American National Standard

ANSI/AAMI SP10:2002/(R)2008
& ANSI/AAMI SP10:2002/A1:2003/(R)2008
& ANSI/AAMI SP10:2002/A2:2006/(R)2008

Manual, electronic, or automated sphygmomanometers

Association for the Advancement of Medical Instrumentation

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ANSI/AAMI SP10:2002/(R)2008
& ANSI/AAMI SP10:2002/A1:2003/(R)2008
& ANSI/AAMI SP10:2002/A2:2006/(R)2008
(Revision of ANSI/AAMI SP9:1994;
ANSI/AAMI SP10:1992; and
ANSI/AAMI SP10:1992/A1:1996)

Manual, electronic, or automated sphygmomanometers

Developed by
Association for the Advancement of Medical Instrumentation

Approved 28 October 2002 and reaffirmed 5 December 2008 by
American National Standards Institute, Inc.

Abstract: This standard establishes labeling, safety, and performance requirements for sphygmomanometers, including electronic, electromechanical, and nonautomated devices that are used in the indirect measurement of blood pressure. Ambulatory blood pressure monitors, which are portable, lightweight, automated devices worn or carried by the patient that are able to obtain and store the results of repeated determinations of blood pressure and heart rate during activities of ordinary daily living, also are included in the scope of this document.

Keywords: blood pressure, electromedical equipment, heart rate, sphygmomanometer

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International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by international designation.)

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IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical

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ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:200x*	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161: 2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2002	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
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Committee representation

Association for the Advancement of Medical Instrumentation

Sphygmomanometer Committee

This standard was developed by the Sphygmomanometer Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Sphygmomanometer Committee** had the following members:

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In Memoriam

The AAMI Sphygmomanometer Committee would like to gratefully acknowledge the late Myron L. (Mike) Cohen, PhD, of CAS Medical Systems, whose input and leadership contributed to the writing of this document. Dr. Cohen was responsible for coordinating the early drafting of this document and served as the industry cochair of the committee until the time of the document's first ballot.

Mike Cohen personified dignity and integrity. He always chose the right way to do things, rather than the easy way. His work on the AAMI committee included several trips abroad to try to harmonize U.S. and European standards in order to make the standards more useful for both clinicians and manufacturers. Those who worked with Mike will miss his leadership. Mike was a true Renaissance man who loved opera and baseball, dining and fishing, and, most of all, his wife Sally, his children, and his grandchildren.

Acknowledgements

The AAMI Sphygmomanometer Committee thanks Alan Berson, PhD, formerly of the National Heart, Lung, and Blood Institute, for his contributions as former cochair of the committee. The committee also thanks the following people for their contributions in drafting and reviewing this standard: Rosalie Dunn, PhD, and Michael Proschan, PhD, of the National Heart, Lung, and Blood Institute; Charles D. Ehrlich of the National Institute of Standards and Technology; Terrence M. O'Brien of Omron Healthcare, Inc.; Eoin O'Brien, MD, and Neil Atkins, PhD, of Beaumont Hospital in Ireland; and Joydeb K. Roy of the U.S. Food and Drug Administration.

The committee would especially like to thank Bruce Friedman, D.Eng, of G.E. Medical Systems for taking on the role of interim cochair during the absence of Myron Cohen, PhD. Dr. Friedman is responsible for taking the document from the ballot stage to finalization.

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Foreword

This standard was developed by the AAMI Sphygmomanometer Committee. The objective of this standard is to provide labeling, safety, and performance requirements that will help ensure that consumers and health care professionals are supplied with safe, accurate devices for the indirect measurement of blood pressure. It is hoped that the provisions of this standard will contribute positively to the accuracy of noninvasive blood pressure measurements of all subjects and specifically to the detection and control of hypertension in the population of the United States by setting forth requirements for the labeling and performance of sphygmomanometers used in the diagnosis of the disease.

This American National Standard is the result of updating and combining the standards SP9:1994, *Nonautomated sphygmomanometers*; SP10:1992, *Electronic or automated sphygmomanometers*; and SP10:1992/A1:1996, an amendment to the 1992 standard addressing special considerations for devices intended for pediatric use. A secondary objective, as important as the primary objective, was to develop a standard similar to that standard being developed by CEN for the European Community. Our philosophy here was not to follow the CEN Standard in every minutia, but to reconcile the two standards such that if a manufacturer were to satisfy one of the standards, then that manufacturer would satisfy the other with little or no additional design effort.

Blood pressure measured within an artery generally differs from that measured indirectly by techniques that do not require intra-arterial catheters. The efficacy of an indirect blood pressure measurement device can be determined by comparing its measurements with direct intra-arterial measurements. Alternatively, the noninvasive cuff/stethoscope technique, based on Korotkoff sounds identified by an individual trained in auscultation, has been found, however, to produce results directly related to intra-arterially measured blood pressures and to be valuable for determining whether an individual has elevated blood pressure. The technique also is used with individuals who are on medication to assess how well their blood pressure is being controlled. Other indirect blood pressure measurement techniques should be at least as accurate as the cuff/stethoscope, nonautomated technique. This standard permits either validation method.

This standard is organized so that materials common to all sphygmomanometers are within the general section. Subsections are listed for material needed for manual sphygmomanometers and material needed for electronic, electromechanical, or automated sphygmomanometers, where applicable. The concepts incorporated in this document should not be considered inflexible or static. This standard, like any other, must be modified as advances are made in technology and new data becomes available. AAMI standards development procedures require that all standards be reviewed and, if necessary, updated at least once every five years.

As used within the context of this document, “shall” indicates requirements strictly to be followed in order to conform to the standard; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the recommended practice; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulations.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the American National Standard *Manual, electronic, or automated sphygmomanometers* (ANSI/AAMI SP10:2002), but it does provide important information about the development and intended use of the document.

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Manual, electronic, or automated sphygmomanometers

1 Scope

1.1 General

This standard establishes safety and performance requirements for all sphygmomanometers, whether nonautomated, automated, or electronic, that are used with an occluding cuff for the indirect determination of arterial blood pressure.

1.2 Inclusions

Included within the scope of this standard are aneroid, mercury gravity, and electronic sphygmomanometers used in conjunction with a stethoscope or other manual methods for detecting Korotkoff sounds and with any other type of display.

Also included within the scope of this standard are all devices that sense or display pulsations, flow, or sounds in connection with the measurement, display, or recording of blood pressure. These devices may or may not employ electrical means for measurement and display. These devices might or might not have an automatic cuff inflation. This standard covers neonatal or newborn through adult categories.

Ambulatory blood pressure monitors, which are portable, lightweight, automated devices worn or carried by the patient that are able to obtain and store the results of repeated determinations of blood pressure and heart rate during activities of ordinary daily living, are included in this standard.

NOTE—For an explanation of the need for this standard and the rationale for its provisions, see annex A.

1.3 Exclusions

Excluded from the scope of this standard are devices for direct, intra-arterial measurement of blood pressure. The use of automated monitors that measure blood pressure on the finger are not covered in this standard.

2 Normative references

The following documents contain provisions which, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the documents indicated below.

2.1 AMERICAN HEART ASSOCIATION. *Recommendations for human blood pressure determination by sphygmomanometers.* Dallas: American Heart Association, 1994.

2.2 AMERICAN NATIONAL STANDARDS INSTITUTE. *Voltage ratings for electric power systems and equipment (60 Hz).* ANSI C84.1-1982, 1982. American National Standard.

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Developing safe, effective, and reliable medical software.* AAMI MDS, 1991.

2.4 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment—Part 1–2: General requirements for safety—Collateral standard: Electromagnetic compatibility: Requirements and tests*, second edition. IEC 60601-1-2, 2001.

2.5 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment—Part 2: Collateral standard: Particular requirements for safety, including essential performance of automatic cycling non-invasive blood pressure monitoring equipment.* IEC 60601-2-30, 1999.

2.6 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment—Part 1: General requirements for safety.* IEC 60601-1, 1988; Amendment 1, 1991; and Amendment 2, 1995.

2.7 INTERNATIONAL SAFE TRANSIT ASSOCIATION. ISTA 2 Series, *Integrity—Plus test procedures.* 1999 rev.

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2.8 NATIONAL FIRE PROTECTION ASSOCIATION. *Standard for health care facilities.* ANSI/NFPA 99-1996, Annex 2, "Flammable Anesthetizing Locations."

3 Definitions

For the purposes of this AAMI standard, the following definitions and abbreviations apply.

3.1 adult: Individuals greater than 12 years of age.

3.2 aneroid manometer: Pressure-determining device using a mechanical indicating element or component.

3.3 auscultatory gap: Early temporary disappearance of sound that can occur during the latter part of Phase I and Phase II.

NOTE—In some subjects, particularly hypertensives, sounds heard over the brachial artery when the cuff pressure is high disappear as the pressure is reduced and then reappear at some lower level. This can cause underestimation of systolic blood pressure and, less commonly, overestimation of diastolic blood pressure.

3.4 auscultatory method: Indirect method to measure arterial blood pressure that relies on the detection of Korotkoff sounds under an occluding cuff.

3.5 automated sphygmomanometer: Instrument used for the indirect (noninvasive) measurement of arterial blood pressure that automatically inflates and deflates the cuff, and determines blood pressure from signals obtained from the cuff and/or a separate transducer.

3.6 blinded study: Validation study in which two observers independently record data from the reference device. Each observer is unaware of the reading obtained by the other observer or the test device.

3.7 calibration: Act or process of standardizing by determining the deviation of a measurement from an established standard of known accuracy (e.g., one traceable to the National Institute of Standards and Technology).

3.8 electronic manometer: Pressure-determining device using an electronic pressure transducer and electronic display mechanism.

3.9 electronic sphygmomanometer: Instrument used for the indirect (noninvasive) measurement of arterial blood pressure that automatically determines blood pressure from signals obtained from the cuff and/or a separate transducer. Cuff inflation and deflation may be controlled by the user or by the instrument.

3.10 Korotkoff sounds: Sounds heard over the artery used to determine blood pressure by the auscultatory method.

3.11 mercury gravity manometer: Pressure-determining device using a column of mercury as its indicating element.

3.12 neonatal or newborn: Individuals 28 days or less of age if born at term (37 weeks gestation or more); otherwise, up to 44 gestational weeks.

3.13 non-automated sphygmomanometer: Instrument used for the indirect (noninvasive) measurement of arterial blood pressure, which consists of a cuff, inflation bulb, and pressure-indicating device used with a stethoscope.

3.14 normal condition: Condition in which all means provided for protection against safety hazards are intact.

3.15 paired measurement: Parallel blood pressure measurement carried out by the observer and the device under test.

3.16 pediatric: Individuals between 29 days and 12 years of age.

3.17 public use sphygmomanometer: Blood pressure-measuring device that is accessible to the public and may be operated without supervision.

3.18 oscillometry: Indirect method to measure arterial blood pressure that relies on the measurement of oscillations in an occluding cuff.

3.19 outer container: Immediate or unit container of a device intended for home or other unsupervised use.

3.20 single-fault condition: Condition in which a single means for protection against a safety hazard in equipment is defective or a single abnormal condition is present.

3.21 sphygmomanometer: Instrument used for the indirect (noninvasive) measurement of arterial blood pressure.

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3.22 stethoscope: Instrument for detecting and studying sound produced by the body; in the case of blood pressure measurement, for detecting Korotkoff sounds.

3.23 true zero: Position of the aneroid pointer or mercury column meniscus when a manometer is at zero differential pressure.

3.24 automatic cycling non-invasive blood pressure monitoring equipment: Device, or part of a physiological monitoring or measuring system, including its associated accessories, which has the capability to initiate a blood pressure determination automatically.

NOTE—For definitions of *mean difference* and *standard deviation (SD)*, see annex F.

4 Requirements

4.1 Labeling requirements

4.1.1 General

Labeling refers to any printed matter that appears on the device, its accessory items, or its container(s), as well as all documentation that accompanies the device. In addition to federal regulations applicable to the labeling of all medical devices, the following requirements shall apply to devices within the scope of this standard.

4.1.2 Device and outer container labeling

4.1.2.1 Device labeling

The device itself shall display sufficient information for traceability and identification. In addition, the following information shall be displayed on devices intended for public use:

a) Precautions for use, including a statement concerning the need to consult a physician for interpretation of pressure measurements;

b) Proper instructions for operation and verification, if a zero or range control is provided;

c) Adequate operating instructions;

d) Model number of current sphygmomanometer and, if the new device's accuracy is based on a previous validation testing (4.4.5.B) and has not been submitted for validation, the previously approved model number;

e) The performance of the device relative to the accuracy requirements of this standard;

f) The limb circumference appropriate for the cuff(s) supplied with the monitor (4.1.4.4).

4.1.2.2 Outer container

For devices intended for over-the-counter sale, the outer container shall display information needed by the end user including, as a minimum, identification of the appropriate arm circumference (in centimeters [cm] and inches [in], where applicable) and operating range of the transducer or system if different from the standard range specified in 4.4 (in this case, the statement "limited range" shall be displayed). Further, any special requirements for battery-powered devices shall be displayed.

4.1.3 Information manual

An information manual shall be supplied with each device and shall contain, as a minimum:

a) Adequate instructions for use, including a section summarizing precautions for use, identified in the table of contents and directing the user to particular sections within the information manual;

b) A section, if applicable, describing how to unpack, set up, and check the device before placing it in operation, along with information directing the user to a source of assistance or service and advising the user of standard operational procedures, routine care and maintenance, and recommended frequency of recalibration and cleaning;

c) Procedures, drawings, and parts lists adequate to test and repair the system, if the device is field-serviceable by users or their representatives, as well as information on contacting manufacturer service centers;

d) The ability of the device to function according to specifications in the presence of common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation;

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e) An advisory that the accuracy of cuff-pressure transducers/indicators is to be verified at intervals specified by the manufacturer, and a suggested method of validation, including recommended calibration intervals;

f) For home blood pressure units, detailed instructions for the patients indicating the correct measurement techniques, minimally including arm position, proper rest interval before initiation of blood pressure measurement, and proper cuff size measurement, as well as a statement concerning the need to consult a health care professional for interpretation of pressure measurements;

g) A note that any blood pressure recording can be affected by the position of the subject, his or her physiologic condition, and other factors with a listing of these factors;

h) A statement indicating that the system might not meet its performance specifications if stored or used outside the manufacturer's specified temperature and humidity ranges (the manufacturer's specified ranges to be included in the statement);

i) Product warranty information;

j) Whether or not the device is intended for neonatal use, and if intended for neonatal use:

   1) The maximum pressure that can be applied by the monitor and cuff when used with neonates;

   2) The range of blood pressures that the device can accommodate when used with neonates;

   3) The maximum pressure that will be utilized in the neonatal mode to measure the patient's blood pressure under normal operating circumstances; and

   4) The initial inflation pressure to which the device will pump when measuring the blood pressure of a neonate;

k) Any hazards associated with prolonged overinflation of the bladder;

l) Methods for determining malfunctions of the display device;

m) The recommended sterilization procedures (when required);

n) The methods for dealing with mercury spills (for mercury gravity sphygmomanometers); and

o) A statement describing the relationship of blood pressure measurements (systolic, diastolic, and mean pressures) obtained using the device and those obtained using one or both independent methods described in this standard.

Any claims made for the efficacy of blood pressure measurements obtained by the device shall be substantiated by the appropriate verification method, including information advising the user of the availability of the report of the study findings specified in 4.4.A or 4.4.B.

For devices validated against indirect auscultatory measurements using a cuff, stethoscope, and manometer, the statement shall be worded in the following or substantially equivalent language: "Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, *Manual, electronic, or automated sphygmomanometers."*

For devices validated against intra-arterial measurements, the statement shall be worded in the following or substantially equivalent language: "Blood pressure measurements determined with this device are equivalent to those obtained by an intra-arterial blood pressure measurement device, within the limits prescribed by the American National Standard, *Manual, electronic, or automated sphygmomanometers*." For devices validated against intra-arterial measurements, the artery that was used for validation of the device should be disclosed.

For devices validated against both methods, these two statements may be combined.

4.1.4 Component labeling

4.1.4.1 Component replacement

If a component (e.g., cuff, microphone, ultrasonic sensor, pressure transducer) can be replaced by the user, and if replacement could affect the performance of the instrument so that the requirements of 4.4 would not be met, the labeling shall include the following or substantially equivalent statement: "Caution: Substitution of a component different from that supplied might result in measurement error."

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4.1.4.2 Power system labeling

The device shall bear a label near the power cord outlet (or for battery-powered devices, on the AC adaptor) that states the nominal line voltage, nominal current or power, and frequency requirements for operation of the device.

4.1.4.3 Labeling for battery-powered devices

If the user can replace the battery, the device shall bear a label indicating the proper type of battery. If an operator-initiated test is the means of detecting the condition of the battery, the device shall be labeled to indicate that such a test should be performed in order to verify proper operation of the system.

4.1.4.4 Cuff labeling

The cuff shall be labeled or constructed to indicate the range of limb circumferences for which the cuff is intended, and marked or constructed so that when the cuff is applied to a limb, the markings or construction will indicate whether the cuff is the correct size.

4.2 Environmental performance and stability

4.2.1 Storage conditions

The sphygmomanometer shall maintain the requirements specified in this standard after storage for 24 hours (h) at a temperature of –4 °F (–20 °C) and for 24 h at a temperature of 131 °F (55 °C) and a relative humidity of 90 % (noncondensing).

Testing shall be carried out in accordance with 5.2.1 after the test sample has been placed for 24 h at a temperature of –4 °F (–20 °C) and immediately afterwards for 24 h at a temperature of 131 °F (55 °C) in a climatic chamber. Integrated multiparameter monitors may contain components that can be damaged during storage. For these devices, the general temperature range can therefore be reduced to 23 °F (–5 °C) and 122 °F (50 °C). This change shall be stated on the shipping container and in the instructions for use.

4.2.2 Operating conditions

The device, when set up in its normal operating configuration, shall maintain the safety and performance characteristics specified in this standard during operation over the following ranges of environmental conditions, individually or in any usual combination:

a) A range in temperature of 50 °F (10 °C) to 104 °F (40 °C);

b) A range in humidity of 15 % to 90 % (noncondensing);

c) A range in barometric pressure of 105 kPa to 80 kPa (790 mmHg to 600 mmHg).

4.2.3 Vibration and shock

4.2.3.1 Packaged sphygmomanometers

Packaged sphygmomanometers and their accessories shall maintain their safety and performance characteristics after being subjected to the standard drop and vibration test procedures of the International Safe Transit Association (ISTA) standard (normative reference 2.7).

4.2.3.2 Unpackaged sphygmomanometers

See specific requirements in 4.2.3.2.A and 4.2.3.2.B.

4.2.4 Stability

4.2.4.1 Voltage range

AC-powered devices shall perform in accordance with this standard over the voltage range specified in normative reference 2.2 (i.e., 104 Vrms to 127 Vrms).

Battery-powered devices shall incorporate means for indicating the condition of the battery or for protective shutdown in case of battery failure. Battery failure is defined as any condition of the battery that does not allow the instrument to meet the safety and performance requirements of this standard. Techniques such as the following may be used: an operator-initiated test, an automatic indication of impending power system degradation, a constant indication of battery condition, or a protective shutdown device.

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4.2.4.2 Life

The device shall maintain the safety and performance characteristics specified in this standard for a minimum of 10,000 full-scale cycles (where a full-scale cycle is a pressure change from 20 mmHg or less to full scale, and then back to 20 mmHg or less).

4.2.5 Electromagnetic compatibility

All devices with electric or electronic components shall comply with the emissions and immunity requirements set forth in normative reference 2.4.

4.3 Safety requirements

4.3.1 Devices incorporating automatic inflation systems

4.3.1.1 Maximum cuff pressure

For devices intended for public, home, or other unsupervised use, a means of limiting cuff pressure shall be provided so that the maximum cuff pressure will never exceed 300 mmHg. For devices intended for use under professional supervision, a means of limiting cuff pressure shall be provided so that the maximum cuff pressure will never exceed 300 mmHg or 30 mmHg above the upper limit of the instrument's manufacturer-specified operating range, whichever is lower. In addition, the device shall incorporate means to ensure that cuff pressure will not be maintained above 15 mmHg for longer than 3 minutes (min).

For devices intended for neonatal use, a means of limiting the cuff pressure shall be provided so that the maximum cuff pressure will never exceed 150 mmHg when in neonatal mode. In addition, the device shall incorporate means to ensure that cuff pressure will not be maintained above 5 mmHg for longer than 90 seconds (s).

Automatic cycling non-invasive blood pressure monitoring equipment shall meet the requirements of normative reference 2.5.

4.3.1.2 Release rate

An easily accessible and clearly labeled means of allowing the user to deflate the cuff shall be provided.

During the rapid exhaust of the pneumatic system with fully-opened valve, the time for the pressure reduction from 260 mmHg to 15 mmHg shall not exceed 10 s.

For blood pressure-measuring systems having the capability to measure in a neonatal mode, the time for the pressure reduction from 150 mmHg to 5 mmHg during the rapid exhaust of the pneumatic system with fully-opened valve shall not exceed 5 s.

4.3.2 Electrical safety

The device shall meet the requirements called out in normative reference 2.6.

4.3.3 Conductive components

The components of sphygmomanometers and their accessories that are labeled as conductive shall meet the requirements of the specified section of normative reference 2.8 and shall bear the cautionary labeling required by that standard.

4.4 Performance requirements

4.4.1 Aneroid manometers

See 4.4.1.A.

4.4.2 Mercury gravity manometers

See 4.4.2.A.

4.4.3 Electronic manometers

See 4.4.3.A.

4.4.4 Pressure transducer accuracy

See 4.4.4.B.

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4.4.5 Overall system efficacy—Automated systems

See 4.4.5.B.

4.5 Requirements for inflation source and pressure control valves

4.5.1 Inflation source

The inflation source shall be capable of supplying sufficient air to bring a volume of at least 200 cm^3 (12 cubic inches) to a pressure of 300 mmHg in no more than 10 s, unless otherwise stated.

4.5.2 Manually adjustable valve

4.5.2.1 Pressure drop

With the valve closed, the maximum pressure drop with a volume of no more than 80 cm^3 shall be 1 mmHg in 10 s at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.5.2.2 Valve/cuff exhaust rate

The valve shall be adjustable and shall allow pressure reduction to be controlled and maintained at a rate between 2 mmHg/s and 3 mmHg/s, from initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.5.2.3 Release rate

During the rapid exhaust of the pneumatic system with fully-opened valve, the time for the pressure reduction from 260 mmHg to 15 mmHg shall not exceed 10 s.

For blood pressure-measuring systems having the capability to measure in a neonatal mode, the time for the pressure reduction from 150 mmHg to 5 mmHg during the rapid exhaust of the pneumatic system with fully-opened valve shall not exceed 5 s.

4.5.3 Self-bleeding pressure control valve

4.5.3.1 Pressure drop

With the valve closed, the maximum pressure drop with a volume of no more than 80 cm^3 shall be 1 mmHg in 10 s at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.5.3.2 Valve/cuff exhaust rate

When the valve is in the self-bleeding position and when it is used with the cuff for which it is intended, it shall not be possible to reduce the cuff pressure at a rate lower than 2 mmHg/s throughout the 250 mmHg to 50 mmHg range.

4.5.3.3 Release rate

During the rapid exhaust of the pneumatic system with fully-opened valve, the time for the pressure reduction from 260 mmHg to 15 mmHg shall not exceed 10 s.

For blood pressure-measuring systems having the capability to measure in a neonatal mode, the time for the pressure reduction from 150 mmHg to 5 mmHg during the rapid exhaust of the pneumatic system with fully-opened valve shall not exceed 5 s.

4.5.4 Automated valves

see 4.5.4.B.

4.6 Requirements for the inflatable bladder and cuff

4.6.1 Inflatable bladder

4.6.1.1 Dimensions

The cuff bladder length should be approximately 0.80 times the circumference of the limb at the midpoint of the intended range of the cuff. The width of the cuff bladder should be optimally 0.40 times the circumference of the limb at the midpoint of the intended range of the cuff.

If manufacturers of automated devices supply cuffs that are outside of this range or are intended for use on a site other than the upper arm, they shall produce data verifying the accuracy of the system.

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4.6.1.2 Pressure capacity

The bladder and integral tubing shall be capable of withstanding the maximum pressure intended for the cuff.

4.6.2 Cuff

The following requirements apply to bandage, hook, contact closure, and other types of cuffs.

4.6.2.1 Dimensions

For hook, contact closure, and other types of cuffs, the cuff shall, at a minimum, be of sufficient length to completely encircle the largest circumference limb for which it is intended, maintaining its full width throughout this length. For bandage cuffs, the full cuff length shall extend beyond the end of the inflatable bladder by at least the equivalent of the length of the bladder for which the cuff is intended; the total length of the cuff shall be sufficient to ensure that the cuff does not slip or become loose when the bladder is inflated to 300 mmHg.

4.6.2.2 Pressure capacity

The cuff shall be capable of completely retaining the bladder for which it is intended when the bladder is inflated to the maximum pressure intended for the cuff.

4.6.2.3 Cuff closures/construction

The cuff closures and stitching shall be adequate to ensure that the cuff integrity is maintained and the other requirements of this standard are met, after 1,000 open–close cycles of the closure and 10,000 pressure cycles to 300 mmHg.

NOTE—Disposable cuffs are exempt from this requirement.

4.6.3 Cuff with integral bladder

4.6.3.1 Dimensions

The cuff bladder length should be approximately 0.80 times the circumference of the limb at the midpoint of the intended range of the cuff. The width of the cuff bladder should be optimally 0.40 times the circumference of the limb at the midpoint of the intended range of the cuff.

If manufacturers of automated devices supply cuffs that are outside of this range or are intended for use on a site other than the upper arm, they shall produce data verifying the accuracy of the system.

4.6.3.2 Pressure capacity

The cuff and integral bladder and integral tubing shall be capable of withstanding an internal pressure equal to the maximum pressure intended for the cuff.

4.6.3.3 Cuff closures/construction

The cuff closures and stitching shall be sufficient to maintain the integrity of the cuff and integral bladder and to ensure compliance with the other requirements of this standard after 1,000 open–close cycles of the closure and 10,000 pressure cycles to 300 mmHg.

NOTE—Disposable cuffs are exempt from this requirement.

5 Tests

NOTE—This section contains referee test methods by which compliance of the device with the requirements of section 4 can be verified. The paragraph numbers below correspond to the paragraph numbers of section 4 with the exception of the first digit. The methods are intended for type testing, referee testing, or design qualification. These test methods are not intended for use by end users of the device, nor are they intended for use in quality control or lot-to-lot testing by manufacturers.

5.1 Labeling

Compliance with the requirements of 4.1 can be verified by visual inspection.

5.2 Environmental performance and stability

It is the intent of this standard that sphygmomanometers be capable of meeting all safety and performance requirements (4.3, 4.4.A, 4.4.B, and 4.5) during or after exposure to the environmental conditions specified in 4.2.1 through 4.2.4.1 and over the minimum life specified in 4.2.4.2. However, the specification for overall system efficacy of automated systems, 4.4.5.B, entails extensive clinical testing, and it is unreasonable to require that blood

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pressure measurements of subjects be conducted under extreme environmental conditions of temperature, humidity, and altitude. Therefore, it is expected that only the non-clinical safety and performance criteria will be fully and directly verified against the environmental performance requirements. For reasons of practicality, test methods 5.2.2 and 5.2.4.1 require that only pressure indicator accuracy be verified under extreme operating and voltage conditions, because this is a relatively simple test likely to yield a good indication of continued proper performance of the instrument.

It is nevertheless the manufacturer's responsibility to ensure and, if contested, demonstrate that environmental conditions have been taken into account in the design of the instrument and that, whether or not the same units are used for environmental type-testing and for other required testing, the instrument is capable of meeting all safety and performance requirements (including 4.4) under the specified environmental conditions.

5.2.1 Storage conditions

Starting at room temperature, the ambient temperature at which the device is stored in its normal shipping container is lowered to the lower temperature limit specified in 4.2.1, at a relative humidity that precludes condensing. This temperature is maintained for 24 hours, then returned to and allowed to stabilize at room temperature, after which the storage temperature is increased to the upper temperature and humidity limit specified in 4.2.1, noncondensing, and maintained for 24 hours. The storage temperature is once again returned to room temperature and the device is allowed to stabilize. After at least one hour at the stabilized temperature, the device shall meet the requirements of 4.3, 4.4.A, 4.4.B, and 4.5.

NOTE—Time should be allowed for the temperature to stabilize before the humidity is increased, to keep potentially damaging condensate from forming in components.

5.2.2 Operating conditions

The device is set up in its normal operating configuration and subjected to the worst-case conditions of 4.2.2 for one hour. The accuracy test of 5.4 is conducted while these environmental conditions are maintained to verify that the device will continue to meet the pressure indicator accuracy requirement of 4.4. (See also 5.2.)

The sphygmomanometer is subjected to a relative humidity as specified in 4.2.2, at a temperature of 86 °F (30 °C), for a period of 4 h. After this period of exposure, and under these conditions, the device is tested to determine compliance with the accuracy requirements of 4.4.A and 4.4.4.B.

5.2.3 Vibration and shock

5.2.3.1 Packaged sphygmomanometers

The test for the packaged device is conducted in accordance with the procedures of normative reference 2.7. After this test, the device shall meet the requirements of 4.3, 4.4.A , 4.4.4.B, and 4.5. (See also 5.2.)

5.2.3.2 Unpackaged sphygmomanometers

See specific tests in 5.2.3.2.A and 5.2.3.2.B.

5.2.4 Stability

5.2.4.1 Voltage range

Using the method of 5.4.4, pressure measurements are obtained at the voltage extremes specified in 4.2.4.1. The device shall comply with the pressure indicator accuracy requirements of 4.4.A and 4.4.4.B. (See also 5.2.)

To assure that battery-powered devices meet the safety and performance requirements of this standard, these devices shall be tested with fresh or fully charged batteries that have been discharged to the limits allowed by the manufacturer. While it might be possible to test the device by using an external power supply, it is suggested that a superior means is to test the performance with batteries that have been discharged to the limits allowed by the manufacturer.

5.2.4.2 Life

After the device is subjected to 10,000 full-scale cycles, as per 4.2.4.2, it shall meet the requirements of 4.3, 4.4.A , 4.4.4.B, and 4.5. (See also 5.2.)

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5.3 Safety requirements

5.3.1 Devices incorporating automatic inflation systems

5.3.1.1 Maximum cuff pressure

5.3.1.2 Release rate

A rigid volume of 500 mL ± 25 mL shall be used to test the adult release rate requirement. A rigid volume of 100 mL ± 5 mL shall be used to test the neonatal or the wrist cuff release rate requirement. The appropriate volume, a calibrated manometer, and the unit under test are connected together. The system is inflated to the maximum pressure, and after a period of 60 s the rapid exhaust valve is operated. The time to deflate to the minimum pressure level is measured.

5.3.2 Electrical safety

Test methods for determining risk current levels are provided in normative reference 2.6.

5.3.3 Conductive components

Test methods for this requirement are provided in the relevant sections of normative reference 2.8.

5.4 Performance requirements

5.4.1 Aneroid manometers

See 5.4.1.A.

5.4.2 Mercury manometers

See 5.4.2.A.

5.4.3 Electronic manometers

See 5.4.3.A.

5.4.4 Pressure transducer accuracy

See 5.4.4.B.

5.4.5 Overall system efficacy—Automated systems

See 5.4.5.B.

5.5 Requirements for inflation source and pressure control valves

5.5.1 Inflation source

The inflation source is connected to a manometer with a closed volume of 200 cm^3 to 220 cm^3. The inflation source shall be employed to pressurize the system to a pressure of 300 mmHg. The inflation time shall be measured to determine compliance with the 10 s requirement of 4.5.1. At an initial pressure of 300 mmHg, the leakage rate shall be verified to be no more than 2 mmHg/min over a period of at least 2 min. The test shall be carried out at a constant temperature between 59 °F and 77 °F (15 °C and 25 °C).

If for technical reasons the test as described cannot be performed, an alternative test procedure must be specified by the manufacturer.

5.5.2 Manually adjustable valve

5.5.2.1 Pressure drop

The valve is connected to a manometer with a closed volume of 60 cm^3 to 80 cm^3. A suitable timing device is used to determine compliance with the pressure drop requirement of 4.5.2.1 at differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

5.5.2.2 Valve/cuff exhaust rate

The valve is connected to a manometer with a closed volume of 60 cm^3 to 80 cm^3. Using a suitable timing device, tests shall be performed to determine compliance with 4.5.2.2. The exhaust rate shall be tested over a period of at least 5 s. The tests are repeated with a closed volume of 200 cm^3 to 220 cm^3.

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5.5.2.3 Release rate

See 5.3.1.2.

5.5.3 Self-bleeding pressure control valve

5.5.3.1 Pressure drop

The valve is connected to a manometer with a closed volume of 60 cm^3 to 80 cm^3. A suitable timing device is used to determine compliance with the pressure drop requirement of 4.5.3.1 at differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

5.5.3.2 Valve/cuff exhaust rate

The valve is connected to a manometer with a closed volume of 60 cm^3 to 80 cm^3. When the valve is in the self-bleed position, the cuff is inflated and deflated as necessary to determine, with a suitable timing device, compliance with 4.5.3.2.

5.5.3.3 Release rate

See 5.3.1.2.

5.6 Requirements for the inflatable bladder and cuff

5.6.1 Inflatable bladder

5.6.1.1 Dimensions

Compliance with the requirements of 4.6.1.1 can be verified by inspection. Clarification of this requirement is provided in A.4.6.1.1.

5.6.1.2 Pressure capacity

5.6.2 Cuff

5.6.2.1 Dimensions

Compliance with the requirements of 4.6.2.1 can be verified by inspection.

5.6.2.2 Pressure capacity

5.6.2.3 Cuff closures/construction

The cuff shall be tested when wrapped around a mandrel to simulate actual use. The 1,000 open–close cycles shall be tested while the cuff is deflated. The 10,000 pressure cycles also shall be tested while the cuff is wrapped around a mandrel. The two tests may be completed sequentially or may be interlaced (e.g., 10 pressure cycles followed by one open–close cycle).

5.6.3 Cuff with integral bladder

5.6.3.1 Dimensions

Compliance with the requirements of 4.6.3.1 can be verified by inspection.

5.6.3.2 Pressure capacity

5.6.3.3 Cuff closures/construction

See 5.6.2.3.

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Section A: Manual sphygmomanometers

4.2.3.2.A Unpackaged sphygmomanometers

Unpackaged sphygmomanometers and their accessories shall maintain their safety and performance characteristics, or shall provide a clear indication that performance is degraded, after being subjected to the tests of 5.2.3.2.A.

4.4.A Performance requirements

4.4.1.A Aneroid manometers

4.4.1.1.A Range

The range of the manometer shall be from 0 mmHg to at least 260 mmHg, unless the manometer is designed for a special purpose and is so labeled.

4.4.1.2.A Graduations

The graduation lines from 20 mmHg to the top of the range of the manometer shall be spaced at maximum intervals of 2 mmHg, with each 10-unit division emphasized. The maximum interval between numerals shall be 20 mmHg. If a digital display is used, its resolution shall be 1 mmHg.

4.4.1.3.A Accuracy of pressure measurement

At any single condition within the ambient temperature range of 50 °F to 104 °F (10 °C to 40 °C) and the relative humidity range of 15 % to 90 % (non-condensing), both for increasing and for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the scale range shall be ± 3 mmHg (± 0.4 kPa) or 2 % of the reading above 200 mmHg.

4.4.1.4.A Repeatability

For a given manometer, each repeated reading throughout the graduated range shall agree with one another within 4 mmHg, when measured under static conditions at successively lower pressures. All readings should meet the requirement of 4.4.1.3.A.

4.4.1.5.A Test zone

When measured under static conditions at temperatures between 64 °F (18 °C) and 91 °F (33 °C), the test-zone-indicating mark or marks at zero pressure shall not span an interval greater than 6 mmHg. The true-zero indication shall fall within the test zone, preferably at the midpoint.

4.4.1.6.A Restraint of pointer movement

No pin stop or other travel-limit device shall be used to artificially restrict pointer movement within 15 angular degrees of zero.

4.4.1.7.A External adjustments

The instrument shall be designed so that external adjustments of calibration and dial position with respect to movement cannot be made without specialized tools.

4.4.1.8.A Manometers without integral pressure control

When manometers without integral pressure control valves are connected to a volume of 200 cm^3, the maximum pressure drop shall be 1 mmHg in 10 s at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.4.1.9.A Manometers with integral pressure control

The manometer and its built-in valve shall meet the requirements of 4.5.2

4.4.1.10.A Pointer-manometer exhaust rate

The pointer shall fall freely from the top of the pressure range to 20 mmHg in a maximum of 2 s with zero back pressure.

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4.4.1.11.A Pressure-sensitive element

The environment of the pressure-sensitive element shall be open to the atmosphere.

4.4.1.12.A Pressure capacity

The manometer shall be capable of withstanding a differential pressure of 300 mmHg without evidence of damage, and shall meet all other requirements of this standard after application of this pressure.

4.4.2.A Mercury gravity manometers

4.4.2.1.A Range

The range of the mercury gravity manometer shall be from 0 mmHg to at least 260 mmHg, unless the manometer is designed for a special purpose and is so labeled.

4.4.2.2.A Graduations

The graduation lines from 0 mm to the top of the range shall be placed at maximum intervals of 2 mm, with each 10-unit division emphasized. The maximum interval between numerals shall be 10 mm. The calibrated mercury tube shall be visible for a distance of at least 3 mm below the zero mark.

4.4.2.3.A Accuracy of pressure measurement

At any single condition within the ambient temperature range of 50 °F to 104 °F (10 °C to 40 °C) and the relative humidity range of 15 % to 90 % (non-condensing), both for increasing and for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the scale range shall be ± 3 mmHg (± 0.4 kPa) or 2 % of the reading above 200 mmHg.

4.4.2.4.A Repeatability

For a given manometer, each repeated reading throughout the graduated range shall agree with one another within 4 mmHg, when measured under static conditions at successively lower pressures. All readings should meet the requirement of 4.4.2.3.A.

4.4.2.5.A Mercury column exhaust rate

The mercury column shall fall freely from the top of the range to 20 mmHg in no more than 2 s with zero back pressure.

4.4.2.6.A Tube dimensions

The calibrated mercury tube shall have a minimum inside dimension of 3.9 mm.

4.4.2.7.A Pressure-sensitive element

The environment of the pressure-sensitive element shall be open to the atmosphere.

4.4.2.8.A Leakage

When manometers are connected to a volume of 200 cm^3, the maximum pressure drop shall be 1 mmHg in 10 s at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.4.2.9.A Mercury spillage

Mercury gravity manometers shall incorporate a device at the top of the calibrated tube that both permits the inward and outward flow of air and prevents the passage of liquid mercury. The bottom of the calibrated tube shall be fitted with a means of keeping the mercury in the reservoir of the instrument during shipment. The reservoir itself shall be fitted with a device to prevent mercury from flowing out of the reservoir neck and into the attached tubing.

4.4.2.10.A Pressure capacity

The manometer shall be capable of withstanding a differential pressure of 300 mmHg without evidence of damage, and shall meet all other requirements of this standard after application of this pressure.

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4.4.3.A Electronic manometers

4.4.3.1.A Range

The range of the electronic manometer shall be from 0 mmHg to at least 260 mmHg, unless the manometer is designed for a special purpose and is so labeled.

4.4.3.2.A Resolution

The resolution of the displayed values will be 1 mmHg.

4.4.3.3.A Accuracy of pressure measurement

At any single condition within the ambient temperature range of 50 °F to 104 °F (10 °C to 40 °C) and the relative humidity range of 15 % to 90 % (non-condensing), both for increasing and for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the scale range shall be ± 3 mmHg (± 0.4 kPa) or 2 % of the reading above 200 mmHg.

4.4.3.4.A Repeatability

For a given manometer, each repeated reading throughout the graduated range shall agree with one another within 4 mmHg, when measured under static conditions at successively lower pressures. All readings should meet the requirement of 4.4.3.3.A.

4.4.3.5.A Pressure-sensitive element

The environment of the pressure-sensitive element shall be open to the atmosphere.

4.4.3.6.A Leakage

When manometers are connected to a volume of 200 cm^3, the maximum pressure drop shall be 1 mmHg in 10 s at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.7.A System leakage

The sphygmomanometer system shall not lose pressure at a rate greater than 1 mmHg/s.

5.2.3.2.A Unpackaged sphygmomanometers

The sphygmomanometer is dropped 6 times (once on each side) from the height specified in 4.2.3.2.A to a rigidly supported hard surface (3-inch-thick concrete covered by 1/8-inch-thick asphalt tile, or equivalent). After these drops, the sphygmomanometer is evaluated according to 5.4.

5.4.1.A Aneroid manometers

5.4.1.1.A Range

Compliance with the requirements of 4.4.1.1.A can be determined by visual inspection.

5.4.1.2.A Graduations

Compliance with the requirements of 4.4.1.2.A can be determined by visual inspection.

5.4.1.3.A Accuracy

See 5.4.4.B

5.4.1.4.A Repeatability

The test procedure of 5.4.1 is repeated 10 times, with successive line pressures adjusted to obtain identical pressure levels, indicated by the reference standard, in each of the trials. For each line pressure setting, the range of indicated manometer pressures shall be within 4 mmHg for all 10 trials.

5.4.1.5.A Test zone

A zero differential pressure is applied to the sphygmomanometer. The pointer should not indicate measurements outside of the zero-indicating mark or marks (test zone). The pressure is then increased to a value above 20 mmHg. The pressure is then decreased so that the indicator points to the top limit of the test zone, and the differential pressure is recorded. Next, the pressure is decreased so that the indicator points to the bottom line of the test zone, and the differential pressure is again recorded. The absolute total of these two pressures shall not exceed 6 mmHg.

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