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Blood Pressure Device Validation Standards: An Overview

Dr. Raj Padwal

Professor of Medicine, University of Alberta

Edmonton, Alberta, Canada

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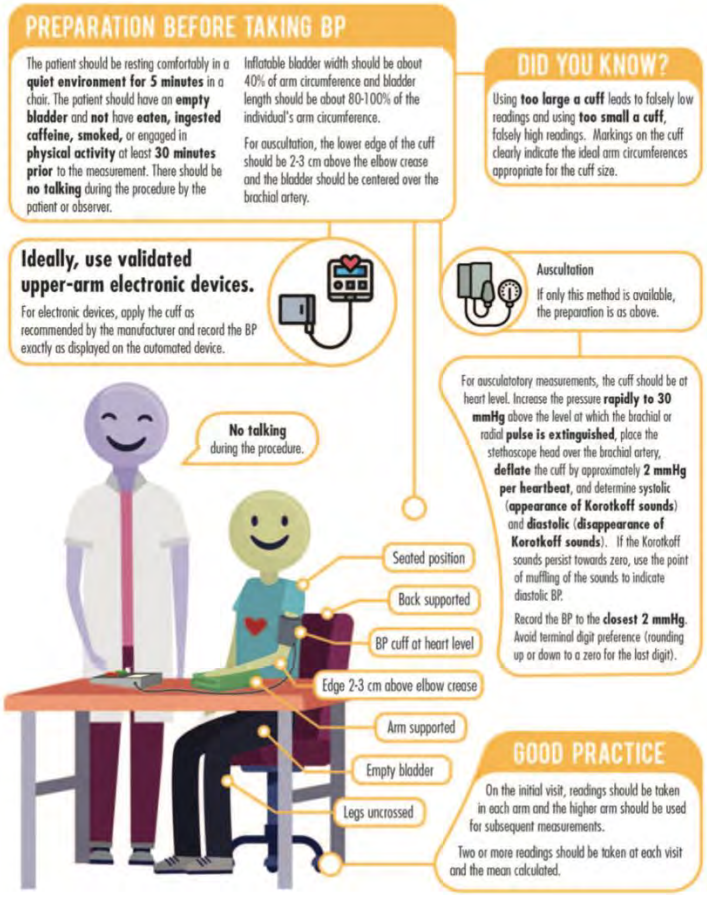
Automated Devices Are Preferred Over Auscultation



- Proper auscultation requires careful attention to proper procedure.
- It is known to be poorly performed.
- It requires extra training.
- All of these factors add additional potential error to the measurement
- procedure.
- Use of automated devices standardizes the measurement procedure.
- But devices must be accurate; hence the importance of validation.

Padwal et al. J Hypertens. 2019

What is Blood Pressure Device Validation?

Accurate BP assessment is clearly a critical component of BP management.

Globally, there is increased emphasis on use of automated devices. Only validated devices should be used. Validation involves testing **to ensure accuracy and precision** according to a globally accepted standard.

Less than 20% of devices on the marketplace are validated.

Lack of awareness	Lack of regulation	Costs of validation

An Important Point About Validation Thresholds

BP measurement standards are designed to pass devices that are relatively inaccurate.

The ISO standard accepts an 85% probability of a tolerable error of 10 mmHg or less.

Most clinicians would view this as relatively lax.
However, this is the global standard.

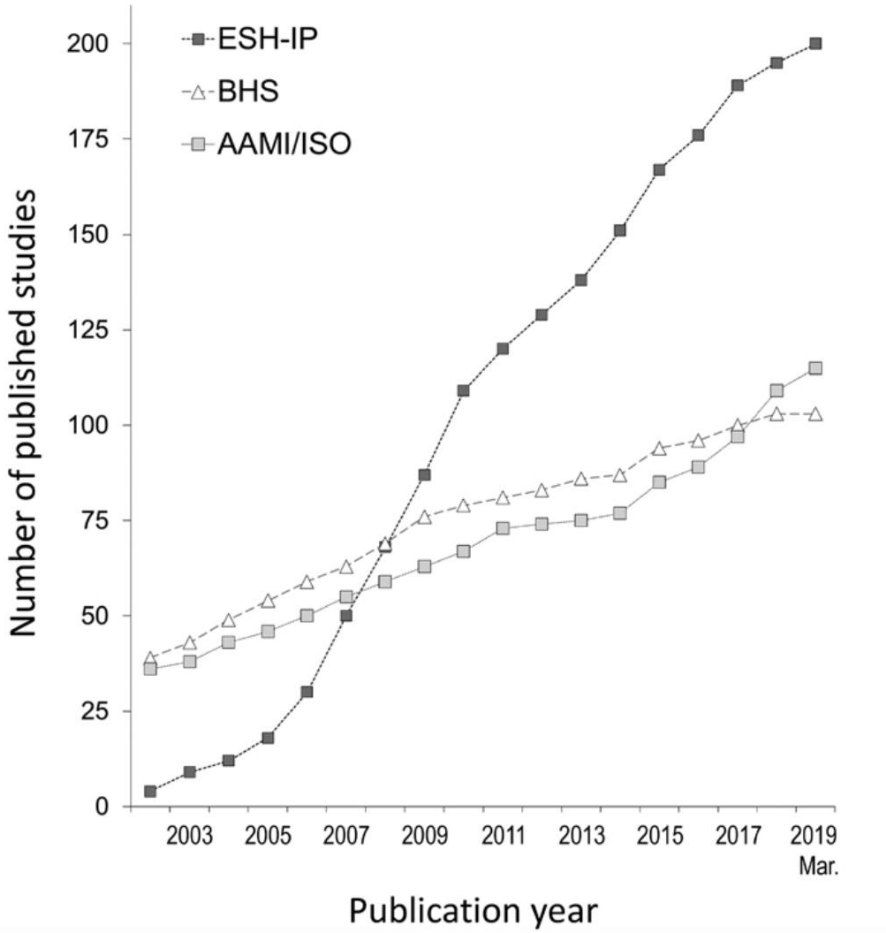
History of Validation Standards

Publication	Organization
1987, 1992, 2002	US Association for the Advancement of Medical Instrumentation (AAMI)[3,5]
1990, 1993	British Hypertension Society (BHS)[4,6]
1999	German Hypertension League (Deutsche Hochdruckliga) (DHL)[7]
2002, 2010	European Society of Hypertension International Protocol (ESH-IP)[8,9]
2004	European Committee for Standardization (CEN)[10]
2009	International Organization for Standardization (ISO)[11]
2009, 2013	American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO)[12,13]
2018	Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO)[14]

- Different organizations have developed different standards.
- The standards have much in common, but also important differences exist.

Stergiou et al. J Clin Hypertens 2018:1094

Comparison of Validation Standards



- The European Society of Hypertension (ESH).
- International Protocol (IP) is the most widely used.
- It is to be phased out, but many devices on the market are validated using ESH alone.
- The low sample size (33) makes performing validation easier.
- However, it also limits power for subgroup analysis.
- As well, the ESH-IP is possibly easier to pass than ISO.

O'Brien et al. Blood Press Monit 2019

Comparison of Validation Standards

Protocol provisions	AAMI SP10:2002 + A1:2003 + A2:2006	EN 1060-4: 2004	ESH-2010	ISO 81060-2:2009 + C1:2011
Manual auscultatory blood pressure as reference				
Validation in a general adult population[a]	■	■	■	■
Validation in a general adult and pediatric population (children ≥ 3 years, adults > 12 years)	■	–	–	■
Validation in different postures (seated, standing, and supine) in a general population	■	–	–	–
Validation in children (≥ 3 years, ≤ 12 years)	■[b]	■[b]	–	■[b]
Validation in pregnant women	–	–	–	■[c]
Validation in other special populations	–	–	–	■[c]
Validation during exercise	–	■	–	■
Validation under real or simulated ambulatory conditions	■	■	–	■
Criteria for accepting observers' simultaneous auscultatory measurements during validation	■	■	■	■
Provisions for sequential same-arm measurements	■	■	■	■
Provisions for simultaneous same-arm and simultaneous opposite-arm measurements	■	■	–	■
Use of mean difference statistics as accuracy criteria for clinical use	■	■	–	■
Use of distribution of device–reference differences as accuracy criteria for clinical use	–	–	■	–
Intra-arterial pressure as reference				
Validation in a general adult population[a]	■	■	–	■
Validation in a general adult and pediatric population (children ≥ 3 years, adults > 12 years)	■	–	–	■
Validation in children (≥ 3 years, ≤ 12 years)	■[b]	–	–	■[b]
Validation in neonates, infants, and young children (< 3 years)	■	■	–	■
Validation in pregnant women	–	–	–	■[c]
Validation in special populations other than pregnant women	–	–	–	■[c]
Use of mean difference statistics as accuracy criteria for clinical use	■	■	–	■

Ng. Blood Press Monit 2013;18:282

Different Validation Standards

Table 5 Differences in various validation protocols

Protocol	Investigator training	Number of participants	Pass criteria Δtest vs. control measurement
EN 1060-4 European Standard	Yes	≥ 85	Systolic 5 ± 8 mmHg Diastolic 5 ± 8 mmHg
Hochdruckliga Quality Seal	Yes	≥ 96	Systolic 5 ± 8 mmHg Diastolic 5 ± 8 mmHg 50% of maximum possible pointscore
BHS British Hypertension Society	Yes	≥ 85	50% < 5 mmHg 75% < 10 mmHg 90% < 15 mmHg
ANSI AAMI Association for the Advancement of Medical Instrumentation	No	≥ 85	Systolic 5 ± 8 mmHg Diastolic 5 ± 8 mmHg
ESH European Society of Hypertension	Yes	≥33	Percent differences within the error range 5/10/15 mmHg

Tholl et al. Blood Press Monit 2016;21:197

Essential Components of ISO 2018 Standards

Aspect	Requirement
Efficacy measure	Threshold for BP measurement accuracy acceptance at estimated probability of tolerable error (≤ 10 mm Hg) ≥85%.
Sample size	≥ 85 participants
General/special populations	A general population study includes participants ≥ 12 years. Special populations: age < 3 years; pregnancy; arm > 42 cm; atrial fibrillation; others may be added. Special population studies include ≥ 35 participants (after successful general population study). Pregnancy: N = 45 (15 normotensive, 15 gestational hypertension, 15 preeclampsia). Korotkoff K5 for reference diastolic BP: Children: N = 35 aged 3-12 years can be included and analyzed together with 50 older participants. Results also reported separately for children (not a pass/fail criterion). Korotkoff K5 for reference diastolic BP.
Cuff sizes	There is a minimum number of participants per cuff depending on number of test device cuffs. Requirements for arm circumference distribution according to range of use of the test device.
Reference BP	Mercury sphygmomanometers or accurate non-mercury devices.
Data collection	Same-arm sequential BP measurement is preferred.
Pass criteria	Average BP difference and SD criteria 1 and 2 of ANSI/AAMI/ISO. Absolute BP differences ≤ 5, 10, 15 mm Hg and scatterplots to be presented. not true

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