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Blood Pressure Device Validation Standards: An Overview

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Automated Devices Are Preferred Over Auscultation

PREPARATION BEFORE TAKING BP

The patient should be resting comfortably in a quiet environment for 5 minutes in a chair. The patient should have an empty bladder and not have eaten, ingested caffeine, smoked, or engaged in physical activity at least 30 minutes prior to the measurement. There should be no talking during the procedure by the patient or observer.

Inflatable bladder width should be about 40% of arm circumference and bladder length should be about 80-100% of the individual's arm circumference.

For auscultation, the lower edge of the cuff should be 2-3 cm above the elbow crease and the bladder should be centered over the brachial artery.

DID YOU KNOW?

Using **too large a cuff** leads to falsely low readings and using **too small a cuff**, falsely high readings. Markings on the cuff clearly indicate the ideal arm circumferences appropriate for the cuff size.

Ideally, use validated upper-arm electronic devices.

For electronic devices, apply the cuff as recommended by the manufacturer and record the BP exactly as displayed on the automated device.

Auscultation

If only this method is available, the preparation is as above.

No talking during the procedure.

Seated position

Back supported

BP cuff at heart level

Edge 2-3 cm above elbow crease

Arm supported

Empty bladder

Legs uncrossed

For auscultatory measurements, the cuff should be at heart level. Increase the pressure **rapidly to 30 mmHg** above the level at which the brachial or radial pulse is extinguished, place the stethoscope head over the brachial artery, **deflate** the cuff by approximately **2 mmHg per heartbeat**, and determine systolic (appearance of Korotkoff sounds) and diastolic (disappearance of Korotkoff sounds). If the Korotkoff sounds persist towards zero, use the point of muffling of the sounds to indicate diastolic BP.

Record the BP to the **closest 2 mmHg**. Avoid terminal digit preference (rounding up or down to a zero for the last digit).

GOOD PRACTICE

On the initial visit, readings should be taken in each arm and the higher arm should be used for subsequent measurements.

Two or more readings should be taken at each visit and the mean calculated.

- 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.

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.

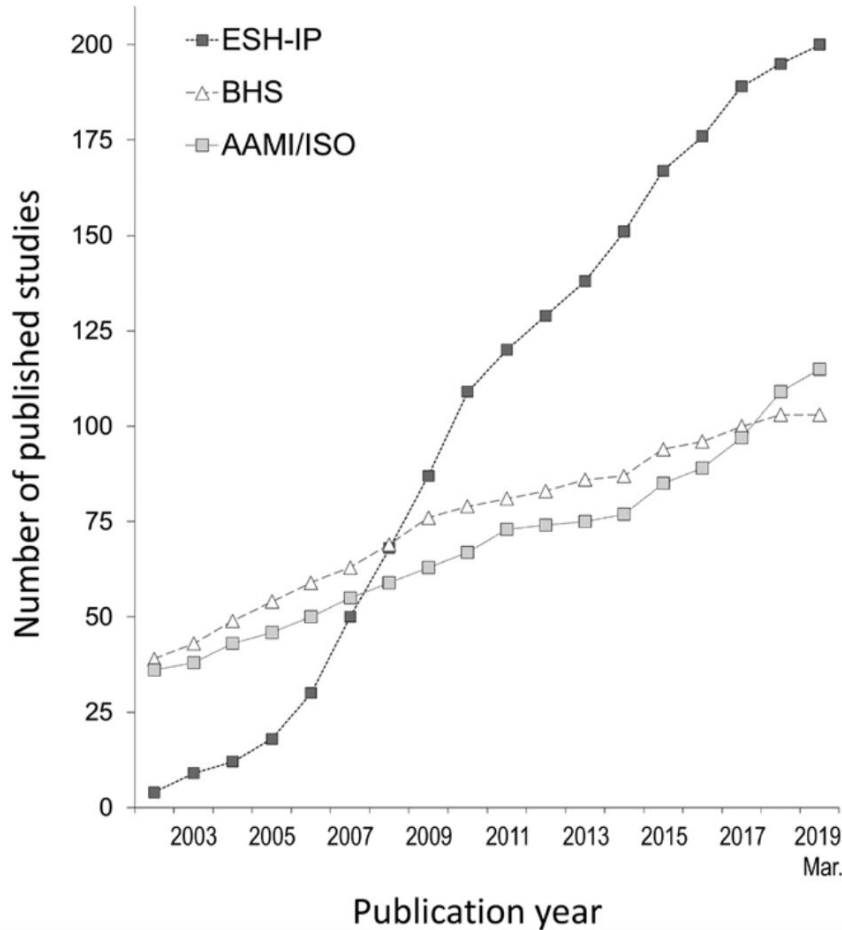
Most clinicians would view this as relatively lax.
However, this is the global standard.

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, <u>2010</u>	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}
<u>2018</u>	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.

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.

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	■	■	–	■

Different Validation Standards

Table 5 Differences in various validation protocols

Protocol	Investigator training	Number of participants	Pass criteria Δ test 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

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) <u>$\geq 85\%$</u> .
Sample size	≥ 85 participants
General/special populations	A general population study includes participants <u>> 12 years</u> . 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 $\leq 5, 10, 15$ mm Hg and scatterplots to be presented. <i>not true</i>



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Thank you!



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