



# GUIDANCE ON MAINTAINING AND CALIBRATING NON-MERCURY CLINICAL THERMOMETERS AND SPHYGMOMANOMETERS

## INTRODUCTION AND DEFINITIONS

The replacement of mercury thermometers and sphygmomanometers (blood pressure measuring device) with non-mercury alternatives is a major step towards mercury-free health care. A separate guidance document deals with technical specifications<sup>1</sup>. This guidance presents general procedures for maintaining and calibrating common types of non-mercury thermometers and sphygmomanometers. General information is also provided on validation protocols for non-mercury devices.

This guidance is intended for several audiences and purposes as described below.

- The main body of the guidance is for users of non-mercury devices in healthcare facilities.
- Annex A describes setting up a maintenance system for large hospitals and medical centers with engineering departments. It suggests minimum requirements for a set-up in a small primary care facility.
- Annex B1 provides details on accuracy testing of non-mercury thermometers. Annex B2 describes accuracy testing and calibration procedures for non-mercury sphygmomanometers. These annexes are intended for large hospitals and medical centers with engineering departments, for health ministries and institutions that test and set requirements for the procurement of medical devices, and for group purchasing organizations.
- Annex C gives an overview of validation procedures for non-mercury thermometers and sphygmomanometers. It is intended for health ministries and institutions that set standards and requirements for medical devices and for group purchasing organizations. The procedures can be used as a guide by large hospitals and medical centers to modify clinical accuracy test procedures.

## DEFINITIONS

**Maintenance** is the periodic servicing of devices to make certain that they are operating properly. Servicing includes regular inspection, cleaning, testing, replacement of worn parts to prevent faults from occurring, and record-keeping. Maintenance also includes calibration at regular intervals (see below). These processes help prevent breakdowns and increase the service life of the device. Maintenance can be done by the health facility, by the manufacturer, by an outside group as part of an outsourcing arrangement (subcontract), or by a combination of these.

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<sup>1</sup> Emmanuel, J. "Guidance on Technical Specifications for Non-Mercury Medical Devices," UNDP GEF Project, 2011; Shimek, J, Emmanuel, J, Orris, P and Chartier, Y, "Replacement of mercury thermometers and sphygmomanometers in health care: Technical guidance," World Health Organization, Geneva, Switzerland, 2011; "Affordable technology: blood pressure measuring devices for low resource settings," World Health Organization, Geneva, Switzerland, 2005; "WHO CVD-risk management package for low- and medium-resource settings," World Health Organizations, Geneva, Switzerland, 2002.

**Calibration** allows the user to check and adjust the internal accuracy of a device. Calibration includes comparing the measurements provided by a test device (a thermometer or sphygmomanometer being tested) against the measurements from an accurate reference. Then, if the measurements are different, calibration includes adjusting the output of the test device to match the output of the reference device. Calibration can be done by the health facility on a regular basis or by the manufacturer as part of warranties or service agreements.

**Validation** is the process of testing a device following an internationally or nationally approved test protocol and verifying that the device meets minimum standard criteria. Unlike calibration which only looks at the internal accuracy of the device through a laboratory test, validation also examines durability, electrical safety, readability, long-term stability, etc. as well as accuracy in a clinical setting. Validation testing may be done by governmental bodies to set minimum requirements for facilities or to guide purchasing decisions by government-run facilities. Validation can also be conducted by non-governmental organizations to assist institutional members, group purchasing organizations, or consumers in general. Some large facilities do validation tests at the facility level on samples provided by vendors before purchasing them in order to confirm that products meet international, national or their own specifications. An overview of the validation process is given in Annex C.

## WHY MAINTENANCE AND CALIBRATION ARE IMPORTANT

Maintenance and calibration are essential during the life of all temperature and blood pressure measuring devices to make sure that they function and can be used properly. This is true for *both* non-mercury and mercury devices. Below are summaries of three major studies that show the problems that typical wear and tear have on devices that have not been maintained or calibrated.

In a clinical comparison of non-mercury thermometers to standard mercury-in-glass thermometers, Leick-Rude and Bloom<sup>2</sup> rejected 25% of the mercury thermometers. These rejected thermometers differed by greater than 0.2°C compared to a reference thermometer. (Note that in the key range of 37 to 39°C, the required accuracy for both mercury and digital thermometers is  $\pm 0.1^\circ\text{C}$ ).

At a large teaching hospital in the UK, Markandu *et al.*<sup>3</sup> examined 444 mercury sphygmomanometers. They found that 21% had mercury oxidation on the columns and 18% had faded markings or rotated columns making them difficult to read. They also found that 20% had columns that were not vertical, 5% had blocked air filters, three were leaking mercury but were still being used, and 38% had ruined tubing at the junction to the mercury reservoir. Of the 17 non-mercury mechanical sphygmomanometers, 12 had needles that deviated from 0 by more than 5 mmHg and one machine had the needle stuck at 120 mmHg. Service history was known for only 23 of the devices and most of the staff were unaware that mercury and non-mercury sphygmomanometers required regular servicing.

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<sup>2</sup> Leick-Rude, MK, Bloom, LF. A comparison of temperature-taking methods in neonates. *Neonatal Netw.* 1998 August, 17(5): 21-37.

<sup>3</sup> Markandu, ND, Whitchener, F, Arnold A and Carney C. The mercury sphygmomanometer should be abandoned before it is proscribed. *J Hum Hypertens* 2000, 14(1): 31-36.

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A study by Knight *et al*<sup>4</sup> looked at mercury and non-mercury devices in use at 86 general practices in a health district in the UK. Of 472 sphygmomanometers in general use, only a handful had service records and none met all the quality standards. A large portion of mercury devices had defects likely to affect measurement technique and only two-thirds were accurate at all pressure levels tested. Only 38.8% of the non-mercury mechanical devices were accurate at all pressure levels tested. Similar types of problems were reported by McCartney and Crawford<sup>5</sup>.

## MAINTENANCE & CALIBRATION OF NON-MERCURY CLINICAL THERMOMETERS

### ALL TYPES OF NON-MERCURY THERMOMETERS:

Always follow maintenance procedures in the manufacturer's instructions. If no maintenance instructions are found, the procedures below can be used as a guide:

**Inspection:** Check the thermometer for general cleanliness. Check the display to make sure that all alphanumeric segments or pixels are working properly to avoid incorrect reading of the display. Check buttons and switches. Check for any worn or broken parts. Return to the manufacturer if there are broken parts or display problems.

**Battery testing:** Check the battery indicator in the display or test the battery with a battery tester. Replace spent or defective batteries according to the manufacturer's instructions. Batteries should be disposed of properly as hazardous waste. If the device uses a charger, make sure the battery charging station is working properly.

**Recordkeeping:** Keep a maintenance record with the following information: serial number or identification number of the device; date of servicing; results of inspection, battery testing, and function testing; type of reference thermometer used and result of accuracy testing if conducted at that time; actions taken; and name of service personnel.

### DIGITAL:

If no maintenance instructions are found for the digital thermometer, the following *additional* procedures can be used as a guide:

**Inspection:** Check the condition of the probe tip. If the thermometer has a removable probe, check the probe cord for breaks in the insulation and check the contacts of the connector. If probe covers are used, check that all probe covers are new and undamaged. Return to the manufacturer if there are broken parts or display problems.

**Cleaning and disinfection:** The exterior of most digital thermometers can be cleaned with mild soap and warm water or with a damp cloth. To disinfect, use 70% isopropyl alcohol or 70% ethanol. For some digital thermometers, the probe tip can be partially immersed in isopropyl alcohol for a short time.

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<sup>4</sup> Knight, T, Leech, F, Jones, A, Walker, L, Wickramasinghe, R, Angris, S and Rolfe, P. Sphygmomanometers in use in general practice: an overlooked aspect of quality in patient care. *J Hum Hypertens* 2001, 15(10): 681-684.

<sup>5</sup> McCartney, P and Crawford, D. Inaccurate, leaky sphygmomanometers are still common. *Brit J Gen Pract* 2003 January, 53(486): 61-62.

**Function testing:** Many digital thermometers have an automatic internal self-test when turned on and display an error message or warning if the thermometer is not functioning properly. In addition to the automatic self-test, check other functions and features that the thermometer may have. For example, check high and low temperature warnings, memory (displays of previous recorded readings), indication when peak temperature or final temperature is reached, audible or visual alerts (beeps or lights), automatic shut-off after a specified period of inactivity, temperature scale selection, etc.

**Accuracy testing and calibration:** While some manufacturers recommend testing for accuracy every two years, an accuracy check at least every six months is recommended. Always test the accuracy if the thermometer has been dropped or if temperature readings are questionable. Many digital thermometers cannot be adjusted. Some advanced digital thermometers come with a calibration tester. If the thermometer exceeds the maximum permissible error within the measuring range, follow the manufacturer's instructions for calibration and adjustment or return the thermometer to the manufacturer for adjustment or replacement. If the manufacturer does not provide procedures for testing accuracy, see Annex B1 for suggested procedures.

## **TEMPORAL IR:**

If no maintenance instructions are found for the temporal (forehead) artery infrared (IR) thermometer, the following *additional* procedures can be used as a guide:

**Inspection:** Check the condition of the probe lens and cone. If the thermometer comes with a charger, check the power adapter or charging station for cleanliness and any worn or broken parts. Return to the manufacturer if there are broken parts.

**Cleaning and disinfection:** The exterior of most temporal thermometers can be cleaned with a soft cloth. The probe lens should be cleaned regularly of any dirt, greasy film and moisture. Cleaning should be done by wiping gently with a small cloth or swab moistened with alcohol or by gently blowing with compressed air. Do not use any abrasive cleaners that may scratch the thermometer. When cleaning the probe lens and cone, one may have to hold the thermometer downwards to prevent moisture from entering the sensor area. If excess moisture gets in, allow the area to dry before using.

**Function testing:** Many temporal IR thermometers have an automatic internal self-test when turned on and display an error message or warning if the thermometer is not functioning properly. In addition to the automatic self-test, check other functions and features that the thermometer may have. For example, check switching from surface to body temperature measurements, focusing or tracking lights, warning if the measuring distance is too close or too far, high and low temperature warnings, memory (displays of previous recorded readings), audible or visual alerts (beeps, buzzers, or flashing lights), backlight, automatic shut-off after a specified period of inactivity, temperature scale selection, continuous scanning, long-term calibration drift correction, etc.

**Accuracy testing and calibration:** Some manufacturers recommend testing for accuracy every year. Others recommend more frequent testing. Some temporal IR thermometers have a self-calibration function, which, their manufacturers claim eliminates the need for calibration. Always test the accuracy if the thermometer has been dropped. Many temporal IR thermometers have no means of adjustment. If the thermometer exceeds the error range described in the manufacturer's instructions, return the thermometer to the manufacturer for adjustment or replacement. If the manufacturer does not provide procedures for testing accuracy, see Annex B1 for suggested procedures.

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### **TYMPANIC IR:**

If no maintenance instructions are found for the tympanic (ear) infrared (IR) thermometer, the following *additional* procedures can be used as a guide:

**Inspection:** Check the condition of the probe (the cone-shaped tube that is inserted into the ear), paying special attention to the probe window. Check that probe covers are new and undamaged. If the thermometer comes with a charger, check the power adapter or charging station for cleanliness and any worn or broken parts. Return to the manufacturer if the probe window or probe tip is damaged or altered in any way.

**Cleaning and disinfection:** The exterior of many tympanic IR thermometers can be cleaned with a soft cloth slightly moistened with alcohol. The probe window must be cleaned regularly of any dust, dirt, fingerprints, and cerumen (ear wax) by gently wiping with a cotton swab slightly moistened with alcohol. Allow the probe window to dry completely before use.

**Function testing:** If there is an automatic internal self-test function, use it to determine if the thermometer is functioning properly. Check other functions and features that the thermometer may have. For example, check high and low temperature warnings, probe cover ejector, probe cover indicator, ear positioning error warning, memory (displays of previous recorded readings), indication when final temperature is reached, audible and visual alerts (beeps and flashing lights), automatic shut-off after a specified period of inactivity, temperature scale selection, etc.

**Accuracy testing and calibration:** Some manufacturers recommend testing for accuracy every two years. Always test the accuracy if the thermometer has been dropped. Many tympanic thermometers have no means of adjustment. If the thermometer exceeds the error range described in the manufacturer's instructions, , return the thermometer to the manufacturer for adjustment or replacement. If the manufacturer does not provide procedures for testing accuracy, see Annex B1 for suggested procedures.

### **COMBINED IR:**

Combined ear/forehead infrared (IR) thermometers are similar to temporal and tympanic IR thermometers except that they generally have removable probe covers when used for temporal artery measurements. Always follow maintenance procedures in the manufacturer's instructions for the combined IR thermometer. If no maintenance instructions are provided, a modification of the procedures above for temporal and tympanic IR thermometers can be used.

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## **MAINTENANCE & CALIBRATION OF NON-MERCURY SPHYGMOMANOMETERS**

### **ALL TYPES OF NON-MERCURY SPHYGMOMANOMETERS:**

Always follow maintenance procedures in the manufacturer's instructions. If no maintenance instructions are found, the procedures below can be used as a guide:

**Inspection:** Check the sphygmomanometer for general cleanliness. Check the condition of the bulb, valves, tubing and cuff. Check tubing for cracks and test for air leaks. Check for any worn or broken parts. Return to the manufacturer if there are broken parts or display problems.

**Cleaning and disinfection:** Check with the manufacturer which cleaning and disinfection method they recommend.

- Some cuffs can be cleaned with a mild enzymatic detergent followed by brushing with a sterile brush, then rinsing with distilled water for five minutes.
- Some cuffs can be washed in cool water with a mild soap or with a detergent-disinfectant, followed by rinsing.
- Some cuffs have removable bladders. The bladders can be cleaned with ethanol while the cuffs can be washed separately in soap and warm water.
- Some cuffs, after removing the bladder, can be cleaned in a washing machine with a gentle cycle, cool or warm water, and a mild detergent but the cuff port must be capped to prevent water from getting inside the cuff.
- After washing, cuffs should be allowed to dry in air.
- The bulb, tubes, and valves can be cleaned with a slightly damp cloth or alcohol pad with 70% alcohol or 0.5% bleach.

If disinfection is needed, some cuffs can be sprayed with a 10% bleach solution, brushed with a sterile brush, then rinsed with distilled water for five minutes, and allowed to air dry.

**Recordkeeping:** Keep a maintenance record with the following information: serial number or identification number of the device; date of servicing; results of inspection, battery testing (if applicable), and function testing; reference manometer used and result of the accuracy test if conducted at that time; actions taken; and name of service personnel.

#### **ANEROID (MECHANICAL GAUGE):**

If no maintenance instructions for the aneroid sphygmomanometer with a mechanical gauge (mechanical dial) are found, the following *additional* procedures can be used as a guide:

**Inspection:** Check the condition of the gauge glass and the readability of the markings in the faceplate. Return to the manufacturer if there are broken parts or display problems.

**Cleaning and disinfection:** Many mechanical manometer gauges can be cleaned with a soft damp cloth or an alcohol pad with 70% alcohol.

**Function testing:** Check for leaks in the system. This can be done by inflating the unit and seeing if the gauge pointer drops slowly. If there is a slow leak, a small amount of soapy water can be used to find the leak. Leaks are usually found in connection points between the tubing and fittings, a defective air release valve, or in a crack in the tubing, cuff, or inflation bulb. Leaks between fittings and tubing or between the inflation bulb and fitting can often be repaired by tightening the connection or by cutting any loose expanded tubing and reconnecting. Cracked tubing or bulbs have to be replaced.

Check for the zero point. This can be done by fully deflating the unit and seeing if the gauge needle returns to zero (0 mmHg) or within the zero zone (a small marked area around the zero point found in some aneroid gauges). If the needle is outside the zero zone, check with the manufacturer on how to adjust the needle. Below are some of the common ways of adjusting the pointer:

- Many gauges have an adjustment screw to reset the zero point; the adjustment screw may be at the back or in the stem where the tubing is connected to the gauge.
  - With other models, the glass is removed from the front of the gauge and the pointer is carefully moved to the zero position.
  - The zero point in some large-face gauges can be adjusted by removing the tube from the underside of the aneroid face, inserting a small flat-head screwdriver or tool provided by the manufacturer into the connector from where the tube was removed, and turning the screwdriver or tool until the needle is at zero.
  - In other gauges, the zero point is adjusted by slightly rotating the dial face.
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Whenever the zero point is off, an accuracy test should be done.

**Accuracy testing and calibration:** Some manufacturers recommend a yearly calibration test, while others recommend a calibration check every two years. For frequently used aneroid sphygmomanometers in a healthcare facility, a calibration test every month is ideal unless maintenance records indicate the need for more or less frequent checks. A sphygmomanometer should always be calibrated if it has been dropped or if the pointer needle is outside the zero zone when the unit is fully deflated. Annex B2 provides examples of detailed procedures for accuracy testing and calibration.

**ELECTRONIC (INCLUDING DIGITAL, AUTOMATED, SEMI-AUTOMATED, AND OSCILLOMETRIC):**

If no maintenance instructions for the electronic sphygmomanometer are found, the following *additional* procedures can be used as a guide:

**Inspection:** Check the display to make sure that all alphanumeric segments or pixels are working properly. This will avoid incorrect reading of the display. Check all cables for breaks in the insulation. In some electronic units, checking for air leaks can be done as follows:

- a) Wrap the cuff around a vertical pipe or tube about the size of an adult's or child's arm (depending on the cuff size);
- b) Make sure that the artery mark is pointing downward;
- c) Temporarily seal the pressure release hole (usually in the back or side of the unit);
- d) Turn on the unit; and
- e) See if there are any leaks as the cuff is inflated.

If the unit comes with a charger, check the power adapter or charging station for cleanliness and any worn or broken parts. Return to the manufacturer if there are broken parts or display problems.

**Cleaning and disinfection:** In general, the electronic units can be cleaned with a dry, soft cloth. Some units can be cleaned with a damp, soft cloth or with a cloth moistened with soapy water.

**Battery testing:** If the unit uses batteries, check the battery indicator in the display or test the battery with a battery tester. Replace spent or defective batteries according to the manufacturer's instructions. If the unit uses rechargeable batteries, replace the batteries when they no longer hold charge for very long. Batteries should be disposed of properly as hazardous waste.

**Function testing:** Many electronic sphygmomanometers have an automatic internal self-test when turned on and display an error message if the unit is not functioning properly. In addition to the automatic self-test, check other functions and features that the unit may have. For example, check automatic and manual modes, pulse monitoring and pulse indication, arm movement detection warning, audible and visual alerts (beeps and flashing lights), memory functions, graph displays, date and time, automatic shut-off after a period of inactivity, wireless communications functions, etc.

**Accuracy testing and calibration:** Some manufacturers recommend testing for accuracy every year, others every two years. Some manufacturers state that their electronic sphygmomanometers do not need re-calibration even when dropped because of the characteristics of their technology. For a healthcare facility, an accuracy test every six months is ideal unless maintenance records indicate the need for more frequent checks. A sphygmomanometer should be tested if it has been dropped. Some electronic sphygmomanometers cannot be tested and/or calibrated by the user and must be sent to the manufacturer or an approved technician or service center for testing and calibration.

Annex B2 provides an example of procedures for accuracy testing and calibration. Digital sphygmomanometers that are based on the traditional auscultative method (listening to internal

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body sounds) but use digital displays, electronic sphygmomanometers that have an auscultative mode, and electronic sphygmomanometers with a calibration check or test mode can be tested for accuracy using a test set-up and procedures similar to those for aneroid sphygmomanometers.

Other electronic sphygmomanometers that use the oscillometric method (measuring the oscillations caused by arterial pressure as the arterial walls expand and contract against the cuff), digital Korotkoff technology, or a combination of these can be tested using clinical accuracy test procedures. If the sphygmomanometer does not meet the pass criteria, return it to the manufacturer for adjustment or replacement.

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July 2013

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ANNEX A

## SETTING UP A MAINTENANCE SYSTEM

Most equipment, including thermometers and sphygmomanometers, require regular, or periodic, maintenance. Reactive maintenance is taking action only when something breaks. Preventive maintenance is taking action on a specific schedule. Preventative maintenance can extend equipment life by detecting, avoiding, or reducing the impact of failures and slowing down wear and tear. Another approach, predictive maintenance, is similar to preventive maintenance except that the service is done based on usage or condition of the equipment rather than on a preset schedule. For example, if a manufacturer predicts battery life of a digital thermometer at 300 measurements, the predictive maintenance schedule would include service before 300 measurements have been taken.

Because of the importance of periodic testing for accuracy, a combination of scheduled preventive maintenance and predictive maintenance is recommended. Preventive maintenance is more labor intensive than reactive maintenance and can sometimes lead to unneeded maintenance or unnecessary replacement of parts if not done carefully. However, a well-planned preventive and predictive maintenance system can reduce long-term costs and avoid problems and costly repairs while increasing the confidence of health providers in the use of the devices.

When developing a preventive and/or predictive maintenance system, support by senior management is essential. Summarizing the failure histories and information on the costs of failures may help get support from management. A maintenance policy should be issued by the facility director or manager. The policy should define which department is responsible for maintenance, such as the facility's engineering department. Having well-respected staff promote the new maintenance policy will help change workplace culture and attitudes about maintenance. Maintenance is often in-house but some large health institutions outsource (subcontract) their maintenance programs.

Developing a maintenance system includes:

1. Conducting an inventory of each device in the facility ( brand name, serial number, location of use or storage, date of purchase, dates of past maintenance and actions taken),
2. Developing a system to manage maintenance information (for example, a maintenance log book or maintenance tracking software),
3. Developing a maintenance plan and schedule based on preventive and/or predictive approaches guided by manufacturers' instructions and the facility's history of past failures,
4. Sharing information with relevant departments (such as procurement, central supply, etc.),
5. Coordinating logistics with departments and wards where the devices are used or stored,
6. Training of maintenance staff, and
7. Allocating an annual budget for maintenance.

Scheduling the maintenance of thermometers and sphygmomanometers should be spaced out and timed in such a way as to ensure availability of these devices when and where they are needed by the medical and nursing staff. The maintenance plan could be part of a quality improvement strategy and include measures of effectiveness, annual review, and updating of the plan.

For a small healthcare facility, the following are minimum requirements for setting up a maintenance system:

1. Assign one or more persons to be responsible for maintenance.

2. Conduct an inventory of the devices that require maintenance.
3. Develop a maintenance plan, including a budget and schedules for periodic inspection and testing.
4. Train the person(s) responsible for maintenance.
5. Implement periodic maintenance and recordkeeping.
6. Review the maintenance plan every year and update the plan as needed.

ANNEX B1

## ACCURACY TESTING OF NON-MERCURY THERMOMETERS

If the manufacturer does not provide instructions for accuracy testing, the following procedures can be used as a guide. All tests should be conducted in a room with a temperature and humidity within the ambient environmental conditions specified by the manufacturer for operating the thermometers. These procedures have been adapted from several existing standards<sup>6</sup>.

### PROCEDURES FOR ACCURACY TESTING OF DIGITAL (ELECTRONIC) THERMOMETERS:

Commercially available constant temperature baths are recommended for accuracy testing. However, since these baths may be too expensive for some health facilities, a simple constant temperature bath as shown in Figure A1 could be used instead. Heat losses from the bath can be minimized by using insulation around the bath and a top cover.

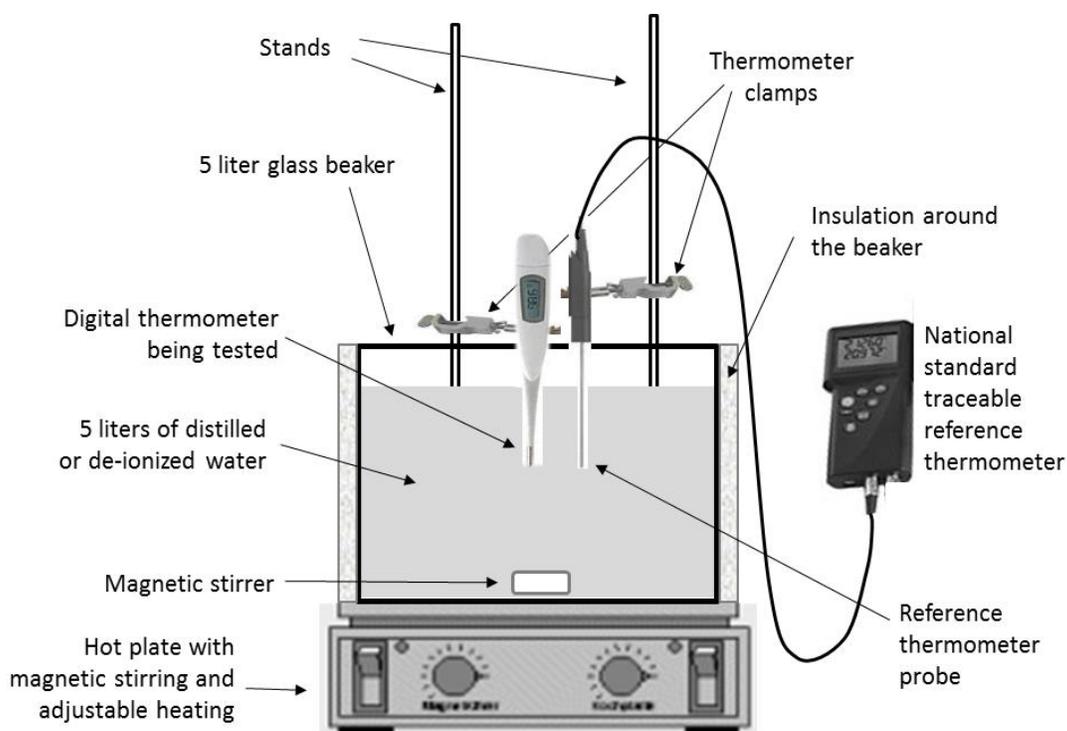


Figure A1. Simple constant temperature bath set-up for digital thermometers

<sup>6</sup> “Standard Operating Procedure for Calibration of Thermometers,” U.S. Environmental Protection Agency, SOP No. EQ-02-04, EPA/OPP Microbiology Laboratory, Ft. Mead, MD, February 21, 2008 (revised); “Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device,” European Standard EN 12470-3:2000+A1, June 2009; “Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature,” ASTM E1112 – 00, Reapproved 2006; “Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement,” International Standard ISO 80601-2-56:2009(E), 1 October 2009.

1. Prepare a well-stirred constant-temperature bath with a capacity of at least 5 liters. Fill the container to capacity with distilled or de-ionized water. Heat the bath gradually to the lowest temperature of the measuring range. Verify the temperature of the bath with a reference thermometer calibrated within 0.03°C on the International Temperature Scale traceable to a national standard laboratory.
2. Upon reaching the desired temperature, monitor the temperature of the bath for several minutes to make sure the bath is in thermal equilibrium.
3. Insert the digital thermometer to be tested as near as possible to the reference thermometer. Make sure there is adequate space for water to flow between them. More than one thermometer can be tested at a time. Make sure that all devices are immersed to the proper depths according to manufacturers' instructions. Note: If the thermometer uses a disposable probe cover or sheath, be sure to place a probe cover or sheath on the test thermometer before inserting in the water bath.
4. Conduct the tests at three points within the practical temperature range of the device, such as at 36, 38, and 40°C. Record measurements when the thermometer has reached thermal equilibrium with the water bath or for the time period specified by the manufacturer.
5. Calculate the error for each individual temperature using the equation  $\text{Error} = (\text{Test thermometer reading}) - (\text{Reference thermometer reading})$ . Note that the error can be positive or negative. For example:

$$\text{Error} = -0.2\text{ }^{\circ}\text{C} = 35.8\text{ }^{\circ}\text{C} - 36.0\text{ }^{\circ}\text{C}$$

6. Compare the maximum error for the measuring range with that of the two standards shown below in Tables A1 and A2 to determine if the digital thermometer meets the required accuracy. The maximum permissible error is the absolute value, i.e., regardless of the plus or minus sign.
7. The tests can be conducted three times to test for repeatability.
8. Keep a record of the test, including: serial number or identification number of the thermometer; date of testing; type of reference thermometer used; for each test temperature, the test thermometer reading, reference thermometer reading, and calculated error; action taken if any; and name of service personnel

Table A1. European standard EN 12470-3:2000+A1:2009:

Parameter	Summary of the Specification	Test Procedure
Maximum permissible error over the specified temperature range	0.1°C Measuring temperature range: 35.5°C – 42.0°C Ambient temperature range: 18°C to 28°C	Method in 7.3 of EN 12470-3:2000
	0.2°C Outside the above measuring range or ambient temperature range	

Table A2. ASTM E1112-00 (reapproved 2006):

Parameter	Summary of the Specification	Test Procedure
Maximum permissible error over the specified temperature range	±0.3°C Measuring temperature range: <35.8°C Ambient temperature range: See below	Method in 5.4 of ASTM E1112-00
	±0.2°C Measuring temperature range: 35.8°C to <37°C Ambient temperature range: See below	
	±0.1°C Measuring temperature range: 37°C to 39°C Ambient temperature range: See below	
	±0.2°C Measuring temperature range: >39°C to 41°C Ambient temperature range: See below	
	±0.3°C Measuring temperature range: >41°C Ambient temperature range: See below	

**PROCEDURES FOR LABORATORY ACCURACY TESTING OF TEMPORAL, TYMPANIC OR COMBINED INFRARED (IR) THERMOMETERS:**

Infrared thermometers require a stable, high emissivity, high precision thermal imaging blackbody traceable to a national standard body for accuracy testing. The thermal imaging blackbody must operate in the measuring range with an overall uncertainty of ±0.2°C or less. EN 12470-5 requires that the radiance temperature of the blackbody is calibrated with an uncertainty not greater than 0.07°C, while ASTM E1965 requires that the uncertainty of the blackbody temperature is not greater than ±0.3°C.

A typical blackbody has a conical cavity, a cylindrical cavity with an inclined flat bottom, or a spherical cavity. The inner surfaces of the cavity are blackened to achieve an emissivity of 0.95 or greater (emissivity is a measure of the ability of a material to emit energy by blackbody radiation). The cavity is heated uniformly usually by a temperature-controlled liquid bath or by Peltier elements (thermoelectric heating/cooling). Blackbody devices used for testing and calibration have a platinum resistance thermometer traceable to a national standard body. The blackbody should have a high temperature uniformity and temperature stability.

IR thermometers may have an adjusted mode. In the adjusted mode, the displayed temperature of the IR thermometer is based on a calculated value that accounts for variations in ambient temperature, emissivity, site of measurement, etc. It is important to note that laboratory accuracy testing should be done in the unadjusted mode. If the IR thermometer cannot be operated in the unadjusted mode, a correction method has to be applied to the calculated unadjusted temperatures from the adjusted mode readings. The correction method has to be obtained from the manufacturer. The equation for calculating the error makes use of the test thermometer reading in the unadjusted mode.

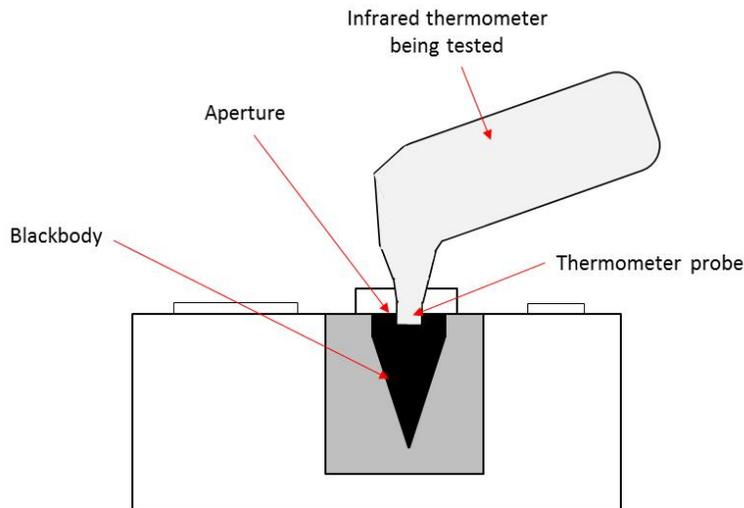


Figure A2. Typical set-up for testing IR thermometers

Portable and desktop thermal imaging blackbodies are commercially available. Some are designed for testing at one temperature (for single-point verification). For accuracy testing, a blackbody with adjustable reference temperature settings, accurate within the narrow measuring range of clinical infrared thermometers, should be used. Some infrared thermometer manufacturers offer portable blackbodies for use with their own thermometers.

1. Turn on the blackbody and allow it to warm up and stabilize according to the manufacturer's instructions. Set the first test temperature at the low end of the measuring range. (It is generally easier to test going from low to high temperatures.) Allow the temperature to stabilize.
2. Check to make sure the probe lens or window of the IR thermometer being tested is clean. For tympanic IR thermometers designed to be used with a detachable probe cover, be sure to attach the probe cover before testing. For combined IR thermometers, conduct the test with and without a probe cover.
3. Test the IR thermometer following the instructions of the blackbody manufacturer.
  - In most blackbody devices, testing entails inserting the probe of the IR thermometer into the blackbody aperture or opening and taking a reading.
  - In some blackbody devices, testing requires inserting the reference thermometer into the aperture first, recording the reading of the reference thermometer, removing the reference thermometer and inserting the test IR thermometer, and recording the reading of the reference thermometer.
  - In some blackbody devices, the measurement of the reference thermometer is already displayed so after the test thermometer is inserted into the aperture, both the readings of the test and reference thermometers are recorded.
4. Conduct the tests at three temperature points within the practical measuring range of the device, preferably at 35, 37, and 41°C for tympanic IR thermometers, and at 23, 30 and 38°C for temporal IR thermometers. Be sure to allow the blackbody temperature to stabilize before taking measurements. For tympanic and combined IR thermometers, use a new disposable probe cover for each temperature reading. Record measurements as noted above.
5. Calculate the error for each individual temperature using the equation  $\text{Error} = (\text{Test thermometer reading}) - (\text{Reference thermometer reading})$ . Note that the test

thermometer reading must be in the unadjusted mode and the error can be positive or negative. For example:

$$\text{Error} = -0.2\text{ }^{\circ}\text{C} = 35.8\text{ }^{\circ}\text{C} - 36.0\text{ }^{\circ}\text{C}$$

6. Compare the maximum error for the measuring range with that of the standards shown below in Tables A3 and A4 to determine if the IR thermometer meets the required accuracy. The maximum permissible error is the absolute value, i.e., regardless of the plus or minus sign.
7. Keep a record of the test, including: serial number or identification number of the thermometer; date of testing; name of blackbody device used; for each test temperature, the test thermometer reading, reference thermometer reading, and calculated error; action taken if any; and name of service personnel.

Table A3. ASTM E1865-98 (reapproved 2009) for temporal IR thermometers

Parameter	Summary of the Specification	Section
Maximum permissible laboratory error for given blackbody temperature range	0.3°C	5.4 (see test method in 6.1.5)
Minimum measuring range	22 to 40.0°C	5.2

Table A4. European standard EN 12470-5:2003 for tympanic IR thermometers:

Parameter	Summary of the Specification	Test Procedure
Maximum permissible error over the specified temperature range	±0.2°C      Measuring temperature range: 35.5°C – 42.0°C Ambient temperature range: 18°C to 28°C	Method in 7.4 and 7.5 of EN 12470-5:2003
	±0.3°C      Outside the above measuring range or ambient temperature range	
Minimum measuring range	35.5°C – 40.0°C	Method in 7.3 of EN 12470-5:2003
Maximum permissible clinical repeatability	±0.3°C for every patient age group (newborn, children, adults) for which the infrared ear thermometer is intended for use	Method in 7.7 of EN 12470-5:2003

ASTM E1965-98 (reapproved 2009) for tympanic IR thermometers:

Parameter	Summary of the Specification	Section
Maximum permissible laboratory error for given blackbody temperature range	0.3°C      < 36°C	5.3 (see test method in 6.1.4)
	0.2°C      36°C – 39°C	
	0.3°C      > 39°C	
Minimum measuring range	34.4 to 42.2°C unless otherwise labeled	5.2
Clinical accuracy	To be determined and disclosed upon request for each device model, each adjustable display mode, and for every age group intended for use	5.5.1 (see also 6.2)

## ACCURACY TESTING AND CALIBRATION OF NON-MERCURY SPHYGMOMANOMETERS

The traditional method to measure blood pressure is auscultation (listening to internal body sounds) of the Korotkoff sounds using a mercury sphygmomanometer. The mercury column manometer (including its placement, angle, clarity of markings and scale resolution) is only one potential source of error in blood pressure measurements. Other sources of error relate to:

- User error (including wrong placement of the cuff, poor arm positioning, inappropriate air pressure deflation rate, inadequate patient rest period, wrong placement of the stethoscope disc or cup, clothing obstruction on the arm);
- Observer bias (including prejudicial influence by what the observer wants the blood pressure to be, uncertainty in hearing the auscultatory gap for systolic pressure and the Korotkoff phase IV versus phase V for diastolic pressure, visual acuity in reading the meniscus, terminal digit preference when rounding off);
- Problems with associated pieces of equipment (including wrong cuff size, leaks in the tubing);
- Patients' clinical conditions that result in inter-observer variability (including atrial fibrillation, pre-eclampsia); or
- White coat hypertension (the tendency for a patient's blood pressure to increase in a clinical setting compared to measurements made at home).

Laboratory accuracy testing is used to check the accuracy of the pressure indicating device, whether it is a mercury column, aneroid gauge, or digital display. In the lab, the aneroid gauge or digital display can be measured against and calibrated to a reference manometer, such as an electronic manometer with a high accuracy of  $\pm 0.1$  mmHg (compared to a well-maintained mercury sphygmomanometer with rated accuracies of only  $\pm 3$  mmHg). But after the accuracy of the pressure indicating device has been tested and adjusted, the accuracy of blood pressure measurements in clinical and general practice will still depend on technique, observer bias, patients' conditions, and the other sources of error described above.

This section presents procedures for laboratory testing of auscultative sphygmomanometers including aneroid mechanical dial and face gauges, shock-resistant gearless gauges, digital auscultative sphygmomanometers, and automated or semi-automated electronic sphygmomanometers with an auscultative or calibration check mode.

Automated electronic sphygmomanometers using oscillometric techniques, some of which are designed for the arm, wrist or finger, are difficult to test for accuracy in a laboratory. Oscillometric sphygmomanometers measure the oscillations caused by arterial pressure as the arterial walls expand and contract against the cuff. The pressure transducer in the cuff or electronic unit generates electrical signals. Oscillometric sphygmomanometers use algorithms that determine pulse and maximum amplitudes or analyze dynamic waveforms to calculate systolic and diastolic pressures. Some electronic sphygmomanometers also employ an infrasound method to detect low frequency and sub-audible Korotkoff vibrations. Others have a sound sensor and integrate a digital Korotkoff sound analysis in their algorithms. For these types of sphygmomanometers, a clinical accuracy test is appropriate. However, clinical accuracy validation protocols are involved and time-consuming (see Annex B) but screening-type tests may be possible as described at the end of this section.

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**PROCEDURES FOR LABORATORY ACCURACY TESTING AND CALIBRATING ANEROID (MECHANICAL GAUGE) SPHYGMOMANOMETERS**

Figure A3 below shows common aneroid sphygmomanometers:

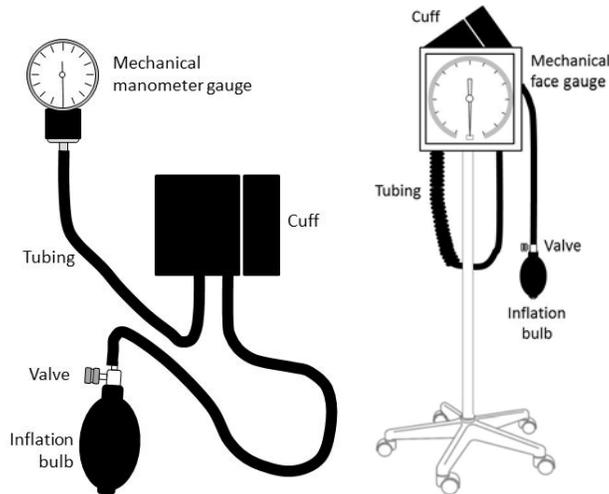


Figure A3. Parts of Common Aneroid Sphygmomanometers

The procedures in this section are adapted from existing laboratory accuracy test protocols.<sup>7</sup>

To test the accuracy of an aneroid pressure gauge, the following devices are needed:

- A reference manometer (preferably an electronic manometer traceable to a national standard)
- One or two “Y” or tee connectors with tubing and Luer fittings
- An inflation bulb with valve or an adjustable manual syringe pump

Some test set-ups recommend using the cuff placed around a cylinder or adding a 500 cc volume vessel (e.g., metal container) to allow the tester to increase pressure gradually and avoid suddenly exceeding the maximum gauge pressure.

Some test set-ups suggest using a mercury sphygmomanometer as the reference manometer but as explained above, mercury sphygmomanometers may themselves be inaccurate. A well-maintained mercury sphygmomanometer has a rated accuracy of  $\pm 3$  mmHg, whereas typical reference electronic manometers have accuracies in the order of  $\pm 0.1$  mmHg to around  $\pm 1$  mmHg traceable to a national standard. These reference electronic manometers with high accuracies and an operating range of at least 0 to 300 mmHg are commercially available.

Figure A4 below gives examples of various accuracy test set-ups for aneroid sphygmomanometer gauges.

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<sup>7</sup> Section 7.1 of “Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measuring type.” ANSI/AAMI/ISO 81060-1:2007; Annex A.2. of “Non-invasive automated sphygmomanometers.” International Recommendation OIML R 16-2, Edition 2002 (E); and calibration instructions in the users manuals of various sphygmomanometers.

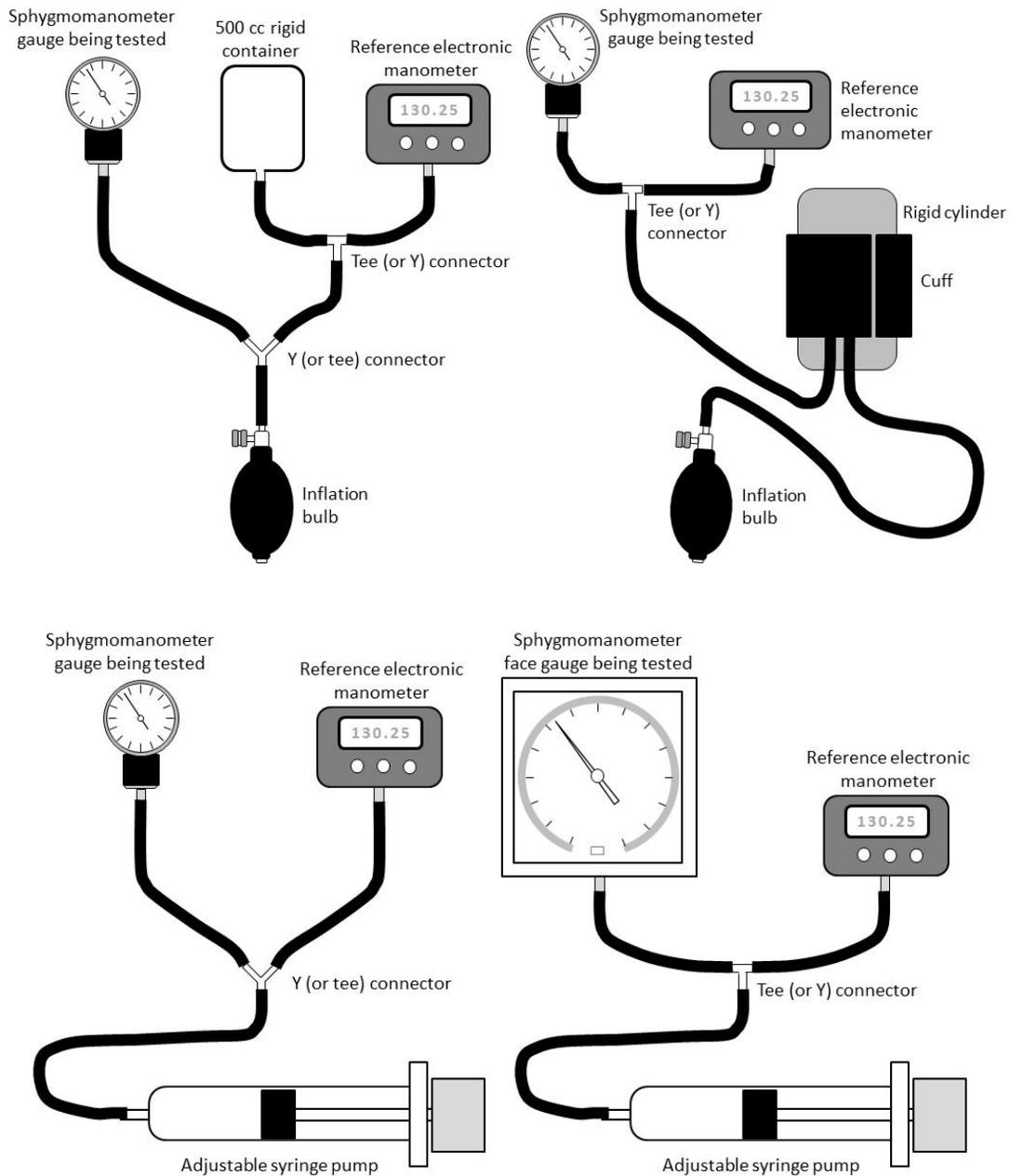


Figure A4. Laboratory Accuracy Test Set-Up for Aneroid Sphygmomanometers

1. Connect the pressure gauge being tested to the reference manometer using plastic Y or tee connectors and plastic or rubber tubing to an inflation bulb or adjustable syringe pump as shown in the figures above. Adding a 500 cc vessel (hard plastic or metal container) or using the cuff wrapped around a rigid cylinder (about 10 cm diameter) is recommended if an adjustable manual syringe pump is not used.
2. Make sure the pointer is at zero when no pressure is applied before beginning the test. Adjust the pointer if necessary.

3. Using the inflation bulb or syringe pump, pressurize the gauge to about 280 mmHg and close the valve. Observe if the pressure is stable. If not, check the set-up for air leaks.
4. If the pressure is stable, increase the pressure to slightly above 300 mmHg and release the pressure no faster than 10 mmHg per second.
5. Stop the pressure release no less than every 50 mmHg. Record both the reading of the gauge being tested and the reference manometer reading. For example, readings can be taken at 300, 250, 200, 160, 120, 100, 80, 60, 40, and 0 mmHg. At a minimum, take readings at 300, 250, 200, 150, 100, 60, and 0 mmHg. Check to make sure the pointer returns to the zero mark.
6. Compare the gauge readings with the correct value indicated by the reference manometer. If the gauge is accurate to within  $\pm 3$  mmHg, the aneroid sphygmomanometer is within the required accuracy and acceptable for clinical use.
7. If one or more of the readings exceeds  $\pm 3$  mmHg, determine if the error is linear or non-linear. A linear error is when the readings are at a consistent value above or below the correct reading. A non-linear error is when the readings deviate by different amounts. Examples are given below. It is important to find out if the error is linear or non-linear since the method of re-calibrating the instrument depends on the type of error.

Example of a Linear Error		
Reference manometer reading	Reading of aneroid gauge being tested	Difference
40	46	+ 6
60	66	+ 6
80	86	+ 6
100	106	+ 6
120	126	+ 6
160	166	+ 6
200	206	+ 6
250	256	+ 6
300	306	+ 6

Example of a Non-Linear Error		
Reference manometer reading	Reading of aneroid gauge being tested	Difference
40	31	-9
60	54	-6
80	77	-3
100	100	0
120	123	3
160	166	6
200	203	3
250	251	1
300	298	-2

8. Follow the manufacturer's instructions to re-calibrate the instrument. Below are examples of typical re-calibration procedures for aneroid gauge dials to give an idea of what is entailed:
  - a. Example 1: Remove the retaining ring and glass from the gauge. Carefully remove the needle and dial face to reveal the bellows. Locate the concave triangle with a pin at its center. To fix a linear error, move the pin toward the sides of the triangle, right or left. To fix a non-linear error, move the pin linearly within the triangle, up or down using very small adjustments. Replace the dial face, needle, glass and retaining ring. Repeat the accuracy test above to see if the accuracy is within  $\pm 3$  mmHg compared to the reference manometer. Repeat the adjustments until the required accuracy is achieved.
  - b. Example 2: Remove the glass, pointer, and dial until you see the triangle with concave sides, on one side of which is a pin. To correct a linear error, bend the pin very slightly along the line of the triangle side. To correct a non-linear error, bend the pin very slightly away or towards the triangle. Replace the dial face, needle, and glass. Repeat the accuracy test above to see if the accuracy is within  $\pm 3$  mmHg compared to the reference manometer. Repeat the adjustments until the required accuracy is achieved.

- c. Example 3: Unscrew the bezel and remove the crystal, pointer, and dial. Place a test dial and test pointer on the pinion and connect the gauge to the test set-up. Apply 320 mmHg pressure to the gauge and then release pressure to 300 mmHg. Place the manufacturer supplied calibration tool into the radius plate slot. If the reading is less than 300 mmHg, rotate the tool counter-clockwise until the gauge reaches 300. If the reading is greater than 300 mmHg, rotate the tool clockwise until the gauge reaches 300. Release the pressure and test for the zero point. Rotate the dial if the pointer is off the zero mark. Repeat the test at 300 mmHg until the span is set. Replace the crystal and bezel and repeat the calibration test at different pressure intervals to ensure that the required accuracy is achieved.

#### **PROCEDURES FOR LABORATORY ACCURACY TESTING AND CALIBRATING ELECTRONIC (DIGITAL, AUTOMATED OR SEMI-AUTOMATED) SPHYGMOMANOMETERS WITH AUSCULTATIVE OR CALIBRATION CHECK MODES**

Some electronic sphygmomanometers cannot be tested or calibrated by the user but have to be sent to the manufacturer or an approved service center.

The procedures below are for electronic sphygmomanometers that have a calibration check or test mode where the pressure can be set manually or provided by an external source. This test can compare the readings from the device against a reference manometer.

To test the accuracy of an electronic monitor, the following devices are needed:

- A reference manometer (preferably an electronic manometer traceable to a national standard)
- One or two “Y” or tee connectors with tubing and Luer fittings
- An inflation bulb with valve or an adjustable manual syringe pump, unless the pressure can be manually selected

Some test set-ups recommend using the cuff placed around a cylinder or adding a 500 cc volume vessel to allow the tester to increase pressure gradually and avoid suddenly exceeding the maximum gauge pressure.

Some test set-ups suggest using a mercury sphygmomanometer as the reference manometer but as explained above, mercury sphygmomanometers may themselves be inaccurate. A well-maintained mercury sphygmomanometer has a rated accuracy of  $\pm 3$  mmHg, whereas typical reference electronic manometers have accuracies in the order of  $\pm 0.1$  mmHg to around  $\pm 1$  mmHg traceable to a national standard. These reference electronic manometers with high accuracies and an operating range of at least 0 to 300 mmHg are commercially available.

Figure A5 below gives an example of an accuracy test set-up for a digital auscultatory sphygmomanometer in calibration check or test mode. The procedures for digital auscultatory sphygmomanometers that use inflation bulbs as shown below are similar to the procedures for mechanical aneroid sphygmomanometers in the previous section.

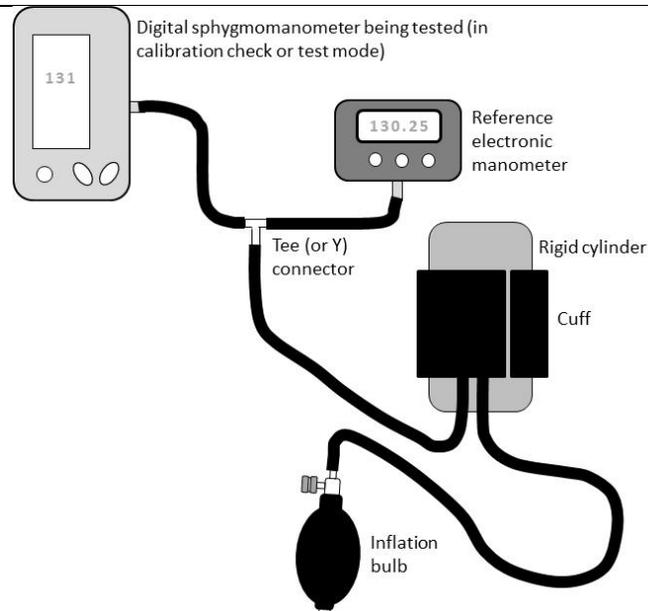


Figure A5. Laboratory Accuracy Test Set-Up for Digital Sphygmomanometers

The set-up shown in Figure A6 below can be used for some electronic sphygmomanometers that have an auscultative mode.

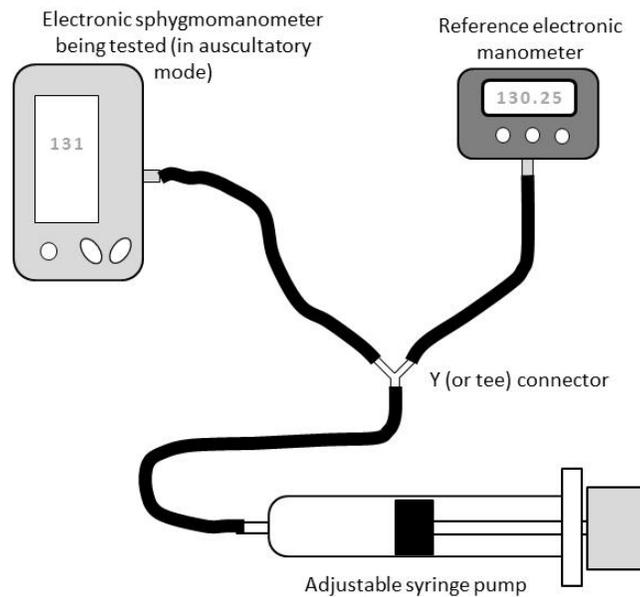


Figure A6. Laboratory Accuracy Test Set-Up for Some Electronic Sphygmomanometers

A typical procedure for some electronic sphygmomanometers with auscultative modes entails:

- Temporarily sealing the pressure release hole usually at the back or side of the unit.
- After the electronic sphygmomanometer is turned on and placed in auscultatory mode, the unit is allowed to pressurize until it stops.
- Using the adjustable syringe pump, the pressure is then adjusted to the 300 or 280 mmHg ( $\pm$  2 mmHg) using the readings of the reference manometer.
- The readings of the electronic sphygmomanometer are then recorded.

- The procedure is repeated every 20 mmHg decrements down to 20 mmHg following the readings of the reference manometer.

### **CLINICAL ACCURACY TESTING OF ELECTRONIC (OSCILLOMETRIC) SPHYGMOMANOMETERS**

The section on Validation of Non-Mercury Sphygmomanometers in Annex B describes clinical accuracy testing protocols by the European Society of Hypertension (ESH) and the American Association for the Advancement of Medical Instrumentation (AAMI).

These procedures are time-consuming for use as a periodic accuracy test of existing sphygmomanometers in a health facility. The ESH International Protocol requires at least 33 subjects with nine sequential blood pressure measurements conducted on each subject by two trained observers using a reference sphygmomanometer and a third observer recording the readings of the device being tested. The AAMI protocol requires 85 subjects with three simultaneous or sequential blood pressure measurements conducted on each subject by two trained observers using a reference sphygmomanometer and the device being tested. These test procedures would be too cumbersome to use every six months for all of a health facility's electronic sphygmomanometers that cannot be tested using the laboratory accuracy test procedures described above.

Four other less cumbersome options for screening sphygmomanometers and determining which ones should be sent back to the manufacturer for further testing and adjustment are described below.

One option is to modify one of the existing protocols for sequential measurements by reducing the number of subjects and/or measurements. Note that the requirement of 85 subjects in the AAMI protocol was based on a 98% confidence interval ( $\alpha = 0.02$ ) and a statistical power of 95% ( $\beta = 0.05$ ) assuming a normal distribution. The sample size of 85 was also determined from the statistics for a t-distribution with a 95% confidence interval and 98% statistical power.

A second option is to use a modified version of the phase 1 assessment procedure proposed by ESH's Working Group on Blood Pressure Monitoring in the 2002 International Protocol<sup>8</sup>. Phase 1 involved taking 15 subjects and measuring their blood pressures as describe in Annex B, calculating the differences between the test device and reference manometer as described in the protocol, and determining how many measurements fall within 5 mmHg, 10 mmHg and 15 mmHg. The Pass/Fail criteria is shown below:

Out of 45 pairs of measurements			
	Number of pairs of measurements in which the difference between test device and observers is $\leq 5$ mmHg	Number of pairs of measurements in which the difference between test device and observers is $\leq 10$ mmHg	Number of pairs of measurements in which the difference between test device and observers is $\leq 15$ mmHg
Need one of these to pass →	25	35	40

<sup>8</sup> E O'Brien *et al.* Working Group on Blood Pressure Monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults. *Blood Pressure Monitoring* 2002; 7(1): 3-17.

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A third option is to use a modified version of a method proposed by the Japan ISO Working Group for a sphygmomanometer standard<sup>9</sup>. They suggested four simultaneous measurements between the reference manometer and test device using both arms, switching sides each time, and changing the order of measurement between reference and test devices with every subject. Compensation for lateral blood pressure differences between the two arms is done by averaging the four readings (the two reference and two test readings in each arm). They reported that their four simultaneous measurements with both arms and alternating devices with each arm provided better reproducibility and inter-participant consistency in the error calculation than using the standard two-arm simultaneous and same-arm sequential methods.

A fourth option is based on a rapid accuracy estimation method for automatic blood pressure measuring devices proposed by Naschitz and co-workers<sup>10</sup>. In their 1999 study, they selected 15 subjects in different blood pressure range categories. Blood pressure was measured simultaneously on the left arm with a cuff connected to both the test device and reference sphygmomanometer. The readings from the test device and reference device were taken simultaneously by two trained observers who could not see each other's data. Numerous measurements were taken with each subject at rest and in standardized postural stress while the subject was secured to a tilt table with adhesive girdles. Measurements were made starting in the supine (horizontal) position, followed by tilting to a 70° head-up position with the arm supported at heart level, followed by another supine phase, etc. They used the criteria that the device was acceptable if at least 65% of readings fell within 5 mmHg, 85% within 10 mmHg, and 95% within 15 mmHg of the reference sphygmomanometer. The method by Naschitz and colleagues is a same-arm simultaneous technique but taking measurements using a tilt table at different postural challenges. This allowed them to take many paired measurements with only 15 subjects.

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<sup>9</sup> Shirasaki, O, Asou, Y and Takahashi, Y. New clinical validation method for automated sphygmomanometer: a proposal by Japan ISO-WG for sphygmomanometer standard. *Blood Pressure Monitoring* 2002; 12(6): 381-383.

<sup>10</sup> Naschitz, JE *et al.* Rapid estimation of the accuracy of automatic blood pressure measuring devices (READ). *Journal of Human Hypertension* 1999; 13(7): 443-447; Naschitz, JE *et al.* In-field validation of automatic blood pressure measuring devices. *Journal of Human Hypertension* 2000; 14(1): 37-42.

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ANNEX C

## IMPORTANCE OF VALIDATION IN THE PROCUREMENT PROCESS

**Validation** is the process of testing a device following an internationally or nationally approved test protocol and verifying that the device meets minimum standard criteria. Validation examines durability, electrical safety, readability, long-term stability, etc.. It also examines accuracy in a clinical setting. Clinical accuracy takes into account the inherent variability of what is being measured (e.g., blood pressure changing from moment to moment), the technique used by the clinician, and other factors in a clinical setting and measure clinical bias and repeatability. Unfortunately, the term “validation” has sometimes been used to mean that a device has been subjected to a validation test protocol without having necessarily passed the test.<sup>11</sup>

In this guidance, validation refers to both testing the device and confirming that it meets minimum requirements under international standards.

Reliable and up-to-date validation data provide purchasing staff and individual purchasers with evidence-based information on device accuracy and other performance criteria. The importance of validation was highlighted in a study by Akpolat *et al.*<sup>12</sup> who found a direct relationship between accuracy and validation. The researchers requested individuals to bring their home sphygmomanometers to a university hospital for testing. Of 74 automated sphygmomanometers tested, the researchers found that 68% of validated sphygmomanometers were accurate compared to only 15% of non-validated devices. Validated devices meant that the same make and model had been independently evaluated for accuracy following the International Protocol of the European Society of Hypertension, the Association for the Advancement of Medical Instrumentation, and/or the British Hypertension Society, and the make and model were reported by the dabl<sup>®</sup> Educational Trust as having passed validation testing.

## VALIDATION OF NON-MERCURY CLINICAL THERMOMETERS

Validation of digital clinical thermometers can be done in accordance with EN 12470-3:2000+A1:2009, ASTM E1112-00 (2006), and ISO 80601-2-56:2009. This section gives a general overview of the validation process for thermometers under each of the three standards.

A **reference thermometer** is needed to test accuracy of a test thermometer to within  $\pm 0.1^{\circ}\text{C}$ . The uncertainty in the temperature reading of the reference thermometer must be less than  $\pm 0.02^{\circ}\text{C}$ . Importantly, the calibration of the reference temperature must be traceable to a national standard<sup>13</sup>.

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<sup>11</sup> “Turning up the pressure: Phasing out mercury sphygmomanometers for professional use,” European Environmental Bureau, Brussels, Belgium, June 2009.

<sup>12</sup> Akpolat, T, Dilek, M, Aydogdu, T, Adibelli, Z, Erdem, D and Erdem, E. Home sphygmomanometers: validation versus accuracy. *Blood Pressure Monitoring* 2009; 14(1): 26-31.

<sup>13</sup> Examples of national standards bodies are: Instituto Nacional de Tecnología Industrial (Argentina), National Institute of Metrology (China), National Physical Laboratory of India, National Institute for Standards (Egypt), Laboratoire National de Métrologie et d'Essais (France), Physikalisch-Technische Bundesanstalt (Germany), National Metrology Institute of Japan, Latvian Metrology Bureau, National Metrology Laboratory of the Philippines, Federal Institute of Metrology (Switzerland), National Physical Laboratory (United Kingdom), National Institute of Standards and Technology (United States), Vietnam Metrology Institute - Directorate for Standards and Quality, and the World Meteorological Organization.

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Reference thermometers are generally platinum resistance thermometers (PRTs). Standard platinum resistance thermometers have accuracies as high as 0.0001°C but are expensive and susceptible to shock. Industrial platinum resistance thermometers have accuracies in the order of 0.02°C and are more rugged and much less expensive.

### **VALIDATION TESTS UNDER EN 12470-3**

Under EN 12470-3, tests can be done on each individual lot or on a statistically representative sampling. The test should be carried out in a room with an ambient temperature of 23°C ± 5°C with a relative humidity of 50% ± 20%. The test apparatus is comprised of a well regulated and well stirred water bath containing at least 5 liters of water and the reference thermometer. The temperature of the water bath should be controlled to have a temperature stability of better than ± 0.02°C and the temperature difference within the test space of the bath should not exceed ± 0.01°C. The EN standard requires that the thermometer provides a visual or auditory warning when the measured temperature is outside the measuring range specified by the manufacturer, typically 35.5 to 40.2°C. The standard also requires a maximum permissible error of 0.1°C within the measuring range. The test thermometer is immersed in the water bath to the depth specified by the manufacturer. At a constant temperature 0.3°C below the minimum and 0.3°C above the maximum values of the measuring range, the thermometer should give a visual or auditory warning. At a constant temperature 0.3°C above the minimum and 0.3°C below the maximum, there should be no alarm. Within the measuring range, measurements should be obtained at every full degree Celsius when the thermometer has reached thermal equilibrium or as specified by the manufacturer. The difference between the readings of the test thermometer and the reference thermometer should not exceed the maximum permissible error. This test must be performed on at least 10 thermometers to determine if there are any inhomogeneities that could result in exceeding the maximum permissible error in small sub-ranges. If there are no inhomogeneities, the subsequent tests could be done on just three equally spaced points within the measuring range.

In addition to accuracy and warnings when outside the measuring range, the full set of validation tests under EN 12470-3 include: visual inspection of the digital increment and size of numerical values, time response, effect of energy dissipation in the probe, long term stability, ambient operating range, effect of storage, effect of thermal shock, effect of humidity, electromagnetic compatibility, effect of mechanical shock, water resistance, warning when supply voltage is outside specified limits, functional safe test, electrical safety according to EN 60601-1, and inspection of information supplied by the manufacturer and markings.<sup>14</sup>

### **VALIDATION TESTS UNDER ASTM E1112**

Under ASTM E1112, the well stirred water bath must have a volume greater than 1 liter and its temperature must be accurately calibrated within 0.03°C. Tests are conducted within the measuring range to compare measurements of the test thermometer against the reference thermometer. The full set of validation tests also includes tests of accuracy under different environmental conditions, effects of storage conditions, inspection of labeling, inspection of the graduated intervals in the display, inspection of resolution and readability, battery indication, electrical safety according to UL 544, cleaning tests, and inspection of instructions provided by the manufacturer including recommended recalibration instructions.<sup>15</sup>

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<sup>14</sup> “Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device,” European Standard EN 12470-3:2000+A1, June 2009.

<sup>15</sup> “Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature,” ASTM E1112 – 00, Reapproved 2006.

## VALIDATION TESTS UNDER ISO 80601-2-56

ISO 80601-2-56, issued by the International Organization for Standardization (ISO), applies to digital clinical thermometers. Laboratory accuracy tests require a water bath with temperature stability better than  $\pm 0.02^{\circ}\text{C}$  and a temperature gradient not exceeding  $\pm 0.01^{\circ}\text{C}$ . The temperature of the bath should be measured by a reference thermometer with a total uncertainty not greater than  $0.07^{\circ}\text{C}$ . Tests are conducted in a climate chamber and the test thermometer is allowed to stabilize for a minimum of 30 minutes at the mid-range of the operating environmental conditions (i.e., the ambient temperature and humidity). Measurements of the test thermometer and the reference thermometer are recorded, and the tests are repeated at  $1^{\circ}\text{C}$  of the upper limit and  $1^{\circ}\text{C}$  of the lower limit of the rated output temperature range. The tests are again repeated at four points of the operating environmental conditions, combining the upper and lower limits of temperature and humidity. The standard also describes a test for time response; clinical accuracy validation tests; inspections and functional testing related to markings, units of measure, instructions for use, alarm conditions or no output if the temperature or ambient condition is outside the range or in case of a low voltage of the power source; and basic safety of medical electrical equipment according to IEC 60601-1.<sup>16</sup>

The ultimate goal of temperature measurement in medicine is to obtain an accurate determination of core body temperature of a patient. Laboratory accuracy—which reflects an instrument’s design, internal random fluctuations in electrical signals, electrical drift, manufacturing tolerances, etc.—is tested by comparing measurements of a temperature-controlled liquid or blackbody as taken by the test thermometer versus a reference thermometer. Clinical accuracy is based on measurements of a body site of a human subject. EN 12470-5 and ASTM E1965 also describe testing for clinical accuracy for tympanic IR thermometers. EN 12470-5 requires a maximum permissible clinical repeatability of  $\pm 0.3^{\circ}\text{C}$  for every patient age group (newborn, children, and adults) for which the infrared ear thermometer is intended for use. ASTM E1965 requires that the clinical accuracy must be disclosed upon request for each device model, each adjustable display mode, and for every age group intended for use.

**Clinical accuracy tests** measure both clinical bias with stated uncertainty, and clinical repeatability. These tests are done on three groups of subjects: infants from newborn to one year, children from greater than one year to five years, and adults greater than five years old. ASTM E1965 recommends at least 30 test subjects for each group, while EN 12470-5 requires at least 50 subjects. Both standards require both febrile and non-febrile subjects, with EN 12470-5 requiring at least 30% of subjects in each group to be febrile (temperature over  $38^{\circ}\text{C}$ ). The clinical trial is performed at an ambient temperature of  $21 \pm 3^{\circ}\text{C}$  and a relative humidity of  $50\% \pm 20\%$  under EN 12470-5. For tympanic IR thermometer tests, ASTM E1965 recommends excluding subjects with external ear inflammation, auditory canal obstructions, use of medication that affect body temperature within three hours of the test, or immunization within seven days of the test.

Under EN 12470-5, three consecutive readings are taken with the test IR thermometer on the same subject at the same body site and by the same operator. The time between readings should be between 1 and 3 minutes. The clinical repeatability  $S_R$  for each age group is calculated by

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<sup>16</sup> “Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement,” International Standard ISO 80601-2-56:2009(E), 1 October 2009.

$$S_R = \frac{1}{n} \sum_{i=1}^n \frac{R_i}{1.65}$$

(Equation 1)

where  $R_i$  is the span between the maximum and minimum readings of the three consecutive measurements of subject  $i$ , and  $n$  is the total number of subjects in the age group.

Under ASTM E1965, clinical repeatability  $S_R$  as the pooled standard deviation of all temperature deviations for all  $n$  subjects is calculated by

$$S_R = \sqrt{\frac{\sum_{i=1}^n (D_{1i}^2 + D_{2i}^2 + D_{3i}^2)}{6n}}$$

$$D_{1i} = T_{2i} - T_{1i}$$

$$D_{2i} = T_{3i} - T_{2i}$$

$$D_{3i} = T_{1i} - T_{3i}$$

(Equations 2-5)

where  $T_{1i}$ ,  $T_{2i}$ , and  $T_{3i}$  are the first, second, and third temperature readings by the same operator of the same body site of the subject  $i$ .

In addition to repeatability, both standards also require a measurement of clinical bias which reflects the difference between temperature measurements by the IR thermometer being tested and the temperatures of the subjects as measured by a reference thermometer at a reference body site. Laboratory accuracy of the reference thermometer should be validated beforehand. The test under EN 12470-5 requires three consecutive readings of the temperature with the test IR thermometer at the same body site of the same subject by the same operator, followed by one reading with the reference thermometer by the same operator, with the time between readings not less than one minute. EN 12470-5 gives the following equations for clinical bias  $\Delta T_b$  and  $\Delta T_{bi}$  the clinical bias for subject  $i$ , as well as the standard deviation  $S_b$  of the clinical bias:

$$\Delta T_b = \frac{1}{n} \sum_{i=1}^n \Delta T_{bi}$$

$$\Delta T_{bi} = \frac{1}{3} \sum_{j=1}^3 (T_{ij} - T_{Ri})$$

$$S_b = \sqrt{\frac{\sum_{i=1}^n (\Delta T_{bi})^2 - n(\Delta T_b)^2}{n-1}}$$

(Equations 6-8)

For ASTM E1965, clinical bias for each adjusted mode of operation of the IR thermometer is calculated as the root-sum-of-squares of the standard deviation of the data comparing the measurement from the test IR thermometer in a given adjusted mode versus the measurement using a reference thermometer at a selected body reference site.

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Because of the importance of validation, many vendors provide certificates of compliance or other documentation to indicate that their thermometers have been validated according to one or more of these international standards. An example of a report that provides data on validation of thermometers is the thermometer review by the Device Evaluation Service of the Medicines and Healthcare products Regulatory Agency of the UK Department of Health.<sup>17</sup>

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<sup>17</sup> Crawford, D, Greene, N and Wentworth S. “Thermometer review: UK market survey 2005,” MHRA 04144, Medicines and Healthcare products Regulatory Agency, London, UK. January 2005.

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## VALIDATION OF NON-MERCURY SPHYGMOMANOMETERS

There are several validation standards and protocols for evaluating blood pressure devices. They include the International Protocol by the European Society of Hypertension (ESH)<sup>18</sup>; ANSI/AAMI/ISO 81060-1 and -2<sup>19</sup> joint standard of the American National Standards Institute (ANSI), American Association for the Advancement of Medical Instrumentation (AAMI) and International Organization for Standardization (ISO); ANSI/AAMI/IEC 80601-2-30<sup>20</sup> joint standard of ANSI, AAMI and the International Electrotechnical Commission (IEC); European Standard EN 1060<sup>21</sup> (also adopted as British Standard BS 1060 and German Standard DIN 58130); the British Hypertension Society (BHS) protocol of 1990 (revised in 1993)<sup>22</sup>; and International Recommendation OIML R 16-2<sup>23</sup> of the International Organization of Legal Metrology (OIML). As of early 2013, IEEE P1708 and P1721 standards<sup>24</sup> were also being developed.

In the overview below, the topics covered by the ANSI/AAMI/ISO/IEC standards and the OIML recommendations are presented as examples. Clinical accuracy protocols are also compared and discussed.

The ANSI/AAMI/ISO 81060-1:2007 standard covers a range of requirements including: the units of measurement, legibility and durability of markings, markings of non-automated sphygmomanometers, usability of reading, marking of the cuff, electrical safety, mechanical safety, mechanical strength, the measuring range, error limits of the pressure indicator, requirements related to air leakage, pressure reduction rate, rate of rapid exhaust, cuff sizes, integrity of cuff and bladder, tubing connectors, tamper proofing, marking and zero for aneroid sphygmomanometers, hysteresis error (error of the measurement value when approaching it with increasing pressure versus decreasing pressure), materials of construction, ability to be cleaned and disinfected or

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<sup>18</sup> O'Brien, E *et al.* European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. *Blood Pressure Monitoring* 2010; 15(1): 23-38.

<sup>19</sup> "Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measuring type." ANSI/AAMI/ISO 81060-1:2007; "Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type." ANSI/AAMI/ISO 81060-2-2009.

<sup>20</sup> "Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers." ANSI/AAMI/IEC 80601-2-30:2009.

<sup>21</sup> "Non-invasive sphygmomanometers. General requirements." BS EN 1060-1:1995+A2:2009; "Non-invasive sphygmomanometers. Supplementary requirements for mechanical sphygmomanometers." BS EN 1060-2:1995+A1:2009; "Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems." BS EN 1060-3:1997+A2:2009; "Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers." BS EN 1060-4:2004.

<sup>22</sup> O'Brien, E *et al.* The British Hypertension Society protocol for the evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *J Ambulatory Monitoring* 1991; 4(3): 207-228; O'Brien, E *et al.* Short report: An outline of the revised British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertension* 1993; 11(6): 677-679; O'Brien, E *et al.* The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertension* 1993; 11(suppl 2): S43-S62.

<sup>23</sup> "Non-invasive automated sphygmomanometers." International Recommendation OIML R 16-2, Edition 2002 (E).

<sup>24</sup> "P1708 - Standard for Wearable Cuffless Blood Pressure Measuring Devices (draft)" and "P1721 - Standard for Objective Measurement of Systemic Arterial Blood Pressure (draft)" Institute of Electrical and Electronics Engineers, under development.

sterilized, and the instructions for use. The ANSI/AAMI/IEC 80601-2-30:2009 standard covers, among others: protection against electrical and mechanical hazards, protection against radiation hazards, protection against excessive temperatures and other hazards, accuracy of controls and instruments, protection against hazardous outputs, fault conditions, electromagnetic compatibility, maximum inflating time, automatic cycling modes, and clinical accuracy.

For automated sphygmomanometers, the OIML recommendations include: units of measurement, maximum permissible errors of the cuff pressure indication and of the overall system, performance under specific environmental conditions, requirements for the cuff and bladder, requirements for the display, effects of voltage variations, requirements related to the pneumatic system, electromagnetic compatibility, stability of cuff pressure indication, measuring range, digital scale interval, signal input and output ports, alarms, safety, metrological controls, testing and verification, sealing, marking, and information to be supplied by the manufacturer.

With regards to clinical accuracy, the International Protocol of the European Society for Hypertension requires two mercury sphygmomanometers as references, good quality stethoscopes, the test device, two trained observers and a supervisor, and at least 33 subjects of which at least 10 are male and 10 are female, all 25 years or older. In order to test the range of blood pressures, subjects should be chosen such that there are 10 to 12 subjects in each of the three systolic and three diastolic blood pressure ranges. Low systolic is  $< 130$ , medium is 130-160, and high is  $> 160$  mmHg; low diastolic is  $< 80$ , medium is 80-100, and high is  $> 100$  mmHg. The number of test measurements must be between 22 and 44 in each pressure range. The overall systolic range must be from  $\leq 100$  to  $\geq 170$  mmHg, and the overall diastolic range must be from  $\leq 50$  to  $\geq 120$  mmHg.

The subject is asked to relax for 10-15 minutes and should be seated with legs uncrossed, back supported, and test arm supported at heart level during the test. All blood pressure measurements are taken sequentially on one arm, whichever is more comfortable for the subject. Measurements are taken sequentially, starting with measurements by the observers then alternating with measurements by the test device. The first measurements (observer A, observer B and test device) are used to determine to which systolic and diastolic blood pressure ranges the subject belongs.

After the first measurements, a total of seven sequential, same-arm measurements are taken starting with the observers using the mercury sphygmomanometer (measurement 1 by observer A and B), then the test device (measurement 2), then observers A and B again (measurement 3), then the test device (measurement 4), continuing until measurement 7 (observers A and B). The period between measurements should be at least 30 seconds but no more than 60 seconds. Measurements should be recorded to the nearest 2 mmHg.

Observers must not be able to see each other's measurements and should not be able to see the test device's readings throughout the study. Both observers should record their readings simultaneously and if the supervisor sees that the observers' measurements differ by more than 4 mmHg from each other, the measurements should be taken again.

The difference between the reading of the test device and the mean reading of the two observers are calculated for each measurement. The pairs of blood pressure measurement differences are then classified into three categories ( $\leq 5$ ,  $\leq 10$ , and  $\leq 15$  mmHg). The number of differences in each category is then compared with the Pass/Fail criteria under the International Protocol. Similarly, the number of subjects with two or three of the absolute differences between observer and device measurements within 5 mmHg and the number of subjects with none of the absolute differences between observer and device measurements within 5 mmHg are compared to the Pass/Fail criteria.

Table B1. Pass/Fail Criteria of the European Society of Hypertension International Protocol 2010 for Sequential Measurement (Refer to the International Protocol for details)

Part 1 Requirement			
	Number of pairs of measurements in which the difference between test device and observers is $\leq 5$ mmHg	Number of pairs of measurements in which the difference between test device and observers is $\leq 10$ mmHg	Number of pairs of measurements in which the difference between test device and observers is $\leq 15$ mmHg
Need two of these to pass →	73	87	96
Need all of these to pass →	65	81	93
Part 2 Requirement			
	Number of subjects in which 2 or 3 of the differences between test device and observer is $\leq 5$ mmHg	Number of subjects in which none of the differences between test device and observer is $\leq 5$ mmHg	
Need all of these to pass →	At least 24	At most 3	

The ANSI/AAMI/ISO 81060-2:2009 protocol for clinical validation of automated measurement type of non-invasive sphygmomanometers requires a minimum of 85 subjects. At least three valid blood pressure determinations are taken from each subject, for a minimum of 255 valid paired blood pressure determinations. At least 30% of subjects must be male and 30% must be female. For sphygmomanometers intended for adults, the subjects must be over 12 years old. The protocol has additional requirements on limb circumferences of the subjects in relation to the range of use of the cuff. For the test to be valid, at least 5% of systolic readings must be  $\leq 100$  mmHg, 5% must be  $\geq 160$  mmHg, and 20% must be  $\geq 140$  mmHg. Furthermore, at least 5% of diastolic readings must be  $\leq 60$  mmHg, 5% must be  $\geq 100$  mmHg, and 20% must be  $\geq 85$  mmHg.

The subject should be comfortable with back, elbow and forearm supported, and with the middle of the cuff at the level of the right atrium of the heart. The subject is asked to avoid talking and to relax for 5 minutes before the first reading is taken. The trained observers are instructed to note which Korotkoff sound (fifth phase or fourth phase) they used to determine the diastolic blood pressure.

Two trained observers take simultaneous blood pressure determinations on each subject using a double stethoscope and a reference manometer reading. The reference manometer must have a maximum permissible error of  $\pm 1$  mmHg. The cuff used for the reference manometer is also connected to the test device, which is read by a third observer. The set-up is shown in Figure B1.

Each observer's recording must not be visible to the other and the reading of the test device must not be visible to either of them. The reference value of each blood pressure determination is the average of the two observers' readings. If one or more pairs of observers' readings have a difference greater than 4 mmHg, the pair of readings is excluded and additional readings are taken to obtain a maximum of eight valid pairs of determinations. The period between measurements should be at least 60 seconds.

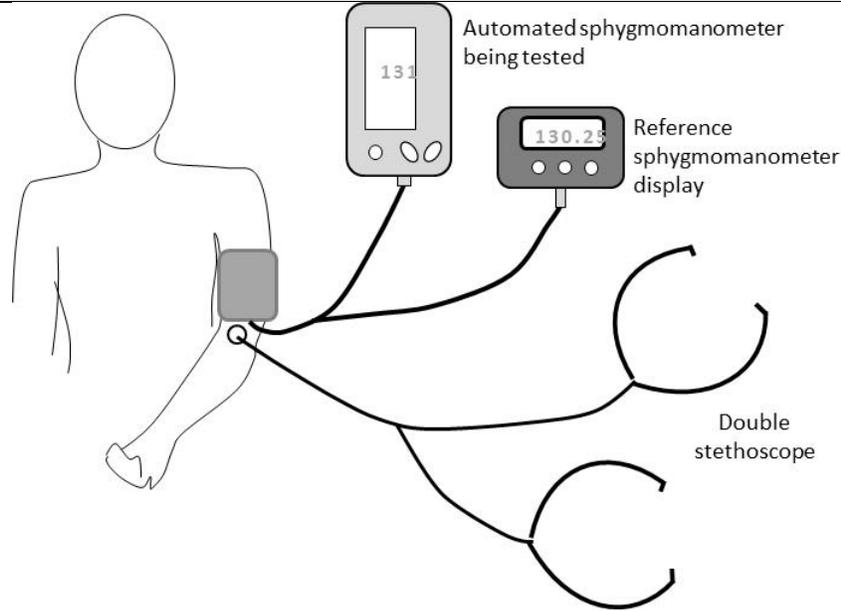


Figure B1. Set-up for the Simultaneous Method in the AAMI protocol

For a test device to pass, it must meet two criteria. Criterion 1 is based on the mean error  $\bar{x}_n$  of paired blood pressure determinations of the systolic and diastolic blood pressures for all subjects, given by the equation below:

$$\bar{x}_n = \frac{1}{n} \sum_{i=1}^n (P_{ti} - P_{ri})$$

(Equation 9)

where  $\bar{x}_n$  is the mean error over all subjects,  $P_{ti}$  is the blood pressure reading of the test device,  $P_{ri}$  is the blood pressure reading of the reference sphygmomanometer, and  $n$  is the number of determinations (equal to 255 for 85 subjects). The standard deviation  $SD_n$  of the mean error for all subjects is given by the equation:

$$SD_n = \sqrt{\frac{1}{n-1} \sum_{i=1}^n (x_i - \bar{x}_n)^2}$$

(Equation 10)

where  $x_i = (P_{ti} - P_{ri})$  of a paired blood pressure determination (i.e., paired determination using the test device and the reference sphygmomanometer).

Criterion 2 uses the mean error and standard deviation of the systolic and diastolic blood pressures of each subject. The mean error for subject  $j$  is given by:

$$x_j = \frac{1}{d} \sum_{k=1}^d (P_{tk} - P_{rk})$$

(Equation 11)

where  $x_j$  is the mean error of the determinations for subject  $j$ ,  $P_{tk}$  is the blood pressure reading of the test device,  $P_{rk}$  is the blood pressure reading of the reference sphygmomanometer, and  $d$  is the number of determinations per subject. The standard deviation  $SD_m$  of the averaged paired determinations per subject is given by:

$$SD_m = \sqrt{\frac{1}{m-1} \sum_{j=1}^m (x_j - \bar{x}_n)^2}$$

(Equation 12)

where  $\bar{x}_n$  is the mean error over all subjects given in Equation 9, where  $m$  is the number of subjects, and  $x_j$  is given in Equation 11.

The Pass/Fail criteria under the AAMI protocol is given in Tables B2 and B3 below. The test sphygmomanometer must meet both criteria in order to pass.

Table B2. Pass/Fail Criterion 1 of the AAMI Protocol (See AAMI protocol for details)

Criterion 1 (for at least 255 paired measurements)			
	Mean error $\bar{x}_n$		Standard deviation $SD_n$
Needed to pass →	≤ 5 mmHg	and	≤ 8 mmHg

Table B3. Pass/Fail Criterion 2 of the AAMI Protocol (See AAMI protocol for details) - maximum permissible standard deviation  $SD_m$  as a function of mean error  $\bar{x}_n$

$\bar{x}_n$	maximum permissible standard deviation $SD_m$ as a function of mean error $\bar{x}_n$ mmHg									
	0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
± 0.	6.95	6.95	6.95	6.95	6.93	6.92	6.91	6.90	6.89	6.88
± 1.	6.87	6.86	6.84	6.82	6.80	6.78	6.76	6.73	6.71	6.68
± 2.	6.65	6.62	6.62	6.55	6.51	6.47	6.43	6.39	6.34	6.30
± 3.	6.25	6.20	6.20	6.09	6.03	5.97	5.89	5.83	5.77	5.70
± 4.	5.64	5.56	5.56	5.41	5.33	5.25	5.19	5.08	5.01	4.90
± 5.	4.79	-	-	-	-	-	-	-	-	-

For example, test sphygmomanometer with a mean error  $\bar{x}_n = 4.2$  must have a standard deviation that does not exceed 5.49 based on Table B3 to pass Criterion 2.

The AAMI protocol also has a same-arm sequential test method. Initially, the two observers determine the subject's blood pressure using the reference sphygmomanometer, wait at least 60 seconds, determine the subject's blood pressure using the test device, clear the memory of the test device (by switching the device off and on, removing the blood pressure module or using a reset command), then wait at least 60 seconds. The initial data are not used. The set-up is shown in Figure B2.

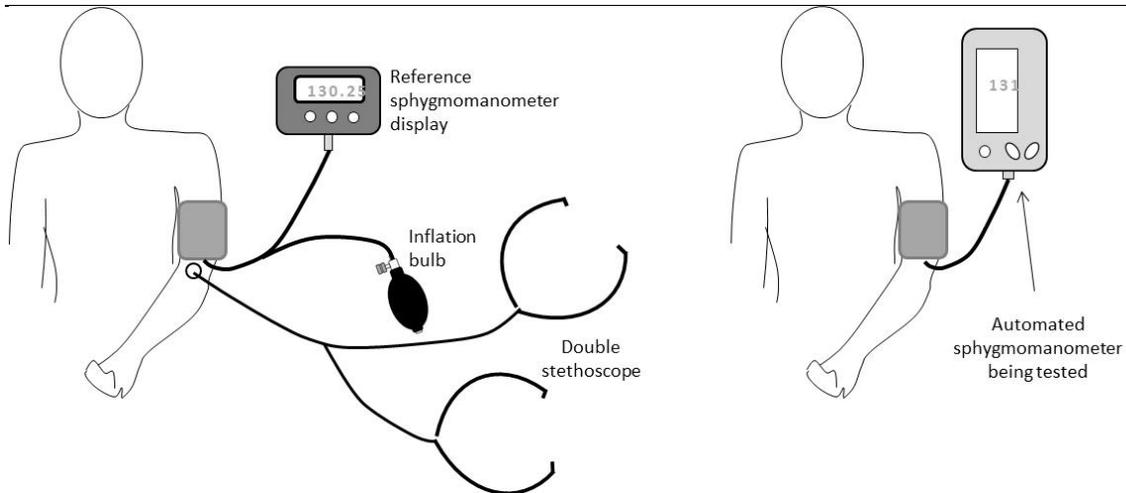


Figure B2. Set-up for the Same-Arm Sequential Method in the AAMI protocol

The starting order of determinations using the test device and reference sphygmomanometer are alternated between subjects or randomized. The two observers determine the subject's blood pressure sequentially and alternately using the reference sphygmomanometer and test device with a wait period of at least 60 seconds between determinations. The process is repeated until the needed number of determinations is reached. All data from a subject is rejected if any two reference systolic blood pressure determinations differ by more than 12 mmHg or if any two reference diastolic blood pressure determinations differ by more than 8 mmHg. Note that the reference sphygmomanometer determination should not be the average of preceding and following blood pressure determinations. The same equations 9-12 and the Pass/Fail criteria in Tables B2 and B3 are used for the same-arm sequential method.

The AAMI protocol also includes an opposite arm method that uses a different set of equations accounting for lateral difference. Validation protocols with reference invasive blood pressure monitoring equipment are also given.

A not-for-profit institution that has evaluated and validated many sphygmomanometers using BHS, AAMI and the International Protocol is the dabl Educational Trust Limited<sup>25</sup>. Other resources include the British Hypertension Society which maintains a database of validated devices for clinical and home use<sup>26</sup>, the French National Agency for the Safety of Medicines and Health Products (L'Agence nationale de sécurité du médicament et des produits de santé or ANSM)<sup>27</sup> in collaboration with the French Arterial Hypertension Society, a Health Care Without Harm Europe and Health and Environment Alliance report "Substituting mercury sphygmomanometers"<sup>28</sup> (October 2006) which includes a list from the British Hypertension Society, the KEMI-Swedish Chemical Inspectorate report on "Mercury-free blood pressure measurement equipment-Experiences in the Swedish healthcare sector"<sup>29</sup> (November 2005), and Sustainable Hospitals<sup>30</sup>.

<sup>25</sup> <http://www.dableducational.org/sphygmomanometers.html>

<sup>26</sup> <http://www.bhsoc.org//index.php?cID=247> and <http://www.bhsoc.org//index.php?cID=246>

<sup>27</sup> [http://ansm.sante.fr/Dossiers-thematiques/Appareils-d-automesure-tensionnelle/Appareils-electroniques-d-automesure-tensionnelle/\(offset\)/0](http://ansm.sante.fr/Dossiers-thematiques/Appareils-d-automesure-tensionnelle/Appareils-electroniques-d-automesure-tensionnelle/(offset)/0)

<sup>28</sup> Available at <http://www.env-health.org/IMG/pdf/Sphygmo.pdf>

<sup>29</sup> Available at [http://www.who.int/ifcs/documents/forums/forum5/pm7\\_05.pdf](http://www.who.int/ifcs/documents/forums/forum5/pm7_05.pdf)

<sup>30</sup> [http://www.sustainablehospitals.org/cgi-bin/DB\\_Report.cgi?px=W&rpt=Cat&id=14](http://www.sustainablehospitals.org/cgi-bin/DB_Report.cgi?px=W&rpt=Cat&id=14)