

Validation Testing of Digital Blood Pressure Monitoring Devices for the Upper Arm According to the ISO 81060-2:2018/ AMD 1:2020 Protocol

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Abstract- The purpose of the study was to ascertain the accuracy of blood pressure monitors commonly available in the market. Six devices were chosen including one professional BP monitor for home, clinical and hospital use, manufactured by Mann Electronics India Private Limited, Kota from the market. These devices did not have accessible validation testing results. The subjects for assessment were adults from the general population with varied age groups and sex. The objective was to establish whether the devices conform to the requirements of ISO 81060-2:2018/AMD1: 2020 protocol

Index Terms- Digital BP Monitor, BP Monitor, Blood Pressure Monitor, Clinical Study, Validation Study.

I. INTRODUCTION

The Digital blood pressure monitors have become prevalent in today's fast moving society where time is at a premium and more often than not it is impractical to visit clinics for regular check-ups for optimum management of hypertension. This has led to proliferation of wide range of BP monitors in the market to guide diagnosis and treatment of hypertension. However, many of the BP Monitors available in the market are not validated and in the absence of systematic validation, the buyers may purchase a device which is inaccurate and therefore, the data is too risky to rely on for diagnosis and subsequent management of hypertension. The purpose of the study was to evaluate the accuracy of MANN BP Monitors and some other popular brands available in the market intended to be used for BP monitoring to have an idea of their accuracy in providing BP readings.

II. METHODOLOGY

The devices chosen for the study are based on oscillometric principle. The medical devices other than

MANN were purchased directly from medical stores and used for the study. All were having upper arm cuff. Medium and large cuff sizes were used to suit the different arm circumference of the subjects chosen for study. The ISO 81060-2:2018/AMD 1:2020 standard was followed for conducting the study.

Participants /Population

The subjects for study chosen were from 19 to 67 years of age with medium and large cuff sizes and varying BMI. Some of

the participants were blood pressure patients while others did not have a history of hypertension. The participants included a mix of male and female in the age group mentioned above. All the participants were consulted and consented prior to including them in the study.

Study Team

The study was conducted by a panel of experienced qualified Doctors/ Technicians and project manager (study coordinator) who were all trained and certified in the basics of conducting validation study of automatic BP devices.

Sl. No.	Name	Qualification	Hospital/Clinic/ Organisation	Role
1.	Dr. Saket Goel	Cardiologist	Kota Heart Research Institute, Kota, Rajasthan, India	Team Leader, Validation Team
2.	Dr. Manoj Saluja	MD, Medicine	Govt. Medical College, Kota, Rajasthan, India	Member Validation team, Trainer and Observer
3.	Dr. G.D. Ramchandani	MD	G Ramchandani Clinic, Kota, Rajasthan, India	Member Validation Team, Trainer and Observer
4.	Ms. Taru Gulati	B. Com, MBA	MANN Electronics India Pvt. Ltd. Kota, Rajasthan, India	Project Manager and Study Coordinator

Devices Used for Study

Device Name / Model no	Product Serial no
MANN / MN 1015 X	MEQ24003-0010
OMRON / HEM-7361T	202305001332V
Alcare / X5	X522110700529
Meditek / BP-11	MLPL 1729
Sanitas / SBM 36	656.33
Microlife / BP3AQ1-2P	231705673

III. BLOOD PRESSURE MEASUREMENTS

The team comprising a panel of senior doctors as mentioned in the table above, reviewed and approved the study. The team was briefed on the methodology of taking observations so as to eliminate any bias in the observed readings. The participants' arms were measured as a reference to select an appropriate cuff size for BP measurements. Connected y-tube standard mercury sphygmomanometer duly calibrated was used for study.

A dual head teaching stethoscope was used by the two observers to record simultaneous reference readings. The participants were rested for 5 minutes before baseline BP readings were taken with the reference BP Monitor. It was ensured that the observers were blinded to each other's recordings to eliminate any chance of bias while noting the observations. After recording the readings, they were handed over to the Study Coordinator who evaluated whether the readings were within 4mmHg. Those readings which differed by more than 4 mm Hg were discarded in accordance with the standard requirement (Ref. ISO 81060- 2:2018/AMD 1:2020). The test device was also used to obtain an initial reading. After both baseline readings were recorded, four reference mercury sphygmomanometer measurements were taken alternately with three test device measurements with 60 second rests observed between readings. Additional readings were taken to replace the excluded readings in order to complete three valid sets of reference, test device, reference BP comparisons.

Readings were excluded for pre-specified observer differences, blood pressure reading variation, participant body movement, talking or when one or both observers were unable to hear a reading. The subject was excluded if readings were repeated for a third time and the two observer's measurements were not within 4 mmHg. Furthermore, subjects with BP variability in reference BP measurements $>12/8$ mm Hg between any two of the four reference BP measurements were excluded with the option to include from these subjects in the analysis two (instead of the three) consecutive valid pairs of reference measurements that fulfil the requirement provided this applied to no more than 10% of subjects.

The Final Study Cohorts

In accordance with the requirements of ISO 81060-2:2018/AMD 1:2020, the objective was to include the participants with an adequate distribution of systolic and diastolic blood pressure, arm circumference and sex ratio to have a fair judgement of the validity of the outcome. Some additional ten participants were identified with the eligible measurements for replacement, in case some of the participants did not meet the study criteria. In any case, the number was restricted to eighty five.

Statistical Analysis

As a first step the mean of the reference readings by the observers and the device readings were ascertained. Then, the difference between the device and the observers' measurements were calculated.

The assessed means and standard deviations of the absolute values of the differences between the SBP and DBP measurements of the devices under test and the reference standard were calculated and compared with Criterion 1 of the ISO 81060-2:2018/AMD 1:2020 standard, viz., whether or not the means were ≤ 5.0 mm Hg and the standard deviation was ≤ 8.0 mm Hg.

The Bland-Altman plots of the differences in SBP and DBP determinations by blood pressure (means of test device and observer measurements) and arm circumference values. We calculated the standard deviations of the differences of the averaged paired determinations of the device under test and the reference measurement for each subject and compared these to Criterion 2 of the ISO 81060-2:2018/AMD 1:2020 standard.

IV. RESULTS

The details of the participants screened, eligible participants, number removed and number included in the analysis are presented in Table 1. The process ensured that the group identified for study (85 participants) meets the requirement of ISO 81060-2: 2018/AMD 1: 2020 standard for systolic, diastolic blood pressure, sex and arm circumference for each of the devices.

The participant characteristics of the group for all the devices are presented in Table 2. Details of the participant group for all the devices are presented in Table 2. The comparison of BP measurements of the test devices and the reference measurements are presented in Table 2. Bland- Altman scatter plots of the differences between the devices under test and the observer measurements for SBP and DBP against their average value are mentioned in Figs 1 to 6.

Table 1: Participant screening and elimination details

S. No	Participant details	Observations					
		Mann	Omron	Aicare	Meditek	Sanitas	Microlife
1	No. screened	85	85	85	85	85	85
2	No. excluded	0	0	0	0	0	0
3	Arrhythmia	0	0	0	0	0	0
4	Poor quality sounds	0	0	0	0	0	0
5	Difference in any two reference SBP by more than 12mm Hg or DBP by more than 8mm Hg	0	0	0	0	0	0
6	Inter-observer difference exceeding standard	0	0	0	0	0	0
7	Persistent movement during measurement	0	0	0	0	0	0
8	Arm circumference outside of range	0	0	0	0	0	0
9	Pregnant	0	0	0	0	0	0
10	Other (participant body movement, talking, BP Variation, Upper arm Circumference <17 cm or >43 cm, etc)	0	0	0	0	0	0
11	Total removed through blinded backwards selection	0	0	0	0	0	0
12	Total included in analytic cohort	85	85	85	85	85	85

Table 2: Participant characteristics and reference blood pressure distribution

S. No	Participant characteristics and reference blood pressure distribution	MANN	OMRON	Aicare	Meditek	Sanitas	Microlife
1	Male (N): Female (N)	51:34	51:34	51:34	51:34	51:34	51:34
2	Age years Range (Low: High)	19:67	19:67	19:67	19:67	19:67	19:67

3	Mean (SD)	10.95/6.13		10.52/5.36	10.52/6.09	10.62/5.95	10.33/ ^{5.08} 10.70/6.24
4	Arm Circumference (cm) Range (Low: High)	Small-41 Nos Medium-19 Nos Large-25 Nos	Small-41 Nos	Small-41 Nos	Small-41 Nos	Small-41 Nos	Small-41 Nos
5	SBP (mmHg) Overall Range (Low: High)	95:182	95:182	98:179	96:180	98:178	98:181
6	≥160 (N: %)	2:0.78	2:0.78	2:0.78	2:0.78	2:0.78	2:0.78
7	≥140	2:0.78	2:0.78	2:0.78	2:0.78	2:0.78	2:0.78
8	≤100	1:0.4	1:0.4	1:0.4	1:0.4	1:0.4	1:0.4
9	DBP (mmHg) Overall Range (Low: High)	60:110	60:109	63:108	60:109	60:110	63:110
10	≥100 (N: %)	1:0.4	2:0.78	1:0.4	1:0.4	1:0.4	1:0.4
11	≥85	16:6.3	12:4.7	13:5.0	11:4.3	16:6.3	6:2.4
12	≤60	1:0.4	0:0	1:0.4	1:0.4	0:0	1:0.4

Bland-Altman Plots for BP Monitors under Test

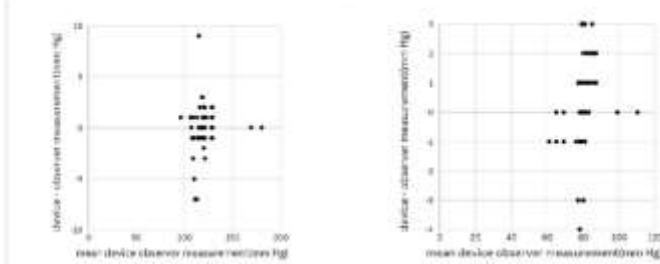


Fig. 1 Bland-Altman Plots for MANN : Bland–Altman Plots of the differences between the Mann measurements and observer measurements for (a) systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP)

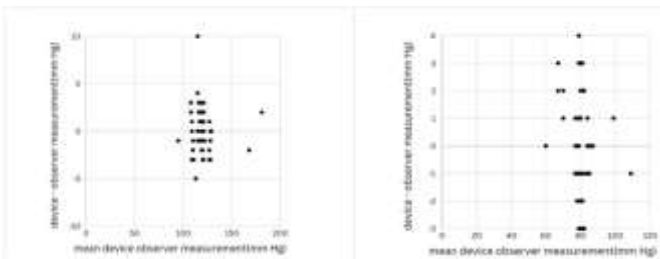


Fig.2: Bland-Altman Plots for OMRON: Bland–Altman Plots of the differences between the Mann measurements and observer measurements for (a) systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP)

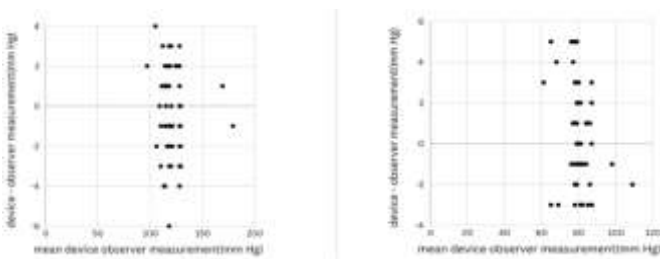


Fig. 3: Bland-Altman Plots for AICare: Bland–Altman Plots of the differences between the Mann measurements and observer measurements for (a) systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP)

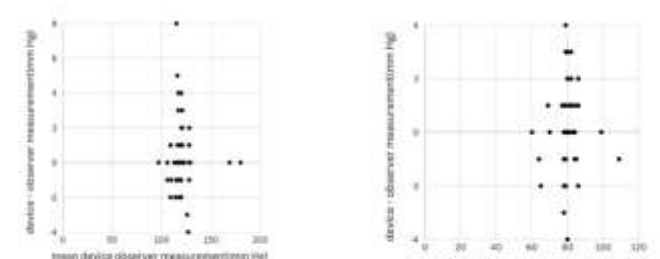


Fig 4: Bland-Altman Plots for Meditek: Bland–Altman Plots of the differences between the Mann measurements and observer measurements for (a) systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP)

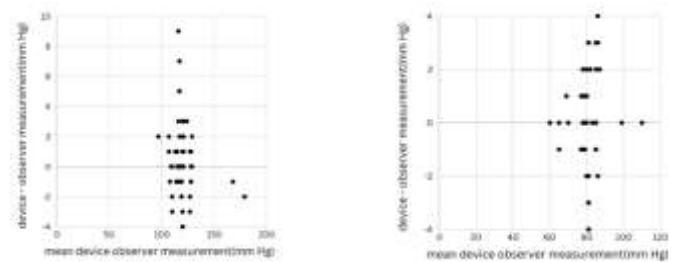


Fig 5: Bland-Altman Plots for Sanitas: Bland–Altman Plots of the differences between the Mann measurements and observer measurements for (a) systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP)

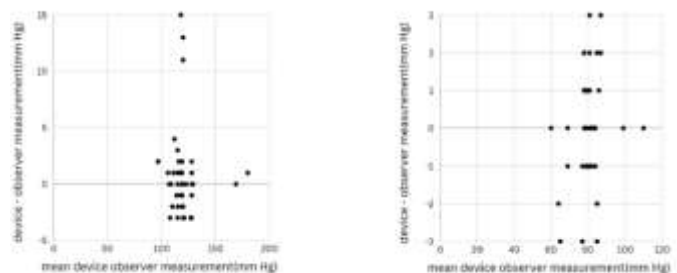


Fig 6: Bland-Altman Plots for Microlife: Bland–Altman Plots of the differences between the Mann measurements and observer measurements for (a) systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP)

Strengths and imitations

Strengths of this study include the testing of multiple commercial digital BP monitors under similar rigorous conditions and achieving the required distribution of subjects by arm size, blood pressure and sex. Limitations are that the study population was limited to a general adult population, and the generalization of these findings to other populations (e.g., pregnant women, children) is unknown. Additionally, while we followed the recommendations for which data points to include or exclude from an expert consultant who trained the study team, we removed and repeated reference measurements with discrepant observer readings but did not remove and repeat the preceding test device measurement when the repeated reference measurement met the criteria for observer agreement. While we believe that this choice is consistent with the ISO 81060-2:2018 + A1:2020 protocol, we acknowledge that this interpretation differs from the one described by other.

Summary

The importance of Digital BP monitoring is becoming increasingly important and is being recognized for hypertension diagnosis and management. However, many devices marketed for professional, clinical and home use do not have published validation information available for testing them using an international standard. Under this circumstance, the accuracy of the available BP Monitors is difficult to

78	Participant 78	M	35	40	118/80-82	121/82-80	119/79-81	117/79-80	118/81-81	120/79-80
79	Participant 79	M	28	19	121/83-63	119/80-62	120/81-63	122/83-60	118/79-59	119/82-62
80	Participant 80	F	32	37	128/78-78	126/77-81	129/79-80	129/81-80	128/78-79	129/79-80
81	Participant 81	F	33	35	119/79-102	121/82-100	118/80-101	120/79-102	122/80-102	119/79-100
82	Participant 82	F	34	31	120/79-102	122/80-102	119/79-100	119/79-102	121/82-100	118/80-101
83	Participant 83	F	42	18	108/76-101	110/81-98	114/76-103	119/78-97	120/79-98	126/79-99
84	Participant 84	F	28	27	118/80-82	121/82-80	119/79-81	117/79-80	118/81-81	120/79-80
85	Participant 85	F	32	26	129/81-80	128/78-79	126/77-81	129/79-80	128/78-78	129/79-80

Abbreviations

S No	Abbreviation	Full form
1	ISO	International Organisation for Standardisation
2	AMD	Amendment
3	SD	standard. Mean
4	SBP	Systolic blood pressure
5	DBP	Diastolic blood pressure
6	CVS	Cardiovascular disease
7	pp	Pulse pressure
8	MAP	Mean arterial pressure
9	mmHg	Millimetres in mercury
10	AHA	American Heart Association

V. CONCLUSION

In conclusion, this study highlights the critical importance of using validated digital BP monitors for accurate hypertension diagnosis and management. Among the tested devices, the MANN BP Monitor demonstrated high accuracy, meeting the stringent requirements of the ISO 81060-2:2018/AMD 1:2020 standard. This establishes the MANN BP Monitor as a reliable tool for both hospital, clinical and home use. These findings reaffirm the significance of systematic validation for ensuring the dependability of BP monitors and reinforce the confidence in the MANN BP Monitor as a trusted solution for precise blood pressure monitoring.

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