List of Titles

American National Standard

ANSI/AAMI SP9:1994

Non-automated sphygmomanometers

AAMI Association for the Advancement of Medical Instrumentation

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SP9 Nonautomated Sphygmomanometers

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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:

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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 in 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)] e-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

When the valve is in the self-bleeding position and when it is used with the cuff for which it is intended, it shall be possible to reduce the cuff pressure at the maximum rate of 6 mm Hg/sec to a minimum rate of 2 mm Hg/sec throughout the 250- to 50-mm Hg range.

4.5.3.2 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.

4.5.4 Hose connectors

The maximum pressure drop, caused by leakage, through joined metal or plastic hose connectors shall be 10 mm Hg in 10 sec for a volume of no more than 80 cc at differential pressures of 250 mm Hg, 150 mm Hg, and 50 mm Hg.

4.6 Requirements for the inflatable bladder and cuff

4.6.1 Inflatable bladder

4.6.1.1 Dimensions

The cuff bladder length shall be at least 0.80 times the circumference of the limb at the midpoint of cuff application. The width of the cuff bladder shall be minimally 0.37 (optimally 0.40) times the circumference of the limb at the midpoint of cuff application.

4.6.1.2 Pressure capacity

The bladder and integral tubing shall be capable of withstanding a differential pressure of 330 mm Hg.

4.6.2 Cuff

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

4.6.2.1 Dimensions

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 mm Hg. For hook, contact closure, and other types of cuffs, the cuff shall, as 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.

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 a minimum pressure of 330 mm Hg.

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 after 10,000 pressure cycles to 300 mm Hg.

NOTE—Disposable cuffs are exempt from this requirement.

4.6.3 Cuff with integral bladder

4.6.3.1 Dimensions

The cuff bladder length shall be at least 0.80 times the circumference of the limb at the midpoint of cuff

application. The width of the cuff bladder shall be minimally 0.37 (optimally 0.40) times the circumference of the limb at the midpoint of cuff application. The cuff shall, as a minimum, be of sufficient length to encircle the largest circumference limb for which it is intended, maintaining its full width throughout this length.

4.6.3.2 Pressure capacity

The bladder and integral tubing shall be capable of withstanding an internal pressure of 330 mm Hg.

4.6.3.3 Cuff closures/construction

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

NOTE—Disposable cuffs are exempt from this requirement.

4.7 Requirements for system leakage

The sphygmomanometer system shall not lose pressure at a rate greater than 1 mm Hg per second.

5 Tests

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, except for the first digit, with the paragraph numbers of section 4. 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. The methods are intended for type testing, referee testing, or design qualification.

5.1 Labeling

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

5.2 Environmental performance and stability

5.2.1 Temperature

5.2.1.1 Storage

Starting at room temperature, the ambient temperature at which the sphygmomanometer is stored is lowered to –34°C (–30°F) and maintained for 24 h. The sphygmomanometer is then allowed to stabilize at ambient room temperature, after which the storage temperature is increased to 65°C (149°F) and maintained for 24 h. Relative humidity shall not exceed 85% during this time. The elevated temperature is then reduced to ambient room temperature, and the sphygmomanometer allowed to stabilize. The sphygmomanometer is then tested according to 5.4.1 to determine compliance with the accuracy requirements of 4.4.1.3, 4.4.1.4, 4.4.2.3, and 4.4.2.4.

5.2.1.2 Operation

Starting at room temperature, the ambient temperature for sphygmomanometer operation is raised to 46°C (115°F) and maintained for 4 h. Relative humidity is kept at 85% or below. Then, the sphygmomanometer is tested by the method of 5.4.1, while these temperature and humidity conditions are maintained, to determine compliance with 4.4.1.3, 4.4.1.4, 4.4.2.3, and 4.4.2.4.

Starting at room temperature, the ambient temperature at which the sphygmomanometer is to be operated is lowered to 0°C (32°F) and maintained for 4 h. After this period, the sphygmomanometer is tested at this temperature according to 5.4.1 to determine compliance with the accuracy requirements of 4.4.1.3, 4.4.1.4, 4.4.2.3, and 4.4.2.4.

5.2.2 Humidity

The sphygmomanometer is subjected to a relative humidity of 85%, at a temperature of 30°C (86°F), for a period of 4 h. After this period of exposure, and under these conditions, the device is tested according to 5.4.1 to determine compliance with the accuracy requirements of 4.4.1.3, 4.4.1.4, 4.4.2.3, and 4.4.2.4.

5.2.3 Vibration and shock

5.2.3.1 Packaged sphygmomanometers

The test for packaged sphygmomanometers is conducted in accordance with the preshipment test procedures of normative reference 2.2. The device is subsequently tested by the methods of 5.4 and, where applicable, inspected visually to ascertain compliance with mercury spillage requirements (4.4.2.9).

5.2.3.2 Unpackaged sphygmomanometers

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

5.2.4 Stability/life

Using the method of 5.4.1, accuracy determinations are made before and after subjecting the sphygmomanometer to a minimum of 10,000 full-scale pressure cycles (where a full-scale pressure cycle is a pressure change from 20 mm Hg or less to within 20 mm Hg of full scale and back to 20 mm Hg or less). In all cases, the observed accuracy shall be consistent with the requirements of 4.4.1.3, 4.4.1.4, 4.4.2.3, and 4.4.2.4.

5.3 Conductive components

Test methods for this requirement are provided in the relevant sections of normative reference 2.1.

5.4 Requirements for the manometer

5.4.1 Aneroid manometers

Accuracy is determined by connecting the manometer to a reference standard (traceable to the National Bureau of Standards) having a maximum error of ± 0.5 mm Hg. The line pressure is then gradually reduced and checked at intervals of not more than 30 mm Hg throughout the full range, in the manner described in 4.4.1.3, 4.4.1.4, 4.4.2.3, and 4.4.2.4; and the accuracy of the indicated pressure with respect to the reference standard is determined.

5.4.1.1 Range

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

5.4.1.2 Graduations

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

5.4.1.3 Accuracy

See 5.4.1.

5.4.1.4 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 mm Hg for all 10 trials.

5.4.1.5 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 mm Hg. 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 mm Hg.

5.4.1.6 Restraint of pointer movement

The manometer is subjected to a below-atmospheric pressure through the hose connector. For the unit to meet the requirements of 4.4.1.6, the pointer shall travel a minimum of 15 angular degrees from the atmospheric pressure point to the pointer restraint device.

5.4.1.7 External adjustments

Compliance with the requirements of 4.4.1.7 can be determined by visual inspection.

5.4.1.8 Manometers without integral pressure control

To determine compliance with 4.4.1.8, the manometer is connected to a volume of between 200 and 220 cc and subjected to the specified pressures for a period of 10 sec.

5.4.1.9 Manometers with integral pressure control

See 5.5.2.

5.4.1.10 Pointer-manometer exhaust rate

When the manometer is subjected to a pressure equivalent to its full range and then released to atmospheric pressure, the indicated pressure shall be consistent with that specified in 4.4.1.10.

5.4.1.11 Pressure-sensitive element

Compliance with 4.4.1.11 can be determined by visual inspection.

5.4.1.12 Pressure capacity

The manometer is subjected to a differential pressure of 300 mm Hg for at least 1 min. At the end of the test, the manometer shall show no evidence of damage and shall meet all other requirements of this standard.

5.4.2 Mercury gravity manometers

The top of the mercury column in the center of the tube shall be used for all pressure readings (see A.4.4.2.6).

5.4.2.1 Range

Compliance with 4.4.2.1 can be determined by visual inspection.

5.4.2.2 Graduations

Compliance with 4.4.2.2 can be determined by visual inspection.

5.4.2.3 Accuracy

See 5.4.1.

5.4.2.4 Repeatability

See 5.4.1.4.

5.4.2.5 Mercury column exhaust rate

When the manometer is subjected to a pressure equivalent to its full range and then released to atmospheric pressure, the indicated pressure shall meet the requirement of 4.4.2.5.

5.4.2.6 Tube dimensions

The inside diameter of the mercury tube is determined by means of acceptable measuring tools and compared to the requirement of 4.4.2.6. For a circular cross section, "dimension" is synonymous with "diameter." For noncircular cross sections, the minimum inside dimension is determined by measuring the shortest wall-to-wall distance passing through the geometric center of the lumen.

5.4.2.7 Pressure-sensitive element

Compliance with 4.4.2.7 can be determined by visual inspection.

5.4.2.8 Leakage

To determine compliance with 4.4.2.8, the manometer is connected to a maximum volume of 200 cc and subjected to the specified pressures for 10 sec.

5.4.2.9 Mercury spillage

The mercury manometer is subjected to a positive pressure applied to its inlet port until the mercury completely fills the tube to the top. An additional pressure of 20 mm Hg is applied for at least 1 min to determine compliance with the first requirement of 4.4.2.9. Next, the mercury gravity manometer is prepared for shipment according to 4.4.2.9 and then turned upside down, vigorously shaken, and visually inspected to determine compliance with the remaining requirements of 4.4.2.9.

5.4.2.10 Pressure capacity

See 5.4.1.12.

5.5 Requirements for the inflation source and pressure control valve

5.5.1 Inflation source

The inflation source is connected to a manometer with a closed volume of between 200 and 220 cc. By means of the inflation source, the system is pressurized to a pressure of 300 mm Hg. The inflation time is measured to determine compliance with the 10-sec requirement of 4.5.1.

5.5.2 Manually adjustable valve

The valve is connected to a manometer with a closed volume of between 60 and 80 cc. A suitable timing device is used to determine compliance with the pressure drop requirement of 4.5.2.1, the valve/cuff exhaust rate requirement of 4.5.2.2, and the release rate requirement of 4.5.2.3.

5.5.3 Self-bleeding pressure control valve

5.5.3.1 Valve/cuff exhaust rate

The cuff is positioned around an appropriate mandrel. 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.

5.5.3.2 Release rate

The valve is connected to a manometer with a closed volume of between 200 and 220 cc. A suitable timing device is used to determine compliance with 4.5.3.2.

5.5.4 Hose connectors

The joined hose connectors are connected to a volume of between 60 and 80 cc, by means of an appropriate hose, inflation source, and manometer. The test system is then subjected to each of the pressures specified in 4.5.4 for a period of 10 sec. The maximum pressure drop as a result of leakage shall be 10 mm Hg.

5.6 Requirements for the inflatable bladder and cuff

5.6.1 Inflatable bladder

5.6.1.1 Dimensions

The dimensions of the inflatable bladder are measured with a suitable measurement device to determine compliance with 4.6.1.1.

5.6.1.2 Pressure capacity

The bladder and integral tubing are inserted into a suitable restraining fixture (e.g., a set of two rigid plates or screens held at a 1/2-in. spacing) and are subjected to an internal pressure of 330 mm Hg for one min. At the end of the test, the bladder and integral tubing shall show no evidence of damage and shall meet all other requirements of this standard.

5.6.2 Cuff

5.6.2.1 Dimensions

The dimensions of the various styles of cuffs are measured with a suitable measurement device.

5.6.2.2 Pressure capacity

The cuff containing its intended bladder is affixed in the normal manner around an appropriate mandrel with a circumference equivalent to that of the largest limb for which the cuff is intended. The cuff is then inflated to a pressure of at least 330 mm Hg to determine compliance with 4.6.2.2. At the end of this test, the bladder and integral tubing shall show no evidence of damage and shall meet all the requirements of this standard.

5.6.2.3 Cuff closures/construction

The cuff closure is subjected to at least 1,000 open-close cycles; the cuff and bladder assembly are affixed in the conventional manner around an appropriate mandrel having a circumference equivalent to that of the largest limb for which the cuff is intended. The assembly is then subjected to at least 10,000 full-scale pressure cycles (from atmospheric pressure to within 20 mm Hg of full scale and back to atmospheric).

5.6.3 Cuff with integral bladder

5.6.3.1 Dimensions

The dimensions of the cuff with integral bladder are measured with a suitable measurement device to determine compliance with 4.6.3.1.

5.6.3.2 Pressure capacity

The cuff with integral bladder is affixed in the usual way around an appropriate mandrel whose circumference is equivalent to that of the largest limb for which the cuff is intended. The cuff is inflated to a pressure of at least 330 mm Hg. At the end of this test, the sphygmomanometer shall show no evidence of damage and shall meet all the requirements of this standard.

5.6.3.3 Cuff closures/construction

The cuff closures are subjected to at least 1,000 open-close cycles; the cuff with integral bladder is affixed in the normal manner around an appropriate mandrel with a circumference equivalent to that of the largest limb

for which the cuff is intended. The cuff with integral bladder is then subjected to at least 10,000 full-scale pressure cycles (from atmospheric pressure to within 20 mm Hg of full scale and back to atmospheric).

5.7 Requirements for system leakage

With the cuff wrapped around a mandrel of appropriate size, the cuff is inflated to a pressure of 250 mm Hg. For at least 10 sec, the sphygmomanometer system shall not lose pressure caused by leakage at a rate greater then 1 mm Hg per sec. This test is repeated for initial cuff inflation pressures of 150 mm Hg and 50 mm Hg.

Annex A
(Informative)

Rationale for the development and provisions of this standard

A.1 Introduction

There is a wide variety of devices available for the measurement of blood pressure. These devices fall into two major categories: (1) invasive systems that utilize indwelling arterial catheters and that provide direct measurement of blood pressure; (2) noninvasive systems that utilize occluding cuffs and that measure blood pressure indirectly. The latter type of device is used widely in hospitals and physicians' offices, in mass screening programs for hypertension, and, increasingly, in homes of individuals who wish to monitor their own blood pressure. The increasingly consumer (nonprofessional) use of indirect blood pressure measurement devices has resulted from the growing public awareness of hypertension as a serious health hazard and from greater recognition of the importance of early detection and treatment of the disease.

Indirect blood pressure measurement devices may be either nonautomated or electronic/automated. The former group of devices is the subject of this standard.

A.2 Need for the standard

Because the significance of blood pressure measurement with sphygmomanometer systems has become increasingly recognized and the number of professional users is rapidly growing, care should be taken to ensure that the available devices are as safe and accurate as possible.

Prior to the development of this standard, industry-wide standards or guidelines did not exist. Users of nonautomated sphygmomanometers could not always be confident that their purchased devices were sufficiently accurate, durable, and reliable. Therefore, work was initiated to define minimum safety and performance requirements for nonautomated sphygmomanometers, together with appropriate test methodologies, that would address this need. It is hoped that this standard will make a positive contribution to the detection and control of hypertension.

The initial work on the standard was carried out with the encouragement and support of the National Heart, Lung, and Blood Institute (NHLBI). Deliberations at a 1979 NHLBI-sponsored consensus-development conference provided much of the basis for the safety and performance criteria recommended in this standard.

A.3 Definitions

For the purposes of this standard, the definitions given in section 3 apply.

A.4 Rationale for the specific provisions of this standard

A.4.1 Labeling requirements

Regulations of the Food and Drug Administration (FDA) control the general labeling of medical devices. Part 820, Chapter 1, Title 21, of the *Code of Federal Regulations* establishes requirements for proper handling, legibility, expiration dates, and many other aspects of labeling as it relates to good manufacturing practices. Part 801, Chapter 2, Title 21, of the *Code of Federal Regulations* and Section 502 of the Federal

Food, Drug, and Cosmetic Act (as amended in October 1976) define what constitutes proper labeling and misbranding for a drug or device. These two groups of requirements constitute the federal regulations referred to in 4.1.1 of this standard. All labeling pertaining to nonautomated sphygmomanometers is controlled by these regulations and must comply with them.

These regulations do not address, however, the detailed information that should accompany particular types of medical devices to help device users make an appropriate choice of device for a given application and to ensure that the device is used correctly. Provision of this detailed information is required by this standard in 4.1.2, 4.1.3, and 4.1.4.

A.4.2 Environmental performance and stability

Nonautomated sphygmomanometers may be exposed to extremes of temperature and humidity during shipment, storage, and use. Since this exposure is often unavoidable, it is important that the device be designed and manufactured so as to remain accurate under adverse environmental conditions. No measurement device, however, is completely invulnerable to all conceivable environmental extremes. Therefore, this standard requires that nonautomated sphygmomanometers remain accurate over defined ranges of operating and storage temperature and humidity. The device is also required to withstand defined vibration and shock conditions, as well as a reasonable number of uses, without degradation of performance. The requirements of 4.2 were considered by the committee to embrace those conditions that the device could reasonably be expected to tolerate.

In establishing these requirements, the AAMI committee reviewed ECRI's "Draft Environmental Requirements and Test Methods for Non-Implantable Medical Devices" (ECRI, 1978), the draft report of an ECRI study sponsored by the FDA. When the final report became available (ECRI, 1979), the committee also consulted this document in developing the environmental performance requirements of the standard; many of the ECRI proposals were adopted for purposes of this standard.

A.4.2.1 Temperature/A.4.2.2 Humidity

Most nonautomated sphygmomanometers are used within a controlled environment (e.g., hospital, clinic, or home). Some, however, are used by ambulance and paramedic personnel and are subjected to extremes of heat, cold, or humidity during use. In addition, it is very difficult to control storage and shipping conditions, so provision shall be made to ensure that instruments can survive temporary abnormal temperatures and humidities and continue to provide accurate readings.

Based on substantial documentation, ECRI's final report proposed that all mobile and portable medical devices be capable of withstanding storage/shipping temperatures in the range of –34°C (–30°F) to 65°C (149°F). The committee established these temperature extremes as the storage temperature range that sphygmomanometers shall tolerate without degradation of performance. Most nonautomated sphygmomanometers are used within a hospital, clinic, or home. The operating range of 0°C to 46°C embraces the range reported by ECRI for this type of protected environment (16°C to 40°C), although some broadening of the accuracy tolerance is allowed at the extremes of the range.

Some devices are, however, used in the ambient environment by emergency care personnel and thus may be subjected to greater temperature extremes than ordinarily encountered in a protected environment. The ECRI report proposed that all devices be required to withstand operating temperatures of –21°C (–6°F) to 46°C (115°F). The AAMI committee did adopt 46°C as the upper limit of the required operating range, although some broadening of the accuracy tolerance is permissible at this temperature level. Since lubricants and other components of the device could not, in practice, be expected to tolerate temperatures less than 0°C, it was deemed inappropriate to require all devices to maintain performance at such low temperature levels.

The relative humidity requirement is consistent with that proposed by ECRI for high-temperature conditions. The requirement that safety and performance be maintained following equilibrium at a relative humidity of

85% at 30°C (86°F) was considered by the committee to present a rigorous challenge to the device.

A.4.2.3 Vibration and shock

Since the device will inevitably be subjected to some mechanical abuse during shipment and use, 4.2.3 requires that nonautomated sphygmomanometers retain their safety and performance characteristics after being subjected to defined drop and vibration procedures. The purpose of the requirement for packaged devices is to ensure that the device will maintain its performance after sustaining the type of mechanical abuse that can be expected during shipment; the NSTA has defined drop and vibration procedures to simulate shipment conditions.

The requirement for unpackaged devices helps ensure that a device for home use will either sustain a reasonable level of mechanical abuse or provide an indication to the user that it is malfunctioning and cannot be expected to give accurate pressure measurements. Since these devices are fragile, the user is largely responsible for proper handling of the instrument. Nevertheless, the device should withstand at least a moderate drop test or else alert the user to malfunction; the particular test chosen (5.2.3.2) is based on typical drop tests for table-top and hand-held instruments, such as those specified by the Underwriters Laboratories' (UL) standard, *Electric and Electronic Measuring and Testing Equipment* (UL, 1979).

A.4.2.4 Stability/life

The standard requires that safety and performance characteristics be maintained for at least 10,000 full-scale pressure cycles. This level approximates 5 years of frequent device use by the home user. The committee recognized that this number of cycles does not approximate 5 years of use at the frequency with which the device could be used in a hospital environment; in fact, this number corresponds to about 6 to 12 months' use in the hospital. For purposes of a minimum performance standard, however, a requirement that the device maintain its accuracy for a minimum of 10,000 full-scale cycles is sufficient for both home-use and professional-use devices. In addition, the experience of manufacturers indicates that most device failures are typically observed by the approximately 8,000th cycle; thus, the 10,000-cycle requirement provides a reasonable margin of safety to ensure performance.

A.4.3 Conductive components

Nonautomated sphygmomanometers are occasionally used in potentially hazardous environments, such as operating rooms, where the presence of such materials as flammable anesthetics may create the possibility of static discharges leading to explosion or fire. Therefore, as a safety precaution, conductive components of nonautomated sphygmomanometers shall comply with relevant sections of normative reference 2.1.

A.4.4 Requirements for the manometer

A.4.4.1 Aneroid manometer

A.4.4.1.1 Range

Many mercury gravity manometers presently being sold and used have a range of 0 to 260 mm Hg. This range has been found to be satisfactory for the measurement of human blood pressure and has been acceptable by the medical profession. If the manometer is not capable of measuring blood pressures up to at least 260 mm Hg, the systolic pressure of a hypertensive individual may not be adequately detected. For purposes of comparison, this range is stipulated here for both aneroid and mercury gravity manometers.

A.4.4.1.2 Graduations

The graduation-line requirements are standard for the industry and have been found to be acceptable by end-users. These requirements are also consistent with those of Federal Specification GG-S-618D for aneroid and mercury gravity sphygmomanometers (GSA, 1978).

A.4.4.1.3 Accuracy

The accuracy requirements of this standard are consistent with the recommendations of the American Heart Association (AHA, 1967), the National Bureau of Standards (Wilson et al., 1927), and the General Services Administration (GSA, 1978). The AHA has recommended an accuracy of ± 3 mm Hg, as have the National Bureau of Standards and the General Services Administration, based on the 30,000-pulsations test. This level of accuracy has been achieved in the past, and as technology advances, there seems to be no reason to broaden the permissible tolerance. An accuracy of ± 3 mm Hg should certainly be produced at room temperature; however, a wider tolerance is permitted under conditions of reasonably extended temperature ranges, such as might occur in ambulances or outdoors.

The performance requirements have been described for static conditions, but there is an obvious need for proper performance under dynamic conditions as well. 4.4.1.10 and 4.4.2.5 require that the instrument respond rapidly during freely falling pressure. These requirements are adequate to demonstrate the instrument's capabilities for dynamic response.

A.4.4.1.4 Repeatability

If the maximum permissible error is ± 3mm Hg, successive readings could differ by as much as 6 mm Hg from each other for any given manometer. The committee considered such an excursion excessive. Most available instruments can obtain a repeatability of 4 mm Hg, which is acceptable in clinical use.

A.4.4.1.5 Test zone/A.4.4.1.6 Restraint of pointer movement

Severe mechanical shock (which may occur, for example, if the instrument is dropped on a hard floor) can cause an aneroid manometer to go out of calibration with no other apparent damage, such as tube breakage or mercury loss. Therefore, it is desirable to incorporate a visual indication, such as a typical zero-indicating mark or marks. A pin stop or other travel-limit device that restrains pointer movement defeats the intended purpose of the zero mark and could result in undetected errors of as much as 40 mm Hg or more in the blood pressure measurement.

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

> Of those instruments which did not record properly, 36.5% (38 of 104) deviated more than ± 7 mm Hg from the mercury standard compared to 1.5% (3 of 207) of those which did record zero properly. Conversely, 88.9% (184 of 207) of the instruments which properly recorded zero were within the ± 3 mm Hg error limit compared to 27.2% (28 of 103) of those which did not register zero accurately....The data presented here demonstrate that aneroid instruments which properly register zero are more likely to be accurate (within ± 3 mm Hg) than those which do not accurately register zero.

The zero reading is therefore a very useful indicator of correct calibration; this is particularly important for unsupervised use of the device in the home, where calibration cannot be checked by more sophisticated means on a regular basis. The value of the zero reading has long been recognized. According to Wilson and associates (1927):

> The position of the hand of an aneroid gauge at zero pressure is a good criterion, although not an infallible one, of the condition of the instrument. If the instrument is provided with a stop so arranged that the pointer will always register zero when under atmospheric pressure alone, no value can be attached to that reading.

More recently, ECRI (1975) reported that:

The scale should have a zero point for checking unpressurized readings. Although an unpressurized reading of zero does not guarantee accuracy at all scale points, failure of the needle to indicate zero is an obvious sign of error. No pin stop should limit needle movement to a possible erroneous zero position.

Federal Specification GG-S-618D prohibits the inclusion of a stop pin at "0" (GSA, 1978), and the Department of National Health and Welfare of Canada has suspended the sale in Canada of sphygmomanometers having "0" stop pins.

A.4.4.1.7 External adjustments

External adjustments of the zero calibration or dial position can cause inaccuracies, unless specialized tools are used and the recalibrations are carried out by specially trained personnel. (It should be noted that Federal Specification GG-S-618D prohibits the use of a dial that can be rotated externally.)

A.4.4.1.8 Manometers without integral pressure control

Excessive leakage can prevent adequate control of the pressure release rate in a total system. The maximum manometer leakage should be 0.1 of that allowed for manually controlled valves.

A.4.4.1.9 Manometers with integral pressure control

A.4.5.2 provides the rationale for the requirements concerning manually adjustable valves; these same requirements and accompanying rationale apply also to manometers with integral pressure control as well.

A.4.4.1.10 Pointer

It is important that the manometer respond accurately to the changing pressures in the occluding cuff. Constrictions in the air-flow system could disturb this response; hence, the pointer requirement.

A.4.4.1.11 Pressure-sensitive element

If the manometer is to perform properly and accurately, the external pressure on the sensing element should be identical to the external pressure on the system being measured. Therefore, the housing for the sensing element in an aneroid sphygmomanometer should be vented to the atmosphere in order to prevent the development of differential pressure caused by changes in temperature or atmospheric pressure.

A.4.4.1.12 Pressure capacity

The manometer itself should be capable of withstanding the same differential pressure as the bladder and tubing.

A.4.4.2 Mercury gravity manometer

A.4.4.2.1 Range

See A.4.4.1.1.

A.4.4.2.2 Graduations

See A.4.4.1.2. The calibrated mercury tube shall be visible for at least 3 mm below the zero mark because users should be able to determine clearly whether the mercury column is actually below the zero mark or simply resting on it.

A.4.4.2.3 Accuracy

See A.4.4.1.3.

A.4.4.2.4 Repeatability

See A.4.4.1.4.

A.4.4.2.5 Mercury column

The time requirement for the free fall of the mercury provides a means of indicating the minimum porosity of the device (used to prevent the passage of liquid mercury) at the top of the calibrated tube. (See also

A.4.4.1.10.)

A.4.4.2.6 Tube dimensions

Too small an inside tubing dimension[3)] can result in measurement errors due to, for example, poor visibility, mercury separation, and excessive meniscus. The minimum tube dimension specified in 4.4.2.6 is sufficient to avoid this type of measurement error.

An excessive meniscus occurring in a very narrow tube is the result of capillary attraction, which causes the mercury level in contact with the tube wall to be below the level in the center of the tube. The angle of contact at the edge of the liquid surface is about 132° between mercury and glass but varies with the cleanliness of the glass surface and the purity of the mercury. It is therefore good practice to use the level of the mercury column in the center of the tube for obtaining more accurate pressure values.

Mercury separation is the most serious risk, because if the filtering element at the top of the calibrated tube becomes blocked by separated mercury, the manometer is then an "air compression" manometer; as pressure is applied, the air above the mercury column becomes compressed and resists the rise of the mercury in response to applied pressure. The minimum tube dimension of 3.9 mm represents a compromise between the minimum of 4.0 mm required by the International Organization of Legal Metrology (OIML, 1973) and the 3.8 mm-diameter tubes of some commercially available sphygmomanometers.

A.4.4.2.7 Pressure-sensitive element

For proper and accurate manometer performance, the external pressure of the sensing element should be identical to the external pressure on the system being measured. The manometer tube for a mercury gravity sphygmomanometer should be vented to the atmosphere to prevent the development of differential pressure due to changes in air compression or temperature.

A.4.4.2.8 Leakage

See A.4.4.1.8

A.4.4.2.9 Mercury spillage

Mercury spillage is impermissible when a mercury loss sufficient to lower the level in the calibrated tube to below "0" will introduce a serious error in readings, even though the error will be uniform over the range of the manometer. Prevention of mercury spillage is also necessary because the loss of a large quantity will make the manometer unusable at the higher end of its scale, if insufficient mercury remains in the manometer to cover the entire range. Mercury spillage may also be a hazard to the user. For these reasons, it is essential that manometers be fitted with devices to prevent the escape of mercury through the top of the tube (by means of a porous device), through the bottom of the tube during shipment (by means of a temporary seal), and through the reservoir.

A.4.4.2.10 Pressure capacity

See A.4.4.1.12

A.4.5 Requirement for the inflation source and pressure control valve

A.4.5.1 Inflation source

Cuff inflation rates that are too high may be painful or startling to the subject or patient; inflation rates that are too low may cause venous congestion. In the latter case, accurate detection of the Korotkoff sounds may be affected, and there could be some effect on the diastolic pressure measurement. The limits chosen for cuff inflation rates reflect present-day practice.

A.4.5.2 Manually adjustable valve

The recommended rate of pressure release established by the AHA is 2 and 3 mm Hg per second (AHA, 1981). To ensure that this rate can be controlled by the valve, the maximum valve leakage should not exceed one-half of the minimum acceptable rate (i.e., 1 mm Hg per second), as determined in a total system under operating conditions. The volume of the smallest cuff in normal use (excluding the neonatal cuff) is approximately 80 cc. The leakage should be measured at three pressures throughout the range to verify proper functioning of the check valve within the adjustable valve, particularly at the lower pressures.

A standard adult cuff has an in-use volume of approximately 200 cc. After the diastolic pressure is determined, the compression should be released on the limb as rapidly as possible. Occasional emergencies necessitate rapid reduction of the bladder pressure to facilitate immediate removal of the cuff. Since the diastolic pressure is usually less than 90 mm Hg, a valve meeting the requirements of 4.5.2.2 should function very satisfactorily at lower pressures.

A.4.5.3 Self-bleeding pressure control valve

An inexperienced layperson taking his or her own blood pressure may sometimes have difficulty controlling the cuff deflation rate while simultaneously concentrating on Korotkoff sounds and observing the constantly changing manometer. Sphygmomanometers with integral self-bleeding valves and self-bleed valve accessories are available that simplify this process and can enhance repeatability and consistency of performance. Since the bleed rate for this type of valve may be user adjusted by varying cuff tightness, the 2- to 6-mm Hg/sec range is considered adequate for home use. (See also A.4.5.2, the rationale for the manually adjustable valve requirements.)

A.4.5.4 Hose connectors

Excessive leakage can prevent adequate control of the pressure release rate in a total system.

A.4.6 Requirements for the inflatable bladder and cuff

The combined blood pressure cuff and bladder act as the interface between the patient and manometer and could introduce major errors, either through improper design of the cuff or bladder or through improper application of the system by the user. The design of the inflation system shall take into consideration the user's ability to apply it routinely with the bladder centered over the artery to be compressed.

In order to minimize measurement errors attributable to the design of the inflation system, dimensional and performance requirements were developed for the inflatable bladder, cuff, and cuff with integral bladder.

A.4.6.1 Inflatable bladder

A.4.6.1.1 Dimensions

The AAMI Sphygmomanometer Committee has been strongly in favor of bladder dimension specifications that are compatible with the AHA's recommendations. Unfortunately, controversy over the optimum dimensions has persisted, resulting in a lack of consistency in AHA published recommendations since 1967. This controversy exists largely because of the paucity of experimental data.

History—Until 1981, it had long been the recommendation of the AHA that:

> The inflatable bag should be long enough to go one-half way around the limb, if care is taken to put it directly over the compressible artery. A bag 30 cm in length, which nearly (or completely) encircles the limb, obviates any risk of misapplication. Several investigators have found that cuff bladders of 35 to 40 cm in length provide a closer approximation of intra-arterial diastolic blood pressure and a reduction in random error (AHA, 1967).

In 1981, however, the AHA published revised recommendations on indirect blood pressure measurement (AHA, 1981). Shortly after the publication of the revised AHA recommendations, Dr. Walter Kirkendall, a

member of both the AHA and AAMI committees, was asked by the AAMI committee leadership to summarize the relationship between the AHA and AAMI recommendations with respect to bladder dimensions. On February 22, 1982, Dr. Kirkendall contributed the following statement to the AAMI committee record:

> ...AAMI proposed standards for non-automated sphygmomanometers...tend to maintain the status quo. The recommendations from the American Heart Association recognize the evidence that bladders which are relatively long and cover approximately 80 percent of the circumference of the arm or more, give somewhat more reliable estimates of the intra-arterial pressures. Obviously, in the [AHA] recommendations, not all of the bladders would extend over 80 percent of the circumference of the arm, but the trend in the recommendations is for the longer bladder to be used. The major difference in the two sets of recommendations is that the recommendations concerning length in the AAMI statement generally tend to recommend a shorter bladder. The AAMI statement concerning width of the bladder is consistent with the AHA recommendations.
>
> I will not repeat [the AHA] committee's reasons for recommending the bladder dimensions for blood pressure cuffs published in the AHA Committee Report. One of the major considerations would be to improve standardization of equipment so that the likelihood of obtaining reproducible results from one clinic to another would be greater. Nevertheless, the Committee is well aware that there [are] major unanswered questions concerning bladder dimensions, including:
>
> 1. Optimal length of the bladder to reflect intra-arterial pressure.
> 2. Optimal widths of the bladder.
> 3. Whether thickening, hardening, or other similar changes of the brachial artery [occurring] in the elderly limits efficiency of the recommended bladders.
>
> Until these and other questions are answered, there will continue to be sharp differences of opinion among physicians, physiologists, and manufacturers concerning bladder size.

The 1981 AHA recommendations for bladder length were as follows:

> The length of the bladder should be approximately twice the recommended width (bladder length equal to 80% of arm circumference). This nearly encircles the arm and minimizes risk of misapplication. Several investigators have found that cuff bladders of 35 to 40 cm in length provide a closer approximation of intra-arterial diastolic blood pressure in the adult of average size and a reduction of random error. However, it has not been conclusively demonstrated that these lengths provide valuable improvement over bladder lengths which are twice the width of the bladder and 80% of arm circumference. (AHA, 1981)

There appears to be a growing clinical consensus in favor of longer bladders, based on the "reason[ing] that a long bladder would allow better transmission of the pressure in the bladder to the underlying artery" (Geddes & Whistler, 1978) and on the view that a bladder nearly encircling the arm "minimizes risk of misapplication" (AHA, 1981). Nevertheless, agreement has not been reached on the exact relationship between bladder length and blood pressure measurement error or, therefore, on the optimum bladder lengths for various arm circumferences.

A set of specific cuff/bladder dimensions was advocated that conformed in varying degrees to the 1981 AHA recommendation that "length of the bladder should be approximately twice the recommended width." The AAMI committee considered adopting a requirement that would codify the AHA recommendation. It was ultimately decided, however, that for purposes of minimum standard, the more conservative, earlier AHA recommendation (i.e., that the bladder should extend at least halfway around the arm) should be adopted.

There were four main reasons for this decision: First, a requirement that bladder length should be *approximately* twice the recommended bladder width was not considered appropriate for a standard, since conformance to the requirement could not be unambiguously demonstrated. Second, more research is needed to establish a precise specification for bladder length that could be justified on the basis of blood pressure measurement accuracy and incorporated into a minimum standard. The committee was concerned that mandating a change in present-day technology, in a field that may still be changing, would be arbitrary and unjustifiable in terms of safety or effectiveness. Third, most commercially available cuffs have an external marking that indicates the position of the center of the bladder in order to facilitate correct application to the limb; this mitigates somewhat the concern about potential measurement errors resulting from misapplication. Fourth, the specification of 4.6.1.1 is a *minimum* requirement that manufacturers are free to exceed as conditions warrant. Indeed, the committee urges users of the standard to keep apprised of relevant research, and the committee stands ready to adopt revisions of the standard whenever a clinical consensus is established on the question of bladder length and adequate research data are available to support a new minimum standard.

With respect to bladder width, the AHA said in 1967:

> The bag must be the correct width for the diameter of the patient's arm, for if it is too narrow, the blood pressure reading will be erroneously high; if it is too wide, the reading may be erroneously low. The inflatable bag should be 20 percent wider than the diameter of the limb on which it is to be used.

In 1981, the AHA suggested that the width of the inflatable bladder should be 40% of the circumference of the limb, measured at the mid-point of the limb (the point halfway between the acromion and the olecranon). These two methods of specifying the width result in almost identical values, but limb circumference is more readily measured than diameter. The 1986 AAMI standard required a bladder width that was 0.38 times the circumference of the largest limb, as this was the precise translation of the then-current AHA recommendation for bladder width/limb diameter (1.2/pi = 0.38).

Prineas (1991) has reviewed the basis for the 0.40 ratio recommendation, noting that most of the experimental work was performed by Geddes. Two recent publications by Sprafka et al. (1991) and Gomez et al. (1992) report on experiments intended to determine differences that occur when deviating from the 0.40 ratio. A deviation downwards results in greater overestimation of blood pressure than the underestimation with an equivalent deviation upwards in the ratio. Prineas has advised the AHA that an acceptable range for the ratio is 37% to 47% for both children and adults. This is considered to be superior to the recommendation of 33% to 43% for children as set forth in the Second U.S. Task Force Report on Blood Pressure in Children (Prineas et al., 1992).

Prineas notes that the choice of a 10% range (37% to 47%) for each cuff is dictated by the need to minimize the number of cuffs.

The optimum length of the cuff bladder has not been well studied. Ideally, the cuff bladder should completely surround the arm. Prineas states that there are no theoretical reasons why an overlapping cuff bladder would produce systematic errors. For practical reasons of commercial availability, however, minimum lengths of 80% and 100% of the limb circumference for adults and children, respectively, are suggested by the AHA. The AHA recommendations include a table of suggested cuff bladder sizes vis-a-vis limb dimensions.

A.4.6.1.2 Pressure capacity

A range of 0 mm Hg to a minimum of 260 mm Hg has been adopted as a minimum requirement for the manometer used in the blood pressure measurement. It is quite probable, however, that the bladder will be included in a system expected to perform satisfactorily at pressures as high as 300 mm Hg. A

10%-over-range protection for the bladder and integral tubing seems reasonable.

A.4.6.2 Cuff

(See also A.4.6.1.)

A.4.6.2.1 Dimensions

The cuff width should accommodate the width of the bladder. The AHA has recommended widths and lengths for seven bladder sizes (AHA, 1981) and has stated that, for contact closure cuffs and hooks cuffs, "the full width should extend beyond the end of the inflatable bladder for about 25 cm" (AHA, 1967). This statement refers to an adult cuff incorporating a bladder 24 cm in length (as per AHA recommendations). Since the AHA publication further recommends that the bladder be of sufficient length "to go one-half way around the limb", it follows that the cuff should maintain its full width while completely encircling the limb. It is believed that maintenance of the full cuff width throughout the cuff's contact with the limb will minimize discomfort to the patient. The AHA further recommends that, if the cloth bandage cuff is used, it should be long enough to encircle the arm several times with its full width extending beyond the end of the inflatable bladder for about 12 cm and then gradually tapering for an additional 40 cm (AHA, 1981).

A.4.6.2.2 Pressure capacity

The AHA (1981) recommendations further indicate that "the cuff should be made of nondistensible material, so that as far as possible, an even pressure is exerted on the extremity under the cuff". Furthermore, ECRI reported (1975) that "the cuff should not stretch nor allow the bag to balloon. Ballooning reduces the effect of bag width and may cause erroneously high pressure readings". Therefore, the bladder, when inflated to its maximum usable pressure, should be completely retained in the cuff.

A.4.6.2.3 Cuff closures/construction

See A.4.2.4 and A.4.6.2.2.

A.4.6.3 Cuff with integral bladder

See A.4.6.1 and A.4.6.2.

A.4.6.3.1 Dimensions

See A.4.6.2.1.

A.4.6.3.2 Pressure capacity

See A.4.6.2.2.

A.4.6.3.3 Cuff closures/construction

See A.4.2.4.

A.4.7 Requirements for system leakage

For proper and accurate performance, the leakage rate of the sphygmomanometer system as a whole should be low enough to permit the system to meet the requirements for accuracy and repeatability. The recommended rate of pressure release established by the AHA is 2 to 3 mm Hg per second. This rate should be controllable by a valve. These criteria can be satisfied if the leakage rate remains below 1 mm Hg per second for the entire system.

Annex B
(Informative)

References

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Annotation 1; Label: AAMI; Date: 10/02/2000 4:36:41 PM
1) National Fire Association, Batterymarch Park, Quincy, MA 02269.

Annotation 2; Label: AAMI; Date: 10/02/2000 4:37:15 PM
2) National Safe Transit Association, 625 North Michigan Avenue, Suite 500, Chicago, IL 60611.