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RESEARCH ARTICLE
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A CLINICAL EVALUATION REPORT OF PERFORMANCE OF BPL DIGITAL BLOOD PRESSURE MONITOR, B20, MEASURED BY OSCILLOMETRIC METHOD AS COMPARED TO THE VALUE MEASURED BY AUSCULTATION WITH A MERCURY SPHYGMOMANOMETER

Dr. Chidananda[1]*, Dr. Kamran[2], Siddhant[3]

[1] *Consultant Physician, MBBS, MD, Ananya Hospital, No. 389, 44, 19th Main Rd, 1st Block, Rajajinagar, Bengaluru - 560010, Karnataka, India
[2] Clinical Adviser, MBBS, BPL Medical Technologies Pvt. Ltd., 11th KM, Arakere, Bannerghatta Road, Bengaluru - 560076, Karnataka, India
[3] Product Head, BPL Medical Technologies Pvt. Ltd., 11th KM, Arakere, Bannerghatta Road, Bangalore - 560076, Karnataka, India

***Corresponding Author:** Dr. Chidananda
*Consultant Physician, MBBS, MD, Ananya Hospital, No. 389, 44, 19th Main Rd, 1st Block, Rajajinagar, Bengaluru - 560010, Karnataka, India

Abstract
This clinical evaluation report presents the performance validation of the BPL Medical 120/80 B20 digital blood pressure monitor, which employs the oscillometric method. The study was conducted in accordance with the ANSI/AAMI/ISO 81060-2:2013 guidelines to compare its accuracy against traditional auscultation using a mercury sphygmomanometer. Conducted at Ananya Multispecialty Hospital, Bangalore, the study involved 162 subjects, ensuring diverse representation by gender and age as per the guidelines. The results demonstrated that the BPL 120/80 B20 meets the stringent accuracy criteria set by ANSI/AAMI/ISO, with mean differences between observer and device readings well within the acceptable range of ±5.2 mmHg for systolic and ±5.65 mmHg for diastolic measurements. These findings confirm that the BPL 120/80 B20 is a reliable and accurate device for blood pressure monitoring, supporting its compliance with international standards for non-invasive sphygmomanometers.

Keywords: Oscillometric Method, ANSI/AAMI/ISO 81060-2:2013, Systolic and Diastolic BP, Measurement Accuracy, Bland-Altman Plot

1. Purpose
The purpose of the study is to validate the accuracy of an upper arm BP monitor (BPL 120/80 B20), according to ANSI/AAMI/ISO guideline.

2. Methods
2.1 Device
The electronic blood pressure monitor (BPL 120/80 B20) was provided by the manufacturer (BPL medical Technologies Pvt ltd, India) for the study. The product is designed to measure the blood

pressure monitor in the hospital or clinical environment. The product has the inbuilt mechanism of measuring the systolic & diastolic via oscillometric or auscultatory method. The oscillometric method of measurement is used for this study. Mostly widely used cuff sizes of medium (M) & large (L) were used in this study having the arm circumference of 22-32cm & 32-42cm respectively. The devices used in this study were calibrated by the National Accreditation Board for Testing and Calibration Laboratories (NABL).

2.2 Subject selection

The study was conducted at the multi-specialty Ananya hospital (Bangalore, India). The measurements were taken in the OPD set up of Ananya Multispecialty hospital. The device measured BP in all the subjects with the same algorithm. Based on the ANSI/AAMI/ISO guideline, this study consisted of 162 subjects.

2.2.1 Gender Distribution

The gender selection was done based on ANSI/AAMI/ISO guideline. At least 30 % of the subjects used in the study were male & at least 30 % of the subjects were female.
Male: 67 (42%)
Female: 95 (58%)

2.2.2 Age Distribution

The BPL 120/80 B20 Blood pressure monitor is intended to be used on adult and adolescent patients. Based on the ANSI/AAMI/ISO guideline, all the subjects used for this study are greater than age 12.

2.3 Procedure

This research followed the "same arm sequential method" outlined in the ANSI/AAMI/ISO guideline. Participants were seated in a calm environment with comfortable room temperature and humidity and instructed to refrain from speaking during the procedure. Blood pressure measurements commenced after a 5-minute rest period, with participants seated in a chair, legs uncrossed, and feet flat on the floor. The chair provided back support and elbow and forearm rests. Two trained observers used a calibrated standard mercury sphygmomanometer to auscultate, with diastolic BP (DBP) determined using the fourth phase (K4) and fifth phase (K5) of Korotkoff sounds and a calibrated electronic blood pressure monitor, B20, for taking measurement via oscillometric method. Measurements were taken with at least 1 minute between each reading.

The situations below were excluded from this study.
- Subjects who have arrhythmia or unclassified ECG.
- When body movement is observed during measurement.
- Korotkoff sound received is of poor quality.
- The subject’s arm circumference is outside the range of designated cuff size.
- Subject offered to stop on the way of testing.

3. Analysis

Data were analyzed according to the requirements and criteria as described in ANSI/AAMI/ISO guideline.

4. Results

4.1 Subjects’ distribution

The subjects’ requirements of ANSI/AAMI/ISO guideline were fulfilled in this study (Table 1).

Table 1. Screening and recruitment details

Total Screened	166

Total Excluded	4
Arrhythmias	4
Poor quality sounds	0
Cuff size mismatch	0
Body movements	0
Blood pressure variation	0
Observers' determination with difference	0
Others	0
Total Recruited	162

4.1.1 Number of subjects

We screened 166 subjects for this study. After excluding 4, 162 subjects were evaluated (Table 1). K5 was used in all subjects (Table 2).

4.1.2 Gender

67 men (42 %) and 95 women (58 %) were included in this study (Table 2).

4.1.3 Age

The mean age of subjects was 39.66 ±16.23 years old (range, 19—91 years old) (Table 2).

Table 2 – Subject Details

	Gender		**Age**	
	Male	Female		
ANSI/AAMI/ISO guideline	≥ 30%	≥ 30%	High - Low	19-91
Study Count (%)	42%	58%	Mean (SD*)	39.66 (16.23)
Study Count (Nos.)	67	95		

**SD-Standard Deviation*

4.1.4 BP Distribution

The BP distribution fulfills the required as per the ANSI/AAMI/ISO guideline. The details are mentioned in (Table 3).

Table 3. Blood pressure distribution

SBP (mmHg)	**Requirement**	**Readings**	**%**	**DBP (mmHg)**	**Requirement**	**Readings**
≥ 160	At least 5%	12	7.4	≥100	At least 5%	18
≥ 140	At least 20%	54	33	≥85	At least 20%	53
≤ 100	At least 5%	16	9.8	≤60	At least 5%	10

Range (SBP)		Range (DBP)	
High	90	High	60
Low	200	Low	110
Mean (SD)	126.4 (20)	Mean (SD)	80.4(10.9)

4.2Measurement accuracy

The BPL Medical 120/80 B20 has fulfilled the validation criteria 1 of the ANSI/AAMI/ISO requirements.

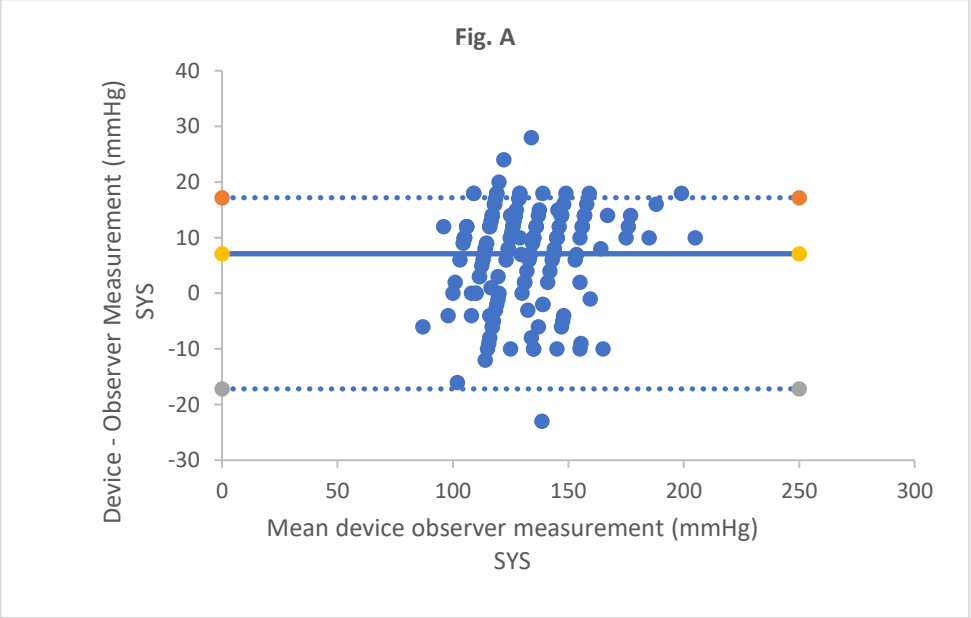
4.3Criteria 1

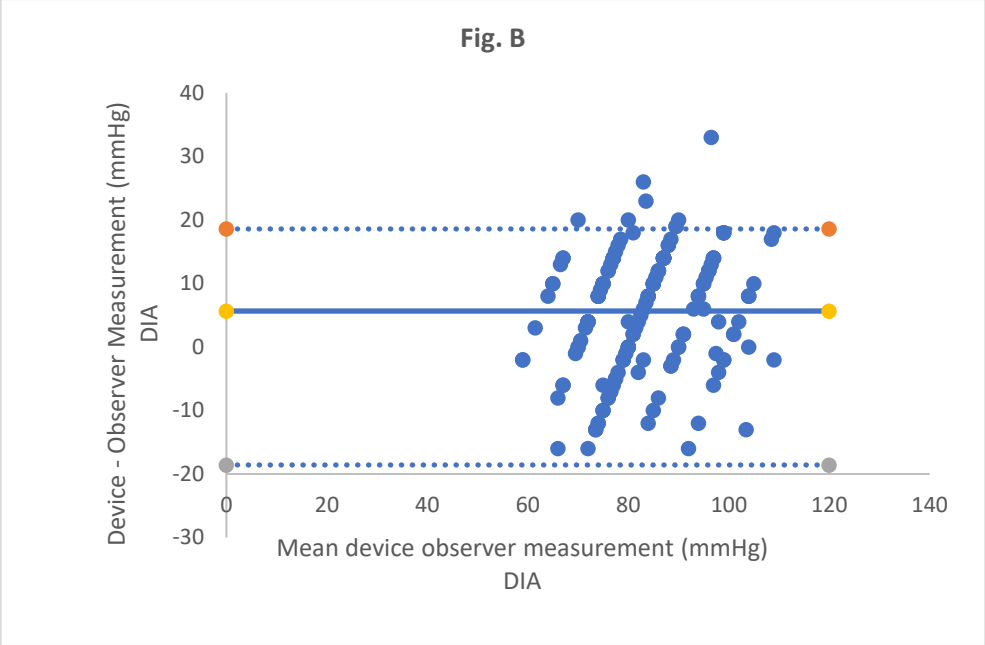
The mean differences between the observers and the BPL B20 were ± 5.2 mmHg for SBP and ± 5.65 mmHg for DBP. These data fulfilled the ANSI/AAMI/ISO requirements to be ≤ 5 ± ≤ 8 mmHg.

5. Discussion

This study aimed to validate the accuracy of the BP monitor, the BPL Medical 120/80 B20 according to ANSI/AAMI/ISO guideline. The results of the present study have fulfilled the accuracy requirements and criteria 1. The results show that the BPL 120/80 B20 readings are accurate enough compared with the reference BP value. Therefore, the present study confirmed that the BPL 120/80 B20 was sufficiently accurate.

Bland-Altman plots for the difference between BPL 120/80 B20 readings and the observer measurements for the systolic (Fig. A) and diastolic (Fig. B) blood pressure





6. Conclusion

The BPL 120/80 B20 has fulfilled the requirements of ANSI/AAMI/ISO guideline.

7. Reference

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