Mercury-Free Technology Substitutes in Healthcare

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Agenda

- Are there special cases were Hg sphygmomanometers are still needed?
- Are non-mercury devices validated?
- Are Hg sphygmomanometers needed for calibration?

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Who am I?

- Thomas Grant
- Director, Product Category Management
  Frontline Diagnostic Products
- 15 years with Welch Allyn
  11 years managing blood pressure products
- Previously based in Corporate office, NY, USA
  Since July 2008, in Nyon, Switzerland

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What are the relative advantages of each technology in obtaining accurate readings?

- American Heart Association task force[1] suggested errors derive from:
    1. faulty equipment
    2. observer bias
    3. failure to standardize measurement technique

1. Bailey RH, Bauer JH. A review of common errors in the indirect measurement of blood pressure. Arch Intern Med. 1993; 153: 2741-2748.

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Potential causes of error (technology specific):

Mercury	Aneroid	Automated
Mercury not at zero level Column not vertical Manometer not at eye level Plugged filter Oxidized mercury	Out of calibration	Patient movement Loose cuff application Arrhythmia

Other causes of error (not technology specific):

- Technique error: Inadequate training, patient position, cuff sizing and application, digit rounding, deflation speed.
- Equipment condition: Leaking cuff, tube, bulb or valve. Poor stethoscope sound quality.

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Technology-specific advantages:

Mercury	Aneroid	Automated
Accurate to +/- 3 mm Hg	Accurate to +/- 3 mm Hg	Accurate to +/- 4 mm Hg
Auscultatory technique	Mercury free	Mercury free
Low cost	Large, easy to read dial	Reduce user-technique errors
	Auscultatory technique	Use less-trained personnel
	Low cost	

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Technology conclusions:

- Every technology has the potential to introduce error, especially **if not properly maintained**.
- High-quality aneroid technology and mercury technology are **equally accurate**, ±3 mm Hg.
- Where labor is expensive or access to well trained personnel is limited, an **automated device** may provide the highest value mercury-free solution.

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Question 1.

Q: Are there special cases were Hg sphygmomanometers are still needed?

A: No.

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What scientific research supports the viability of the mercury-free substitutes?

Key studies:

- Canzanello VJ, Jensen PL, Schwartz GL. **Are aneroid sphygmomanometers accurate in hospital and clinical settings?** Arch Int Med 2001 Mar 12;161:729-731.
- Journal of Human Hypertension, 2000 Jan; 14(1): 31-6 **The mercury sphygmomanometer should be abandoned before it is proscribed.** Markandu ND, Whitcher F, Arnold A, Carney C.
- Klaus Forstner, Physician, M.D. Dipl.-Ing.; Forschungsinstitut für klinische Medizintechnik, Tamm, Germany. **Gear-free, shock-resistant aneroid sphygmomanometer technology greatly improves ability to maintain accurate blood-pressure readings.** December 2006.

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Do standards exist for mercury-free substitutes?

Sphygmomanometers

- ANSI/AAMI SP10, October 2002,
  (Manual, electronic, or automated sphygmomanometers).
- European Standard EN 1060-1 and 1060-2: 1996,
- INMETRO Technical Metrological Regulation Number 24, February 26, 1996 (Brazil).

Question 2.

Q: Are non-mercury devices validated?

A: Yes.

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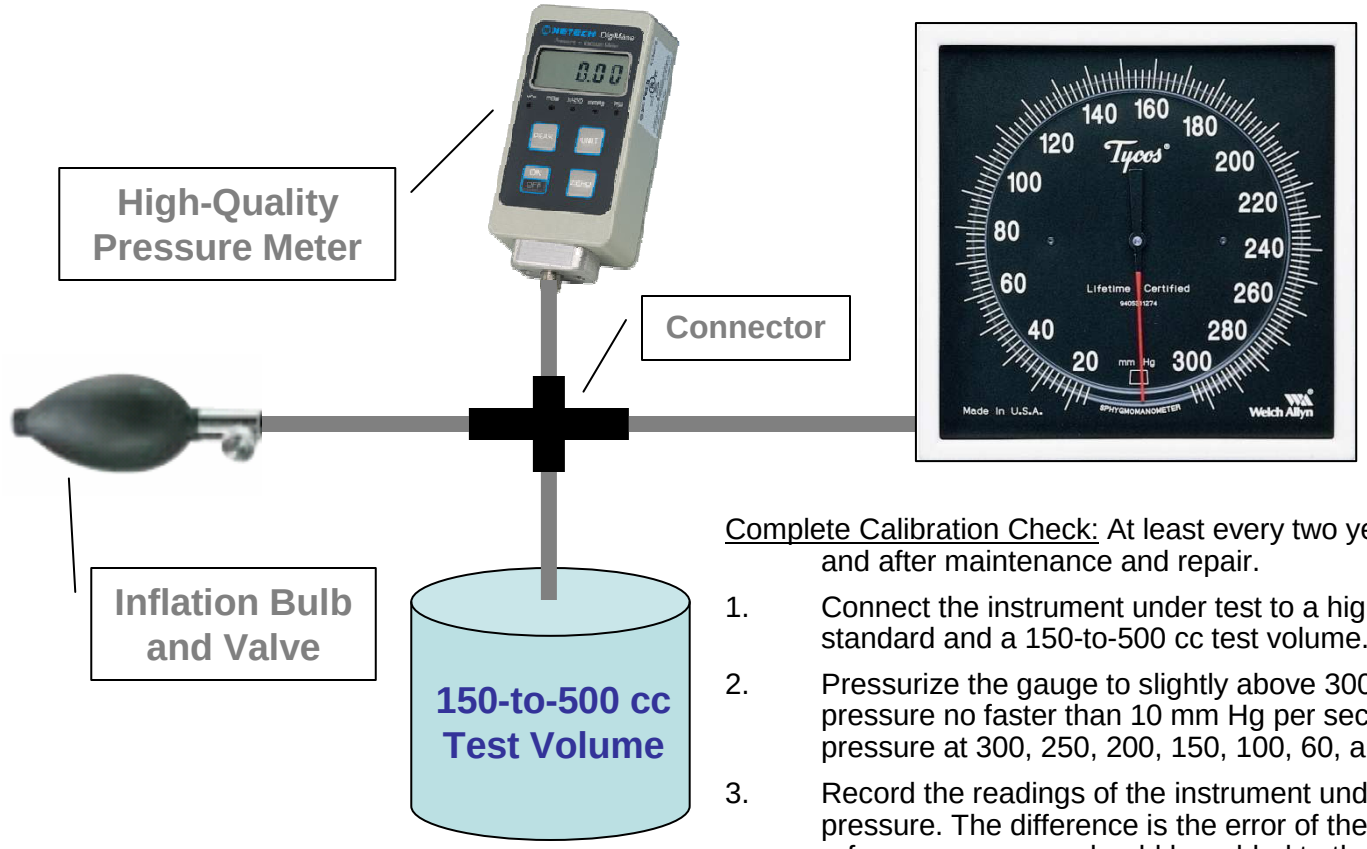
Complete Calibration Check



Complete Calibration Check: At least every two years or according to local law and after maintenance and repair.

1. Connect the instrument under test to a high-quality, known pressure standard and a 150-to-500 cc test volume.
2. Pressurize the gauge to slightly above 300 mm Hg and bleed down the pressure no faster than 10 mm Hg per second, stopping to check the pressure at 300, 250, 200, 150, 100, 60, and 0 mm Hg.
3. Record the readings of the instrument under test and the applied pressure. The difference is the error of the instrument. The error of the reference pressure should be added to the specified accuracy of the instrument under test (+/-3 mm Hg) to determine the working accuracy of your calibration set-up.

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Pressure Standards: Calibration

- Calibration accuracy depends upon the sensitivity of the pressure standard.
- Error is additive:

Device Error + Pressure Standard Error = **Total Error**

Sphygmomanometer ± 3 mm Hg + Mercury Column ± 3 mm Hg = **± 6.0 mm Hg**

Sphygmomanometer ± 3 mm Hg + Digital Pressure Meter ± 0.1 mm Hg = **± 3.1 mm Hg**

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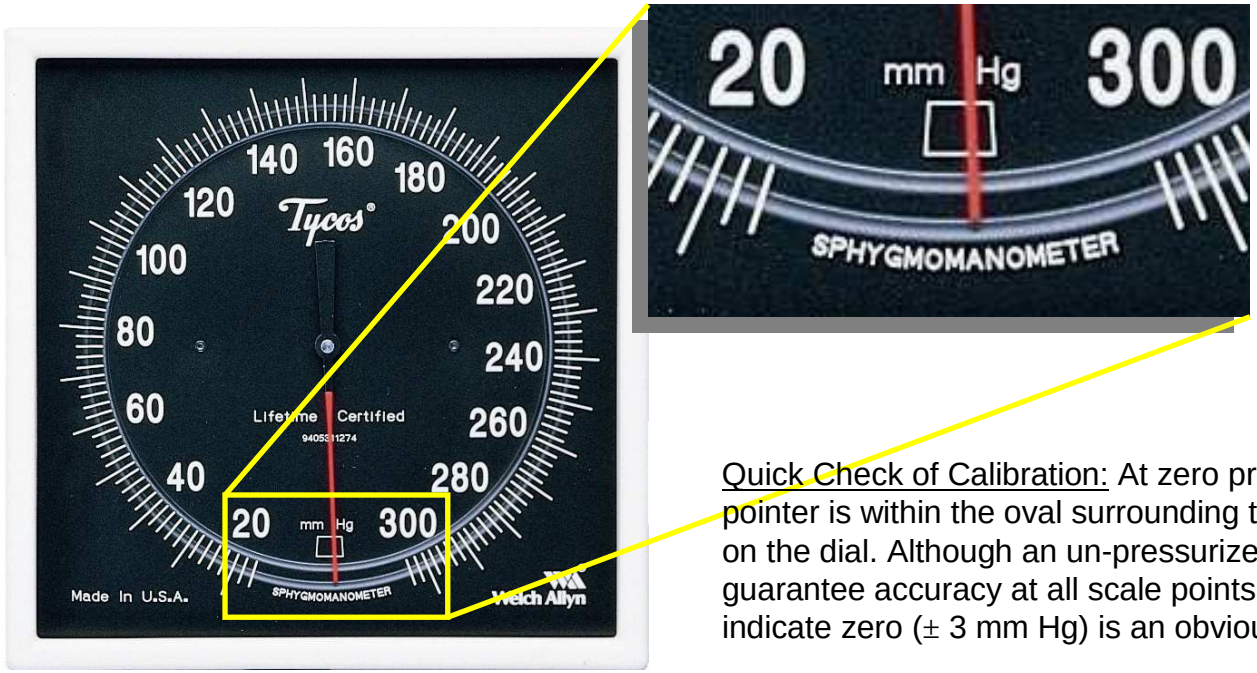
Quick-Check of Calibration



Quick Check of Calibration: At zero pressure, make certain the pointer is within the oval surrounding the zero-pressure gradation on the dial. Although an un-pressurized reading of zero does not guarantee accuracy at all scale points(1), failure of the pointer to indicate zero (± 3 mm Hg) is an obvious sign of error.

(1) For devices that do not incorporate a pin stop or other restraint on pointer movement, it has been found that nearly 89% of gauges that read zero correctly were within a 3-mm Hg error limit (Perlman et al., 1970):

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Question 3.

Q: Are Hg sphygmomanometers needed for calibration?

A: No.

Thank you!

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