

**American
National
Standard**

ANSI/AAMI SP9:1994

**Non-automated
sphygmomanometers**

AAMI

Association for the
Advancement of Medical
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1110 N. Glebe Rd., Suite 220
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McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, DC 20006
Attn: Jacqueline A. Henson, Esq.
Phone: (202) 496-7500

Nonautomated sphygmomanometers

ANSI/AAMI SP9—1994
(Revision of ANSI/AAMI SP9—1985)

American National Standard
Nonautomated sphygmomanometers

Developed by
Association for the Advancement of Medical Instrumentation

Approved 5 April 1994 by
American National Standards Institute

Abstract:

This standard establishes labeling requirements, performance requirements, test methods, and referee test methods for nonautomated sphygmomanometers used in the indirect measurement of blood pressure.

Committee representation

Association for the Advancement of Medical Instrumentation

Sphygmomanometer Committee

This standard was developed by the AAMI Sphygmomanometer Committee. Committee approval of the standard does not necessarily imply that all committee members and reviewers voted for its approval. The committee currently has the following members:

Cochairpersons: Alan S. Berson, PhD
Carroll Robbins

Members: Alan S. Berson, PhD, National Heart, Lung, and Blood Institute
Cesar A. Caceres, MD, Clinical Systems Associates
Janice B. Flynn, RN, MN, Atlanta, Georgia
Sandra S. Garrett, PhD, Medifacts
Rodolfo I. Godinez, MD, PhD, Children's Hospital of Philadelphia
Michael Hayes, W. A. Baum Co.
Michael J. Jamieson, MD, University of Texas Health Sciences Center
Alvis Jordans, FDA Winchester Engineering and Analysis Center
Jack Millay, SpaceLabs Medical, Inc.
Anthony V. Picardi, Defense Personnel Support Center
L. Michael Prisant, MD, FACC, FACP, Medical College of Georgia
Carroll Robbins, Tyco Instruments
Sheldon G. Sheps, MD, Mayo Clinic
Irvine A. Speelman, Propper Manufacturing Company
Brian Steffens, Marquette Electronics, Inc.
Leonard Steinfeld, MD, Mount Sinai Medical Center
Lee Taylor, MD, Protocol Systems, Inc.

Gregory Welyczko, Ohmeda
William White, MD, University of Connecticut Health Center
Michael Willingham, Physio-Control Corp.

Alternates: Glenn Pelikan, SpaceLabs Medical, Inc.
Todd Roberts, Marquette Electronics, Inc.
Edward J. Roccella, PhD, MPH, National Institutes of Health

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

This is the second edition of the American National Standard, *Nonautomated sphygmomanometers*. The standard was developed by the AAMI Sphygmomanometer Committee and first approved in 1985.

Hypertension remains one of the most important public health problems in the United States. Sphygmomanometer readings are the single most valuable way to determine normal/abnormal pressures. Errors, either false positives or false negatives, are likely to have a major impact on the health care of an individual.

The objective of this standard is to provide minimum labeling, safety, and performance requirements for indirect measurement of blood pressure using the conventional cuff/stethoscope technique. This standard addresses accuracy and verification of sphygmomanometer performance; safety in cuff pressurization; and conformance with the American Heart Association's recommendations regarding appropriate sizes of cuff/bladders, bladder pressure release rate, etc.

Substantive changes from the original standard appear in this revision. The modified sections are [4.2.3.2](#) and [5.2.3.2](#) Vibration and Shock for Unpackaged Sphygmomanometers; [4.6.1.1](#) and [4.6.3.1](#) Bladder Dimensions; and [5.4.1.5](#) Test Zone. The height used in the drop test was increased to a more realistic 30 inches. The minimum length of the bladder was increased. The Test Zone referee test was improved.

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

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 as new data become available. AAMI standards development procedures require that all standards are 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 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 regulation.

Recommendations for improving this standard are invited. Comments and suggested revisions should be sent to: AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword is not a part of the American National Standard, *Nonautomated sphygmomanometers* (ANSI/AAMI SP9—1994).

Nonautomated Sphygmomanometers

1 Scope

1.1 General

This standard establishes safety and performance requirements for pneumatic or other nonautomated sphygmomanometers that are used with an occluding cuff for the indirect determination of blood pressure.

1.2 Inclusions

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

1.3 Exclusions

Excluded from the scope of this standard are devices that sense or display pulsations, flow, or sounds in connection with the electronic measurement, display, or recording of blood pressure, regardless of whether they have an automatic inflation system. Indirect measurement systems that do not have an occluding cuff are also excluded from the scope of this standard, as are invasive devices such as those used for direct blood pressure measurement.

NOTE—For an explanation of the need for this standard, as well as the rationale for its provisions, see [annex A](#).

2 Normative references

2.1 NATIONAL FIRE PROTECTION AGENCY.¹⁾ Standard for Health Facilities (Chapter 3, "Use of Inhalation Anesthetics"). ANSI/NFPA 99-1984. Boston: NFPA, 1984.

2.2 NATIONAL SAFE TRANSIT ASSOCIATION.²⁾ Pre-shipment Test Procedures. Chicago: NSTA, 1977.

3 Definitions

For the purposes of this standard, the following definitions apply.

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

3.2 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 Bureau of Standards).

3.3 Korotkoff sounds: Sounds heard over the artery when blood pressure is determined by the indirect (auscultatory) method.

3.4 manometer: Instrument for measuring the pressure of gases and vapors.

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

3.6 outer container: Immediate/unit container (i.e., retail package) of a device intended for home or other unsupervised use.

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

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

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

4 Requirements

4.1 Labeling requirements

4.1.1 General

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 Outer container

The outer container of the device shall display information needed by the end user, including cuff size, and shall also display the statement "limited range," if the manometer range is less than the "standard range" specified in 4.4.1.1 and 4.4.2.1.

4.1.3 Product literature

Product literature shall accompany the device and shall include, but is not limited to, the following information:

- a) the manufacturer's recommendations for calibration checks, cleaning, and care of instrument;
- b) any hazards associated with prolonged overinflation of the bladder;
- c) methods for determining malfunctions of the display device;
- d) the recommended sterilization procedures (when required);
- e) the methods for dealing with mercury spills (for mercury gravity sphygmomanometers);
- f) adequate instructions for use and operation;
- g) a statement concerning the need to consult a health care professional for interpretation of pressure measurements (for devices intended for home or other unsupervised use);
- h) the terms and conditions of the product warranty;
- i) information concerning available service centers;
- j) the accuracy of the sphygmomanometer;
- k) a statement indicating that the system may 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).

4.1.4 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 or not the cuff is the correct size.

4.2 Environmental performance and stability

4.2.1 Temperature

Nonautomated sphygmomanometers and their accessories shall maintain the safety and performance characteristics specified in this standard after storage for 24 hours (h) at temperatures ranging from -34°C (-30°F) to 65°C (149°F) at a relative humidity not to exceed 85%. During operation, nonautomated sphygmomanometers and their accessories shall maintain the safety and performance characteristics specified in this standard at temperatures ranging from 0°C (32°F) to 46°C (115°F) at a relative humidity not

to exceed 85%.

4.2.2 Humidity

Device safety and performance characteristics shall be maintained following equilibrium at a relative humidity of no less than 85% at 30°C (86°F).

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 NSTA (normative reference 2.2).

4.2.3.2 Unpackaged sphygmomanometers

Unpackaged sphygmomanometers shall maintain their safety and performance characteristics or provide a clear indication of failure after being subjected to a drop of 30 inches (in.) in accordance with 5.2.3.2. Only units that maintain their safety and performance characteristics after the 30 in. drop (in accordance with 5.2.3.2) may be labeled "SHOCK RESISTANT."

4.2.4 Stability/life

The sphygmomanometer shall maintain the safety and performance characteristics specified in this standard for a minimum of 10,000 full-scale pressure cycles — where a full-scale pressure cycle is a pressure change from 20 millimeters of mercury (mm Hg) or less to within 20 mm Hg of full scale and back to 20 mm Hg or less.

4.3 Conductive components

The components of sphygmomanometers and their accessories that are labeled as conductive shall meet the requirements of normative reference 2.1 and shall bear the cautionary labeling required by that standard.

4.4 Requirements for the manometer

4.4.1 Aneroid manometers

4.4.1.1 Range

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

4.4.1.2 Graduations

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

4.4.1.3 Accuracy

The error of the manometer, throughout its full range, shall not exceed ± 3 mm Hg, when measured under static conditions at successively lower pressures and in a temperature range of 18°C (64°F) to 33°C (91°F). At temperatures 0°C (32°F) to 17°C (63°F) and from 34°C (93°F) to 46°C (115°F), the manometer's error shall not exceed ± 6 mm Hg.

4.4.1.4 Repeatability

For a given manometer, each repeated reading throughout the graduated range shall agree with one another within 4 mm Hg, when measured under static conditions at successively lower pressures.

4.4.1.5 Test zone

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

4.4.1.6 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 true zero.

4.4.1.7 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 Manometers without integral pressure control

When manometers without integral pressure control valves are connected to a volume of 200 cubic centimeters (cc), the maximum pressure drop shall be 1 mm Hg in 10 sec at initial differential pressures of 250 mm Hg, 150 mm Hg, and 50 mm Hg.

4.4.1.9 Manometers with integral pressure control

The manometer and its built-in valve shall meet the requirements of [4.5.2](#).

4.4.1.10 Pointer-manometer exhaust rate

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

4.4.1.11 Pressure-sensitive element

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

4.4.1.12 Pressure capacity

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

4.4.2 Mercury gravity manometers

4.4.2.1 Range

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

4.4.2.2 Graduations

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

4.4.2.3 Accuracy

The error of the manometer, throughout its full range, shall not exceed ± 3 mm Hg, when measured under static conditions at successively lower pressures in a temperature of 18°C (64°F) to 33°C (91°F). At temperatures from 0°C (32°F) to 17°C (63°F) and from 34°C (93°F) to 46°C (115°F), the manometer's error shall not exceed ± 6 mm Hg.

4.4.2.4 Repeatability

For a given manometer, each repeated reading throughout the graduated range shall agree with one another within 4 mm Hg, when measured under static conditions at successively lower pressures.

4.4.2.5 Mercury column exhaust rate

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

4.4.2.6 Tube dimensions

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

4.4.2.7 Pressure-sensitive element

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

4.4.2.8 Leakage

When manometers are connected to a volume of 200 cc, the maximum pressure drop shall be 1 mm Hg in 10 sec at initial differential pressures of 250 mm Hg, 150 mm Hg, and 50 mm Hg.

4.4.2.9 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 Pressure capacity

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

4.5 Requirements for the inflation source and pressure control valve

4.5.1 Inflation source

The inflation source shall be capable of bringing a volume of at least 200 cc (12 cubic inches) to a pressure of 300 mm Hg in 4 to 10 sec, 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 cc shall be 10 mm Hg in 10 sec at initial differential pressures of 250 mm Hg, 150 mm Hg, and 50 mm Hg.

4.5.2.2 Valve/cuff exhaust rate

The valve shall be adjustable so as to control the pressure drop in a volume of no more than 80 cc at a rate of 20 mm Hg in 10 sec at initial differential pressures of 250 mm Hg, 150 mm Hg, and 50 mm Hg.

4.5.2.3 Release rate

With the valve fully opened, a volume of at least 200 cc shall be reduced from a pressure of 250 mm Hg to a pressure of 20 mm Hg in a maximum of 4 sec.

4.5.3 Self-bleeding pressure control valve

4.5.3.1 Valve/cuff exhaust rate