer to www.cdcvillamaria.it/pag/casa-di-cura-villa-maria/

Novacor

Novacor is one of the world leaders in ambulatory recording. It has been operating in this field successfully for more than 25 years and offers a complete and advanced range of ECG Recorders and Ambulatory Blood Pressure Monitors.

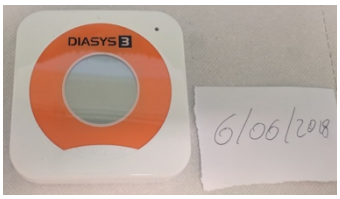
Novacor co-operates with healthcare professionals to improve diagnostic devices continuously to meet clinical needs more closely whilst ensuring each product remains simple to use for the specialist and convenient for the patient. Novacor provides patients and healthcare professionals with products that combine Innovation, Reliability and Quality.

The company has the ISO 13485 certificates. All the products have the CE mark (Dir 93/42 CEE).

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

Device Details

TEST DEVICE

		Assessment
Full Name	Novacor Diasys 3	Requirement satisfactory
Model	DIS-0001-00	Requirement satisfactory
Measurement Site	Upper Arm	Requirement satisfactory
Client Use	Suitable for ABPM.	Requirement satisfactory
Operation Method	Oscillometry, automatic during deflation	Requirement satisfactory
Measurement Occurrence	Single Measurements Only	Requirement satisfactory
Device Photograph		Requirement satisfactory
Manufacturer(s)	NOVACOR 4 Passage Saint-Antoine, 92508 Rueil-Malmaison, FRANCE	Requirement satisfactory
Cuffs	Paediatric (ACC-0215-00): 18 cm to 24 cm Standard (ACC-0213-00): 24 cm to 32 cm Large (ACC-0214-00): 32 cm to 40 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

REFERENCE SPHYGMOMANOMETER

		Assessment
Full Name	BoSo Mercurius E	Information requirement
Model	370-0-101	Information requirement
ISO-81060-1 Certification	Yes plus ISO 13485 and ISO 9001	Information requirement
Manufacturer(s)	Bosch + Sohn GmbH u. Co. KG, Bahnhofstraße 64, D-72417 Jungingen, GERMANY.	Desirable information

REFERENCE CUFF(S)

		Assessment
Name(s) and Model(s)	Bracelet for the measurement of PA for sphygmomanometers (SBEC-2U) 14 cm to 22 cm (SBEC-2U) 22 cm to 32 cm (SBEC-2U) 32 cm to 42 cm	Cuffs Listed: Information requirement Arm Circumferences: Information requirement
ISO-81060-1 Certification	Yes plus ISO 13485 and ISO 9001	Information requirement
Manufacturer(s)	MediCare - El.Med. Garda srl Via San Giuseppe Artigiano 6, 37010 Costermano sul Garda VR, ITALY	Desirable information

REFERENCE STETHOSCOPE

		Assessment
Full Name	Classic Teaching Stetho (for dual simultaneous auscultation)	Desirable information
Model	32542	Desirable information
Manufacturer(s)	Gima S.p.A., Via Marconi 1, 20060 Gessate Milano, ITALY.	Desirable information

Device Details Assessment	**Checks**	21
	Permitted Modifications	0
	Violations	0

AAMI/ANSI/ISO 81060-2:2013 Primary Study

STUDY DETAILS

Protocol	The AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults[1]	
		Assessment
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	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	Inpatients and outpatients	Supplementary Information
NBP Subjects Selection	Healthcare 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			Assessment
Total Screened		**85**	Information requirement satisfactory
Total Excluded		**0**	Information requirement satisfactory
Device Failure	**0**		Information requirement satisfactory
Poor Quality Sounds	**0**		Information requirement satisfactory
Cuff Size Unavailable	**0**		Information requirement satisfactory
Observer Disagreement	**0**		Information requirement satisfactory
Bigeminy	**0**		Information requirement satisfactory
Trigeminy	**0**		Information requirement satisfactory
Isolated VPB	**0**		Information requirement satisfactory
Atrial Fibrillation	**0**		Information requirement satisfactory
Other Reasons*	**0**		Information requirement satisfactory
Total Recruited *(85 Required)*		**85**	Value within requirements
*Explanation Summary			
Not applicable			Information requirement satisfactory

On Treatment Ranges (On Rx / Total)				
SBP	Low	≤ 100 *mmHg*	**0 / 11**	Supplementary Information
	Medium	131 – 139 *mmHg*	**9 / 28**	Supplementary Information
	High	≥ 140 *mmHg*	**24 / 46**	Supplementary Information
DBP	Low	< 80 *mmHg*	**0 / 6**	Supplementary Information
	Medium	80 – 100 *mmHg*	**11 / 33**	Supplementary Information
	High	> 100 *mmHg*	**22 / 46**	Supplementary Information

Screening and Recruitment Details Assessment	**Checks**	13
	Permitted Modifications	0
	Violations	0

Subject Details

	Requirement	Value	Assessment	
Sex				
Male:Female	26..59 (≥ 30%)	**34:51**	Value within requirements	Value within requirements
Age *(years)*				
Range *(Low:High)*	≥ 13	**24:93**	Value within requirements	Value within requirements
Mean (SD)		**72.4 (14.1)**	Desirable Information	Desirable Information
Adults:Children	85:0	**85:0**	Value within requirements	Value within requirements
Arm Circumference *(cm)*				
Range *(Low:High)*		**20:37**	Desirable Information	Desirable Information
Mean (SD)		**28.5 (5.4)**	Desirable Information	Desirable Information
Cuff for Test Device (*cm)*				
Paediatric *(17 – 22)*	15 to 55 (≥ 16.7%)	**24 (28.2%)**	Value within requirements	
Standard *(22 – 32)*	15 to 55 (≥ 16.7%)	**35 (41.2%)**	Value within requirements	
Large *(22 – 42)*	15 to 55 (≥ 16.7%)	**26 (30.6%)**	Value within requirements	
Total	85	**85**	Value within requirements	
Recruitment SBP *(mmHg)*				
Range (Low:High)		**89:187**	Supplementary Information	Supplementary Information
Mean (SD)		**139.1 (24.3)**	Supplementary Information	Supplementary Information
Recruitment DBP *(mmHg)*				
Range (Low:High)		**42:122**	Supplementary Information	Supplementary Information
Mean (SD)		**86.6 (16.9)**	Supplementary Information	Supplementary Information

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

Observer Measurements Range-Requirements

	Requirement	Value	Assessment
SBP (mmHg)			
≤ 100	13 to 204 (≥ 5%, < 80%)	**39 (15.3%)**	Value within requirements
101 to 139	0 to 191 (< 75%)	**89 (34.9%)**	Value within requirements
≥ 140	51 to 242 (≥ 20%, < 95%)	**127 (49.8%)**	Value within requirements
≥ 160	13 to 242 (≥ 5%, < 95%)	**53 (20.8%)**	Value within requirements
DBP *(mmHg)*			
≤ 60	13 to 204 (≥ 5%, < 80%)	**25 (9.8%)**	Value within requirements
61 to 84	0 to 191 (< 75%)	**108 (42.4%)**	Value within requirements
≥ 85	51 to 242 (≥ 20%, < 95%)	**122 (47.8%)**	Value within requirements
≥ 100	13 to 242 (≥ 5%, < 95%)	**58 (22.7%)**	Value within requirements
Total		**255 (100%)**	
DBP sounds used			
K4:K5	Total 85	**0:85**	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)*	**-4:4**	Supplementary Information	Supplementary Information
	Mean (SD)	**0.4 (1.9)**	Supplementary Information	Supplementary Information
DBP *(mmHg)*	Range *(Low:High)*	**-4:4**	Supplementary Information	Supplementary Information
	Mean (SD)	**0.4 (1.8)**	Supplementary Information	Supplementary Information
Repeated Measurements		**2**	Information requirement satisfactory	
		Observer differences > 4 mmHg		

Observer Differences Assessment		
	Checks	1
	Permitted Modifications	0
	Violations	0

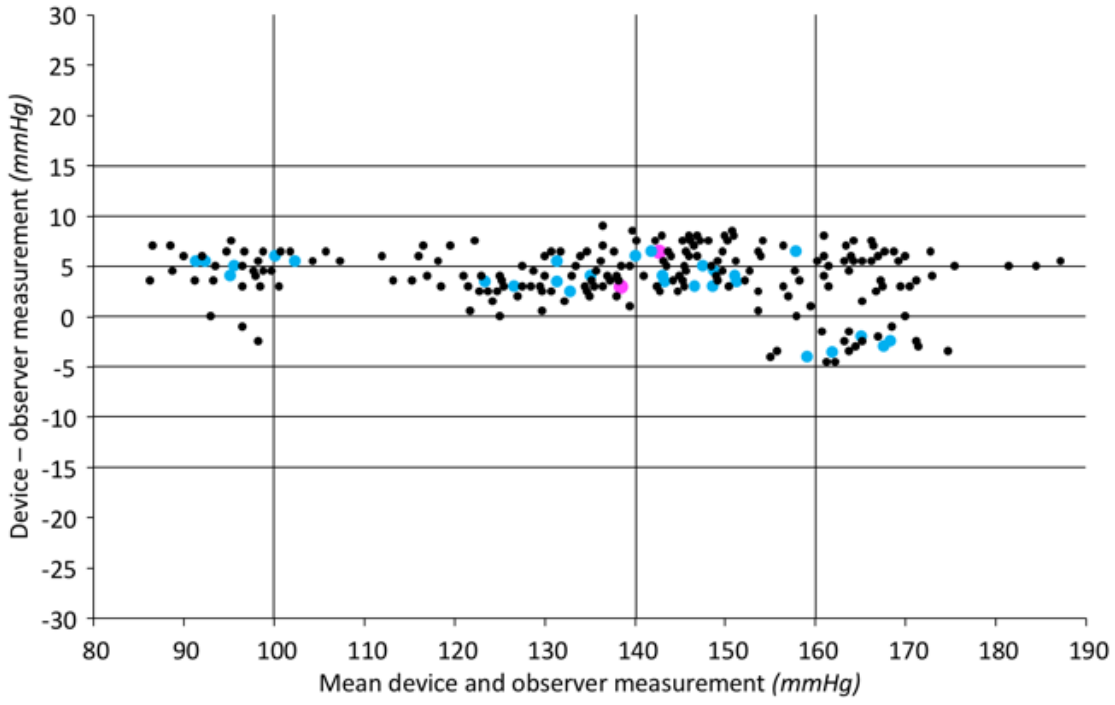
Validation Results

	Pass Req.	Achieved SBP	Achieved DBP	Assessment	
Criterion 1					
Measurement pairs		**255**		Value within requirements	
Mean *mmHg*	≤ 5	**+3.9**	**+3.4**	Value within passing criteria	Value within passing criteria
SD *mmHg*	≤ 8	**2.9**	**2.6**	Value within passing criteria	Value within passing criteria
Criterion 1 Result		**Pass**	**Pass**	Value within passing criteria	Value within passing criteria
Criterion 2					
Number of subjects		**85**		Value within requirements	
Mean *mmHg*		**+3.9**	**+3.4**	Value within passing criteria	Value within passing criteria
SD *mmHg*	≤ 5.70:6.03	**2.9**	**2.6**	Value within passing criteria	Value within passing criteria
Criterion 2 Result		**Pass**	**Pass**	Value within passing criteria	Value within passing criteria
Result		**Pass**		Value within passing criteria	

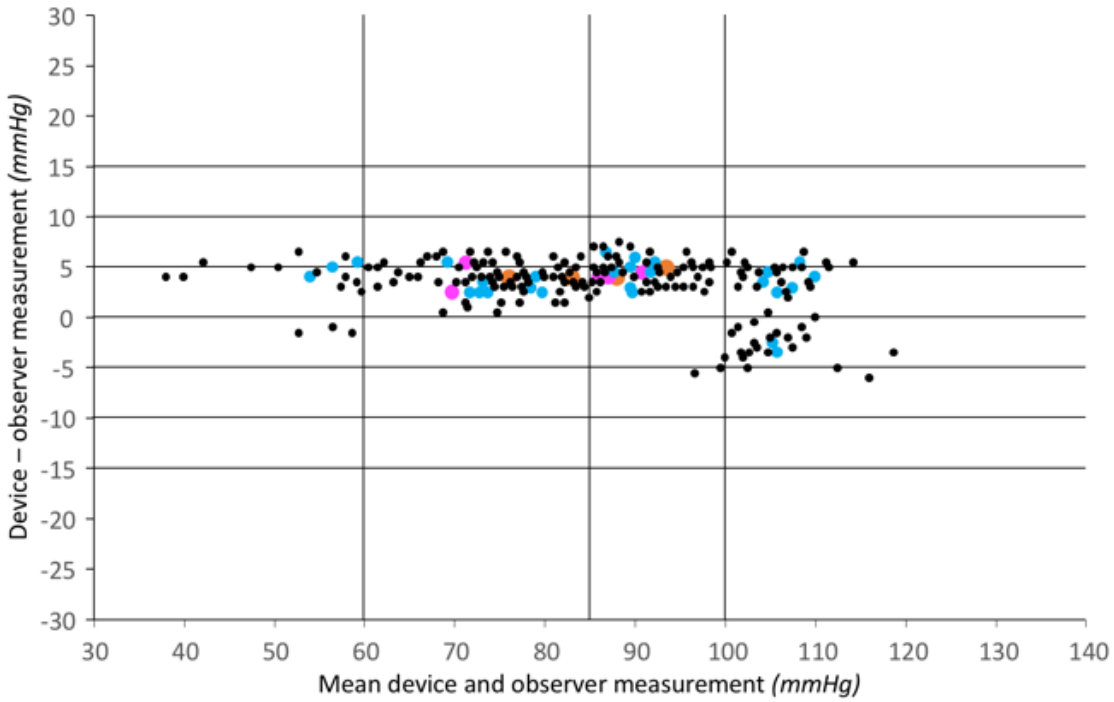
Validation Results Assessment		
	Checks	15
	Permitted Modifications	0
	Violations	0

Plots

SBP



DBP



See Page 6 for Plot Legend

		Assessment
SBP Plot Provided	**Yes**	Information requirement satisfactory
DBP Plot Provided	**Yes**	Information requirement satisfactory

Plots Assessment	**Checks**	2
	Permitted Modifications	0
	Violations	0

AAMI/ANSI/ISO 81060-2:2013 Primary Study Assessment	**Checks**	66
	Permitted Modifications	0
	Violations	0

AAMI/ANSI/ISO 81060-2:2013 Additional Requirements for ABPM Device

STUDY DETAILS

Protocol	The AAMI/ANSI/ISO 81060-2:2013 additional requirements for a sphygmomanometer intended for use in ambulatory monitoring[1]	
		Assessment
Reference Determination	Simultaneous opposite-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	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	Bicycle ergometer stress for ABPM additional requirements	Information requirement satisfactory
HBP Subjects Selection	Inpatients and outpatients	Supplementary Information
NBP Subjects Selection	Healthcare staff	Supplementary Information

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

PROCEDURE

Screening and Recruitment Details

Screening and Recruitment			**Assessment**
Total Screened		**36**	Information requirement satisfactory
Total Excluded		**0**	Information requirement satisfactory
Device Failure	**0**		Information requirement satisfactory
Poor Quality Sounds	**0**		Information requirement satisfactory
Cuff Size Unavailable	**0**		Information requirement satisfactory
Observer Disagreement	**0**		Information requirement satisfactory
Bigeminy	**0**		Information requirement satisfactory
Trigeminy	**0**		Information requirement satisfactory
Isolated VPB	**0**		Information requirement satisfactory
Atrial Fibrillation	**0**		Information requirement satisfactory
Other Reasons*	**0**		Information requirement satisfactory
Total Recruited *(≥ 85 Required)*		**36**	Value within requirements
*Explanation Summary			
Not applicable			Information requirement satisfactory

On Treatment Ranges (On Rx / Total)				
Rest SBP	Low	≤ 100 *mmHg*	**1 / 2**	Supplementary Information
	Medium	131 – 139 *mmHg*	**8 / 19**	Supplementary Information
	High	≥ 140 *mmHg*	**6 / 15**	Supplementary Information
Rest DBP	Low	< 80 *mmHg*	**1 / 2**	Supplementary Information
	Medium	80 – 100 *mmHg*	**9 / 22**	Supplementary Information
	High	> 100 *mmHg*	**4 / 12**	Supplementary Information

Screening and Recruitment Details Assessment	**Checks**	13
	Permitted Modifications	0
	Violations	0

Subject Details

	Requirement	Value	Assessment	
Sex				
Male:Female	≥ 11 (30%)	**14:22**	Value within requirements	Value within requirements
Age *(years)*				
Range *(Low:High)*	≥ 13	**28:88**	Value within requirements	Value within requirements
Mean (SD)		**70.8 (14.6)**	Desirable Information	Desirable Information
Adults:Children	36:0	**36:0**	Value within requirements	Value within requirements
Arm Circumference *(cm)*				
Range *(Low:High)*		**20:36**	Desirable Information	Desirable Information
Mean (SD)		**28.2 (5.7)**	Desirable Information	Desirable Information
Cuff for Test Device (*cm)*				
Paediatric *(17 – 22)*	6 to 24 (≥ 16.7%)	**12 (33.3%)**	Value within requirements	
Standard *(22 – 32)*	6 to 24 (≥ 16.7%)	**13 (36.1%)**	Value within requirements	
Large *(22 – 42)*	6 to 24 (≥ 16.7%)	**11 (30.6%)**	Value within requirements	
Total	36	**36**	Value within requirements	
Resting SBP *(mmHg)*				
Range (Low:High)		**88:164**	Desirable Information	Desirable Information
Mean (SD)		**135.0 (19.7)**	Desirable Information	Desirable Information
> 160 mmHg	4 to 36 (≥ 10%)	**7**	Value within requirements	
Resting DBP *(mmHg)*				
Range (Low:High)		**58:106**	Desirable Information	Desirable Information
Mean (SD)		**81.2 (13.8)**	Desirable Information	Desirable Information
> 100 mmHg	4 to 36 (≥ 10%)	**7**	Value within requirements	

Subject Details Assessment	**Checks**	12
	Permitted Modifications	0
	Violations	0

Stress Details

	Requirement	Value	Assessment	
Resting Pulse Rate *(bpm)*				
Range (Low:High)		**62:88**	Information req. satisfactory	Information req. satisfactory
Mean (SD)		**73.4 (6.6)**	Information req. satisfactory	Information req. satisfactory
Bicycle Ergometer Percentage Load Settings				
Range (Low:High)		**11:18**	Information req. satisfactory	Information req. satisfactory
Mean (SD)		**14.2 (1.8)**	Information req. satisfactory	Information req. satisfactory
Stressed Pulse Rate *(bpm)*				
Range (Low:High)		**70:102**	Information req. satisfactory	Information req. satisfactory
Mean (SD)		**83.8 (8.1)**	Information req. satisfactory	Information req. satisfactory
Pulse Rate Percentage Increase				
Range (Low:High)	≥ 10:≤ 20	**10.9:17.6**	Value within requirements	Value within requirements
Mean (SD)		**14.1 (1.9)**	Information req. satisfactory	Information req. satisfactory
< 10%	0	**0**	Value within requirements	
10% to 20%	36	**36**	Value within requirements	
> 20%	0	**0**	Value within requirements	
Correlation of PR Percentage Increase with Bicycle Ergometer Percentage Load				
r		**0.70**	Supplementary Information	

Stress Details Assessment	**Checks**	19
	Permitted Modifications	0
	Violations	0

Observer Measurements Range-Requirements

	Requirement	Value	Assessment	
SBP (mmHg)				
≤ 100		**6 (5.6%)**	Value within requirements	
101 to 139		**53 (49.1%)**	Value within requirements	
≥ 140		**49 (45.4%)**	Value within requirements	
≥ 160		**21 (19.4%)**	Value within requirements	
DBP *(mmHg)*				
≤ 60		**3 (2.8%)**	Value within requirements	
61 to 84		**64 (59.3%)**	Value within requirements	
≥ 85		**41 (38.0%)**	Value within requirements	
≥ 100		**21 (19.4%)**	Value within requirements	
DBP sounds used				
K4:K5	Total 36	**0:36**	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)*	**-4:4**	Optional data provided	Optional data provided
	Mean (SD)	**-0.9 (1.8)**	Optional data provided	Optional data provided
DBP *(mmHg)*	Range *(Low:High)*	**-4:4**	Optional data provided	Optional data provided
	Mean (SD)	**0.1 (2.1)**	Optional data provided	Optional data provided
Repeated Measurements		**1**	Information requirement satisfactory	
		Low sound quality		

Observer Differences Assessment	**Checks**	1
	Permitted Modifications	0
	Violations	0

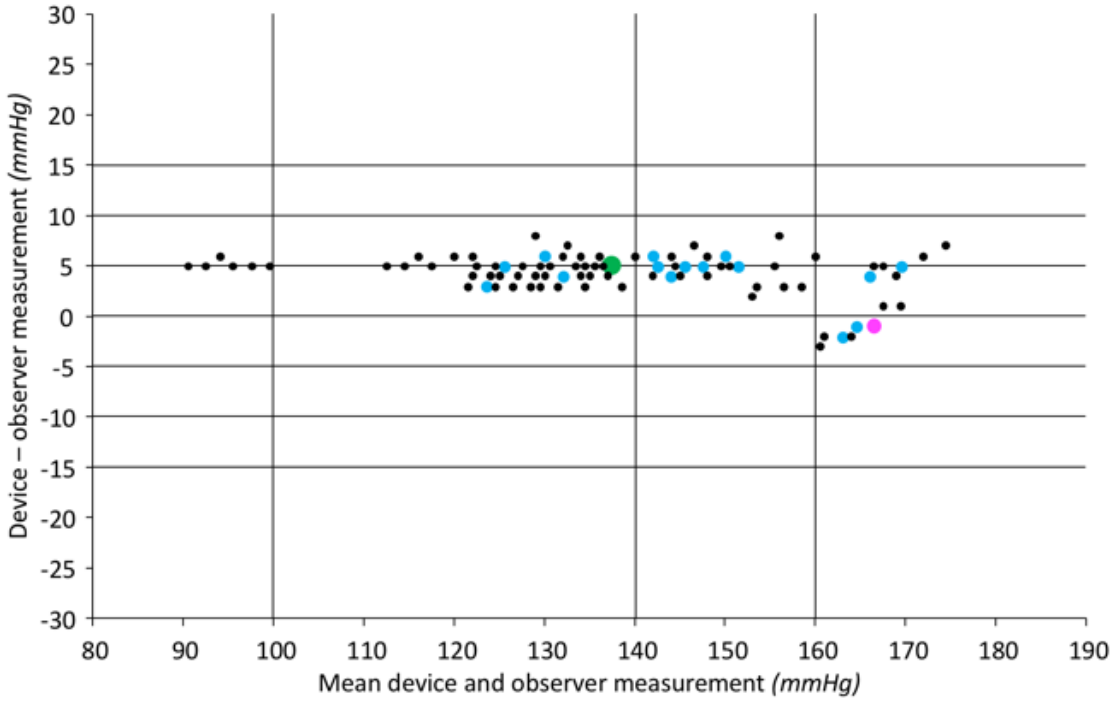
Validation Results

	Pass Req.	Achieved SBP	Achieved DBP	Assessment	
Criterion 1					
Measurement pairs		**108**		Value within requirements	
Mean *mmHg*	≤ 5	**+4.1**	**+3.8**	Value within passing criteria	Value within passing criteria
SD *mmHg*	≤ 8	**2.2**	**2.1**	Value within passing criteria	Value within passing criteria
Criterion 1 Result		**Pass**	**Pass**	Value within passing criteria	Value within passing criteria
Criterion 2					
Number of subjects		**36**		Value within requirements	
Mean *mmHg*		**+4.1**	**+3.8**	Value within passing criteria	Value within passing criteria
SD *mmHg*	≤ 5.56:5.77	**2.0**	**1.9**	Value within passing criteria	Value within passing criteria
Criterion 2 Result		**Pass**	**Pass**	Value within passing criteria	Value within passing criteria
Result		**Pass**		Value within passing criteria	

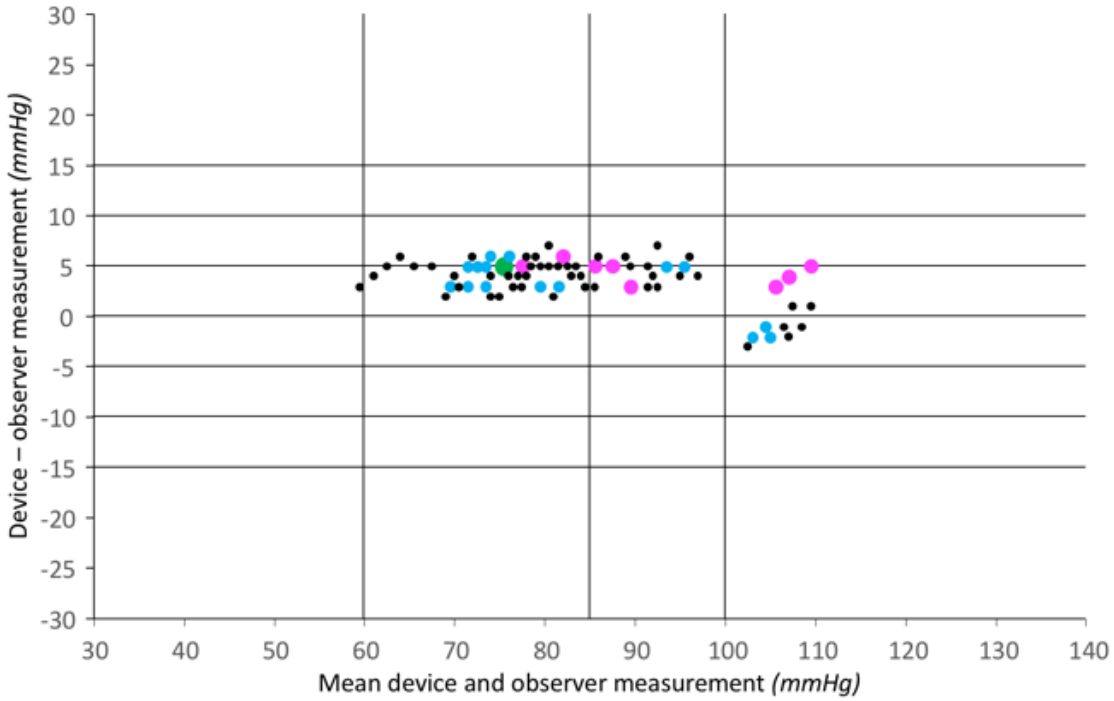
Validation Results Assessment	**Checks**	15
	Permitted Modifications	0
	Violations	0

Plots

SBP



DBP



See Page 6 for Plot Legend

		Assessment
SBP Plot Provided	**Yes**	Information requirement satisfactory
DBP Plot Provided	**Yes**	Information requirement satisfactory

Plots Assessment	**Checks**	2
	Permitted Modifications	0
	Violations	0

AAMI/ANSI/ISO 81060-2:2013 Additional Requirements for ABPM Device Assessment	**Checks**	82
	Permitted Modifications	0
	Violations	0

ESH-IP 2010 Study

STUDY DETAILS

Protocol	The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults[2]	
		Assessment
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	Information requirement satisfactory
Observer Training	By expert in BP measurement	Information requirement satisfactory
Observer Familiarisation	40 test measurements	Information requirement satisfactory
Observers Blinding	From device and each other	Information requirement satisfactory
Sight and Hearing Checked	Yes	Information requirement
Sample		
Population	A general population	Information requirement satisfactory
Circumstances	None	Information requirement satisfactory
HBP Subjects Selection	Inpatients and outpatients	Information requirement satisfactory
NBP Subjects Selection	Healthcare staff	Information requirement satisfactory
Subject Preparation		
Back, elbow and arm supported	Yes	Information requirement
Legs uncrossed	Yes	Information requirement
Cuff centre at right atrium level	Yes	Information requirement
10-15-min rest at start	Yes	Information requirement

Study Details Assessment	**Checks**	17
	Permitted Modifications	0
	Violations	0

PROCEDURE

Table 1: Screening and Recruitment Details

Screening and Recruitment			Assessment
Total Screened		**35**	Information requirement satisfactory
Total Excluded		**2**	Information requirement satisfactory
Ranges Complete	**2**		Information requirement satisfactory
Range Adjustment	**0**		Information requirement satisfactory
Arrhythmias	**0**		Information requirement satisfactory
Device Failure	**0**		Information requirement satisfactory
Poor Quality Sounds	**0**		Information requirement satisfactory
Cuff Size Unavailable	**0**		Information requirement satisfactory
Observer Disagreement	**0**		Information requirement satisfactory
Distribution	**0**		Information requirement satisfactory
Other Reasons*	**0**		Information requirement satisfactory
Total Recruited (33 Required)		**33**	Value within requirements
*Explanation Summary			
Not applicable			Information requirement satisfactory

Recruitment Ranges					
		Req.	**Values**		**Assessment**
SBP					
Total		33		**33**	Value within requirements
Low	< 130 *mmHg*	10..12	**10**		Value within requirements
	< 90 *mmHg*		**0**		Information requirement satisfactory
	90 – 129 *mmHg*		**10**		Information requirement satisfactory
Medium	130 – 160 *mmHg*	10..12	**12**		Value within requirements
High	> 160 *mmHg*	10..12	**11**		Value within requirements
	161 – 180 *mmHg*		**10**		Information requirement satisfactory
	> 180 *mmHg*		**1**		Information requirement satisfactory
DBP					
Total		33		**33**	Value within requirements
Low	< 80 *mmHg*	10..12	**10**		Value within requirements
	< 40 *mmHg*		**0**		Information requirement satisfactory
	40 –79 *mmHg*		**10**		Information requirement satisfactory
Medium	80 – 100 *mmHg*	10..12	**12**		Value within requirements
High	> 100 *mmHg*	10..12	**11**		Value within requirements
	101 – 130 *mmHg*		**11**		Information requirement satisfactory
	> 130 *mmHg*		**0**		Information requirement satisfactory
Total Extremes		0..4	**1**		Value within requirements

On Treatment Ranges				
SBP	Low	< 130 *mmHg*	**1**	Information requirement satisfactory
	Medium	130 – 160 *mmHg*	**5**	Information requirement satisfactory
	High	> 160 *mmHg*	**8**	Information requirement satisfactory
DBP	Low	< 80 *mmHg*	**1**	Information requirement satisfactory
	Medium	80 – 100 *mmHg*	**5**	Information requirement satisfactory
	High	> 100 *mmHg*	**8**	Information requirement satisfactory

Screening and Recruitment Details Assessment		
	Checks	36
	Permitted Modifications	0
	Violations	0

Table 2: Subject Details

	Requirement	Value	Assessment	
Sex				
Male:Female	≥ 10: ≥ 10	**14:19**	Value within requirements	Value within requirements
Age *(years)*				
Range *(Low:High)*	≥ 25	**59:93**	Value within requirements	Information req. satisfactory
Mean (SD)		**76.8 (7.3)**	Information req. satisfactory	Information req. satisfactory
Arm Circumference *(cm)*				
Range *(Low:High)*		**20:37**	Information req. satisfactory	Information req. satisfactory
Mean (SD)		**28.8 (5.2)**	Information req. satisfactory	Information req. satisfactory
Cuff for Test Device (*cm)*				
Paediatric *(17 – 22)*		**8**	Information requirement satisfactory	
Standard *(22 – 32)*		**15**	Information requirement satisfactory	
Large *(22 – 42)*		**10**	Information requirement satisfactory	
Total	33	**33**	Value within requirements	
Recruitment SBP *(mmHg)*				
Range (Low:High)		**92:187**	Information req. satisfactory	Information req. satisfactory
Mean (SD)		**142.1 (28.7)**	Information req. satisfactory	Information req. satisfactory
Recruitment DBP *(mmHg)*				
Range (Low:High)		**42:122**	Information req. satisfactory	Information req. satisfactory
Mean (SD)		**91.0 (18.9)**	Information req. satisfactory	Information req. satisfactory

Subject Details Assessment	**Checks**	22
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements in each Recruitment Range

	Requirement	Value	Assessment	
SBP				
Overall Range *mmHg (Low:High)*	≤ 100:≥ 170	**85:186**	Value within requirements	Value within requirements
Low *(< 130 mmHg)*	22..44	**30**	Value within requirements	
Medium *(130 – 160 mmHg)*	22..44	**44**	Value within requirements	
High *(> 160 mmHg)*	22..44	**25**	Value within requirements	
Maximum Difference	≤ 19	**19**	Value within requirements	
DBP				
Overall Range *mmHg* (Low:High)	≤ 50:≥ 120	**37:120**	Value within requirements	Value within requirements
Low (< 80 *mmHg*)	22..44	**30**	Value within requirements	
Medium (80 – 100 *mmHg*)	22..44	**38**	Value within requirements	
High (> 100 *mmHg*)	22..44	**31**	Value within requirements	
Maximum Difference	≤ 19	**8**	Value within requirements	

Observer Measurements Range Assessment	**Checks**	12
	Permitted Modifications	0
	Violations	0

STUDY RESULTS

Table 4: Observer Differences

	Requirement	Value	Assessment	
SBP *(mmHg)* Observer 2 – Observer 1				
Range *(Low:High)*	–4..+4: –4..+4	**–4:+4**	Value within requirements	Value within requirements
Mean (SD)		**+1.1 (1.6)**	Information req. satisfactory	Information req. satisfactory
DBP *(mmHg)* Observer 2 – Observer 1				
Range *(Low:High)*	–4..+4: –4..+4	**–4:+4**	Value within requirements	Value within requirements
Mean (SD)		**+0.6 (1.6)**	Information req. satisfactory	Information req. satisfactory
Repeated Measurements		**0**	Information requirement satisfactory	

Observer Differences Assessment		
	Checks	9
	Permitted Modifications	0
	Violations	0

Table 5: Validation Results

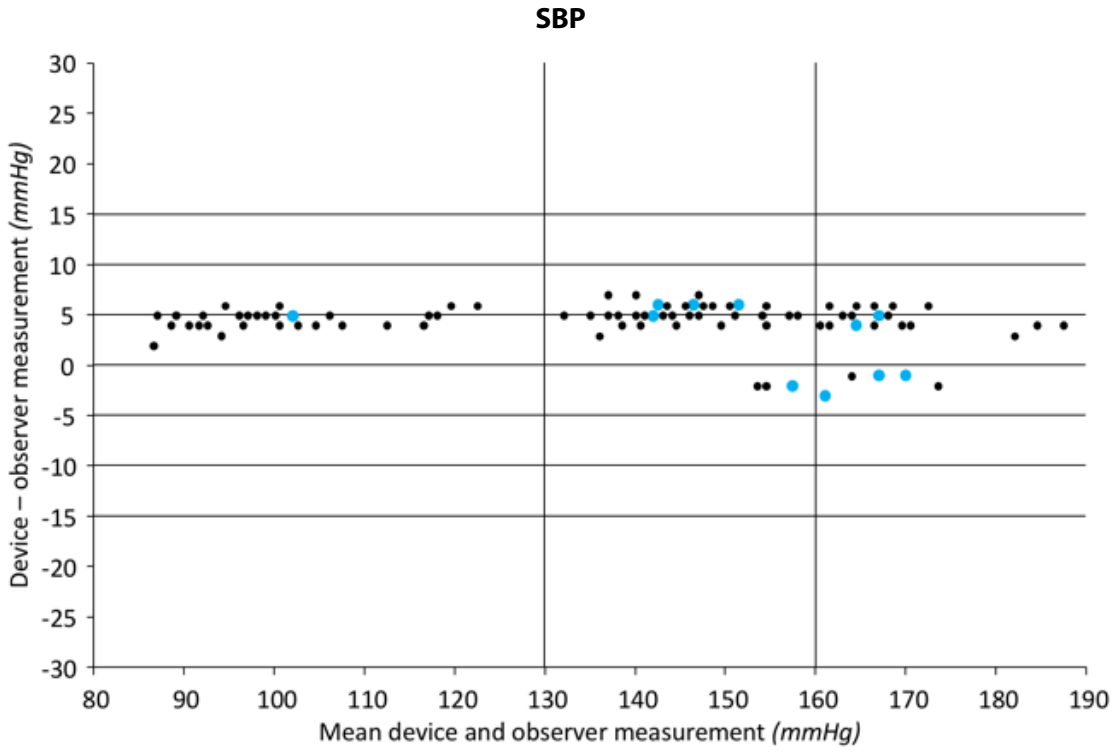
Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 *mmHg*	73	65	**75**	**95**	Value within upper criteria	Value within upper criteria
≤ 10 *mmHg*	87	81	**99**	**99**	Value within upper criteria	Value within upper criteria
≤ 15 *mmHg*	96	93	**99**	**99**	Value within upper criteria	Value within upper criteria
Grade 1			**Pass**	**Pass**	Value within upper criteria	Value within upper criteria
Mean *mmHg*			**4.1**	**3.2**	Information req. satisfactory	Information req. satisfactory
SD *mmHg*			**2.4**	**2.5**	Information req. satisfactory	Information req. satisfactory

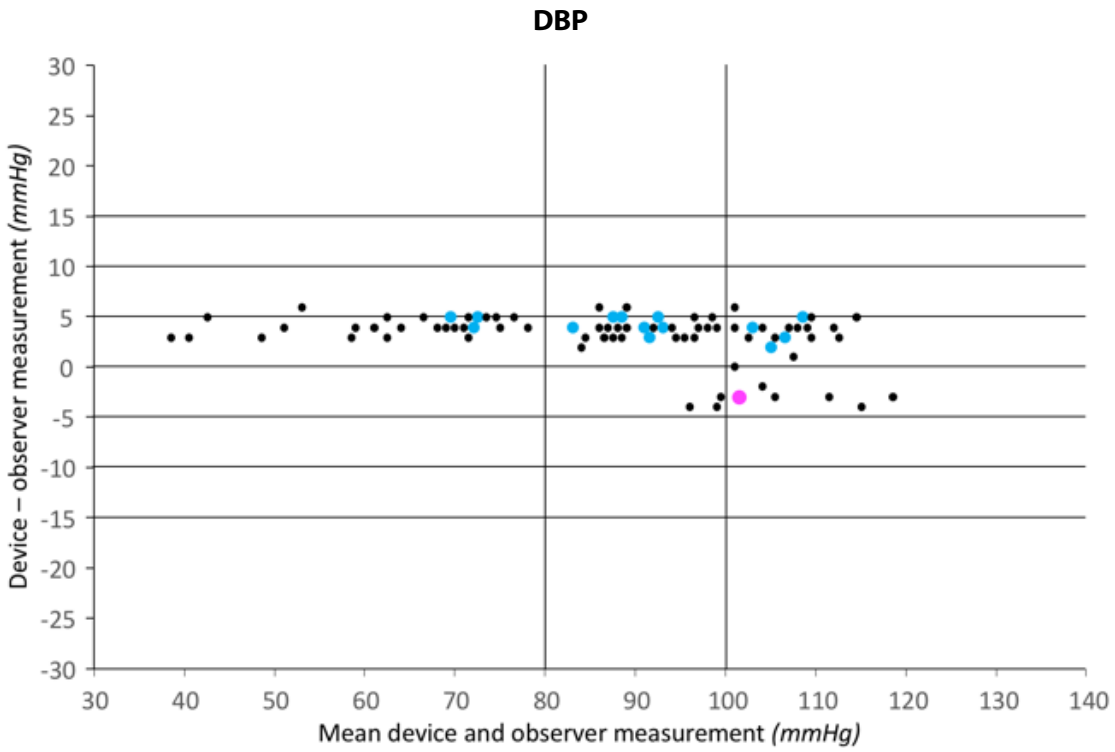
Part 2	Pass Req.	Achieved SBP	Achieved DBP		
2/3 ≤ 5 *mmHg*	≥ 24	**26**	**32**	Value within passing criteria	Value within passing criteria
0/3 ≤ 5 *mmHg*	≤ 3	**3**	**0**	Value within passing criteria	Value within passing criteria
Grade 2		**Pass**	**Pass**	Value within passing criteria	Value within passing criteria
Grade 3		**Pass**	**Pass**	Value within passing criteria	Value within passing criteria

Part 3			
Result	**Pass**	All values within upper passing criteria	

Validation Results Assessment		
	Checks	21
	Permitted Modifications	0
	Violations	0

Plots





See Page 6 for Plot Legend

		Assessment
SBP Plot Provided	**Yes**	Information requirement satisfactory
DBP Plot Provided	**Yes**	Information requirement satisfactory

Plots Assessment	**Checks**	2
	Permitted Modifications	0
	Violations	0

ESH Study Assessment	**Checks**	119
	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	None	Information requirement satisfactory

Limitations Assessment		
	Checks	7
	Permitted Modifications	0
	Violations	0

Recommendations

Overall Summary

Number of checks	295
Number of permitted modifications	0
Number of violations	0

Assessment Summary

The validations have been checked and are verified as having been conducted in accordance with the respective 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 each 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 Novacor Diasys 3 monitor is accurate for blood pressure measurement in adults, in both static and ambulatory settings.

Certification Decision

The Novacor Diasys 3 (DIS-0001-00), with the appropriate Paediatric 18 cm to 24 cm (ACC-0215-00), Standard 24 cm to 32 cm (ACC-0213-00) or Large 32 cm to 40 cm (ACC-0214-00) cuff, is certified by Medaval Ltd., for blood pressure measurement, including ABPM, in adults, as the technology fulfilled the conditions required for a pass in 1) a primary validation study carried out in accordance with the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard, 2) an additional validation study during stress carried out in accordance with the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard for ambulatory monitors and 3) a validation study carried out in accordance with the requirements of the International Protocol of the European Society of Hypertension 2010 Revision.

Date of Approval: 04 March 2019.

References

1. Association for the Advancement of Medical Instrumentation, American National Standards Institute, International Organization for Standardization. AAMI/ANSI/ISO 81060-2:2013, Non-invasive Sphygmomanometers - Part 2: Clinical Investigation of Automated Measurement Type. Geneva, Switzerland: ISO; 2013.
2. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. *Blood Press Monit*. 2010;**15**:23-38. doi: 10.1097/MBP.0b013e3283360e98. *PMID: 20110786*. Erratum in *Blood Press Monit*. 2010;**15**(3):171-2.
3. European Commission – Health Technology and Cosmetics. MEDDEV 2.7/1 rev.4: Guidelines on Medical Devices – Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC. Brussels, Belgium: European Commission; June 2016 (65 p). Available from: http://ec.europa.eu/DocsRoom/documents/17522/attachments/1/translations/
4. The European Parliament and the Council of the European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance). Official Journal of the European Union. 2017 May 05;60(L 117):1-175. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745.

