American National Standard

ANSI/AAMI SP10:2002

Manual, electronic, or automated sphygmomanometers

AAMI Association for the Advancement of Medical Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decisionmaking.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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American National Standard

ANSI/AAMI SP10:2002
(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 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

AAMI Standard

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Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

Printed in the United States of America

ISBN 1–57020–183–8

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Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
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

International designation	U.S. designation	Equivalency
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
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

*FDIS approved; final document in production

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:

Cochairs:	Bruce Friedman, D. Eng. L. Michael Prisant, MD
Members:	Bruce S. Alpert, MD, University of Tennessee at Memphis Gerhard Frick, Microlife Systems AG Bruce Friedman, D. Eng, G.E. Medical Systems David Gallick, Suntech Medical Instruments Matthew A. Gingrich, Datex-Ohmeda Inc. Clarence E. Grim, MD, Medical College of Wisconsin Eric Gustafson, Siemens Medical Systems Michael Hayes, W.A. Baum Company Cindy Jayne, Medtronic Inc. Iwao Kojima, Omron Healthcare Inc. Bruce Z. Morgenstern, MD, Mayo Clinic David Osborn, Agilent Technologies L. Michael Prisant, MD, Medical College of Georgia Edward J. Roccella, PhD, National Institutes of Health Charles Setzer, Welch Allyn Katherine Stankus, Spacelabs Medical Inc. Leonard Steinfeld, MD, Mount Sinai Medical Center Sandy F. C. Stewart, PhD, U.S. Food and Drug Administration William B. White, MD, University of Connecticut Health Center Steven A. Yarows, MD, University of Michigan
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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.

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.

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.

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.

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.

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;

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;

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."

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.

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.

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.

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

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.)

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.

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.

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.

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.

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.

5.4.1.6.A 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.A, the pointer shall travel a minimum of 15 angular degrees from the atmospheric pressure point to the pointer restraint device.

5.4.1.7.A External adjustments

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

5.4.1.8.A Manometers without integral pressure control

To determine compliance with 4.4.1.8.A, the manometer is connected to a volume of 200 cm^3 to 220 cm^3 and subjected to the specified pressures for a period of 10 s.

5.4.1.9.A Manometers with integral pressure control

See 5.5.2.

5.4.1.10.A 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.A.

5.4.1.11.A Pressure-sensitive element

Compliance with 4.4.1.11.A can be determined by visual inspection.

5.4.1.12.A Pressure capacity

The manometer is subjected to a differential pressure of 300 mmHg for at least 60 s. 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.A Mercury manometers

5.4.2.1.A Range

Compliance with 4.4.2.1.A can be determined by visual inspection.

5.4.2.2.A Graduations

Compliance with 4.4.2.2.A can be determined by visual inspection.

5.4.2.3.A Accuracy of pressure measurement

See 5.4.4B. A consistent point on the mercury column shall be used for all pressure readings. (See A.4.4.2.6.)

5.4.2.4.A Repeatability

See 5.4.1.4.A.

5.4.2.5.A 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.A.

5.4.2.6.A 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.A. 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.A Pressure-sensitive element

Compliance with 4.4.2.7.A can be determined by visual inspection.

5.4.2.8.A Leakage

To determine compliance with 4.4.2.8.A, the manometer is connected to a maximum volume of 200 cm^3 and subjected to the specified pressures for 10 s.

5.4.2.9.A Mercury spillage

The mercury gravity 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 mmHg is applied for at least 60 s to determine compliance with the first requirement of 4.4.2.9.A. Next, the mercury gravity manometer is prepared for shipment according to 4.4.2.9.A and then turned upside down, vigorously shaken, and visually inspected to determine compliance with the remaining requirements of 4.4.2.9.A.

5.4.2.10.A Pressure capacity

See 5.4.1.12.A.

5.4.3.A Electronic manometers

5.4.3.1.A Range

Compliance with 4.4.3.1.A can be determined by visual inspection.

5.4.3.2.A Resolution

Compliance with 4.4.3.2.A can be determined by visual inspection.

5.4.3.3.A Accuracy of pressure measurement

The accuracy of the pressure transducing/indicating system is determined by applying a “Y” adaptor to the pressure line and attaching a reference standard (traceable to the National Institute of Standards and Technology) having a maximum error of ± 0.5 mmHg. (See Figure B.3.)

The line pressure is then stepped down from 300 mmHg (or the maximum pressure of the device), in intervals no greater than 30 mmHg in accordance with customary device use, and the accuracy of the indicated pressure with respect to the reference standard is determined.

5.4.3.4.A Repeatability

See 5.4.1.4.A.

5.4.3.5.A Pressure-sensitive element

Compliance with 4.4.3.5.A can be determined by visual inspection.

5.4.3.6.A Leakage

To determine compliance with 4.4.3.6.A, the manometer is connected to a maximum volume of 200 cm^3 and subjected to the specified pressures for 10 s.

Section B: Automated sphygmomanometers

4.2.3.2.B 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.B.

4.3.B Safety requirements

Requirements of 4.3 apply.

4.4.B Performance requirements

4.4.4.B Pressure transducer accuracy

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.

NOTE—If a zero or range control is provided, proper instructions for operation and verification should be attached to the device as a readily visible label. If the zeroing function is performed automatically, then the device should automatically reset to zero when required and meet the accuracy requirement of this section without operator intervention.

4.4.5.B Overall system efficacy

The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the requirements of 4.4.5.1.B (auscultatory method) or 4.4.5.2.B (intra-arterial method) consistent with the labeling (4.1.3).

The selection methods for individuals entered into the study shall not introduce bias. Data shall be included for all subjects entered into the validation study. If technical problems prevent obtaining the required data, a full explanation of and the reasons for data exclusion shall be provided and documented. Technical recommendations for conducting the comparison tests are provided in annex B (auscultatory method) and annex C (intra-arterial method). Additional statistical background is supplied in annex F.

4.4.5.1.B Auscultatory method as the reference standard

Both Method 1 and Method 2 should be used to evaluate the accuracy data.

4.4.5.1.1.B Method 1

The subject database shall be documented and shall contain no fewer than 85 subjects with a minimum of 255 (= 3*85) observations. For any subject not contributing 3 data sets, additional subjects will be tested to reach the minimum number of 255 observations.

The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the following requirement: For systolic and diastolic pressures, treated separately, the mean difference of the 255 individual paired measurements of the test system and the comparison system shall be ± 5 mmHg or less, with a standard deviation of 8 mmHg or less.

4.4.5.1.2.B Method 2

The subject database shall be documented and shall contain no fewer than 85 subjects. Each subject shall contribute 3 paired observations. The data from these 3 observations is then averaged before further data analysis.

The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the following requirement: For systolic and diastolic pressures, treated separately, the mean difference of the 85 averaged paired measurements of the test system and the comparison system meets the standard of a mean difference of and standard deviation as defined in Table 1.

Table 1—Upper limit on the standard deviation of paired differences for given values of the mean of the paired differences.

Mean difference	Standard deviation
0	6.95 or less
± 0.5	6.93 or less
± 1.0	6.87 or less
± 1.5	6.78 or less
± 2.0	6.65 or less
± 2.5	6.47 or less
± 3.0	6.25 or less
± 3.5	5.97 or less
± 4.0	5.64 or less
± 4.5	5.24 or less
± 5.0	4.81 or less

For example, if the mean difference is –1.5 mmHg, the standard deviation shall be 6.78 or less to accept the device. A mean difference greater than 5 mmHg or less than –5 mmHg causes immediate rejection of the device. Linear interpolation is used for mean differences between two values of the table. See annex F for further details.

A report of study findings, which shall be made available by the manufacturer upon request, shall contain at least the following statistics and descriptors (with systolic and diastolic values computed separately):

a) Target population and selection procedure;

b) Number of subjects or patients;

c) Special categories of patients;

d) Range and distribution of arm size;

e) Range and distribution of systolic and diastolic pressures;

f) Range and distribution of heart rate and description of rhythm disturbances and auscultatory gaps;

g) Mean difference and standard deviation for systolic and diastolic measurements between the instrument under evaluation and the reference system;

h) Graphical display of differences against averages for systolic and diastolic measurement pairs, separately (Bland and Altman, 1986);

NOTE—For convenience in the remainder of this standard, this plot is referred to as a Bland-Altman plot.

i) Percentages of readings with differences within 5 mmHg, 10 mmHg, and 15 mmHg;

j) Model serial number of the unit(s) tested; and

k) Whether K4 or K5 is used for determination of diastolic pressure.

4.4.5.2.B Intra-arterial method as the reference standard

NOTE—Intra-arterial methods are invasive and should not be used for patients or subjects solely for the purpose of validating instrument performance. Annex C suggests situations in which such measurements can be obtained for patients in whom intra-arterial lines have been placed for accomplishing clinical studies.

For systolic, mean, and diastolic pressures, treated separately, the mean and standard deviation of the difference of the paired measurements of the test system and the comparison system shall be ± 5 (with a standard deviation) less than or equal to 8 mmHg.

A report of study findings, which shall be made available by the manufacturer upon request, shall contain at least the same information as is required in 4.4.5.1.B for the auscultatory method. In addition, the specific arterial bed(s) in which blood pressure measurements are taken shall be defined.

4.5.B Requirements for inflation source and pressure control valves

4.5.1.B Inflation source

For automated sphygmomanometers with manual valves, refer to the requirements in 4.4.

4.5.4.B Automated valves

4.5.4.1.B Pressure drop

With the valve closed, the maximum pressure drop with a volume of no more than 200 cm^3 shall be 2 mmHg in 10 s at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.5.4.2.B Valve/cuff exhaust rate

The valve shall be adjustable and shall allow pressure reduction to be controlled and maintained at a rate appropriate for the accurate determination of blood pressure as verified in 4.4.B.

4.5.4.3.B 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.

5.2.B Environmental performance and stability

5.2.3.B Vibration and shock

5.2.3.2.B 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 IEC 60601-1, sections 21.5 and 21.6 as appropriate (normative reference 2.6).

5.3.B Safety requirements

5.3.1.B Devices incorporating automatic inflation systems

5.3.1.1.B Maximum cuff pressure

For this determination, a “Y” adapter is hooked in parallel with the reference standard, the inflation system is activated, and the cuff pressure is read. The device shall meet the requirements of 4.3.1.1.

5.3.1.2.B Release rate

Compliance with the requirement of 4.3.1.2 can be verified by visual inspection and by following the manufacturer’s instructions for cuff deflation.

5.4.B Performance requirements

5.4.4.B Pressure transducer accuracy

The accuracy of the pressure transducing/indicating system is determined by applying a “Y” adapter to the pressure line and attaching a reference standard (traceable to the National Institute of Standards and Technology) having a maximum error of ± 1 mmHg. (See Figure B.3 for an example.) The pressure drop in the tubing from the cuff to the “Y” adapter shall not exceed 0.5 mmHg. (It is recommended that the length of the tubing between the cuff and the “Y” adapter be on the order of 4 inches [10 cm].) The line pressure is then stepped down from 300 mmHg in intervals no greater than 30 mmHg and in accordance with customary device use and the accuracy of the indicated pressure with respect to the reference standard is determined. The dynamic accuracy is tested by reducing the pressure from 300 mmHg to zero at a rate of 3 mmHg/s ± 1 mmHg/s, and by reading simultaneously the device and the reference gauge. The difference between the two readings shall comply with 4.4. For systems that do not display pressure

under dynamic conditions, provision shall be made by the manufacturer to allow connection of appropriate auxiliary equipment to obtain measurements.

5.4.5.B Overall system efficacy

NOTE—Because of its complexity, this test for determining overall system efficacy is not intended for quality assurance purposes, but rather for design qualification only. The test may be conducted under environmental conditions that are anywhere within the ranges specified in 4.2.2. (See also 5.2.)

5.4.5.1.1.B Reference standard (Note this is applicable for 4.4.5.1.1 and 4.4.5.1.2)

The sphygmomanometer used as the reference standard shall comply with 4.4.A, except that its maximum calibration error shall be 1 mmHg at the temperature of the test.

Device intended for use in adult population

The device shall be tested over a range of arm sizes and pressures—i.e., at least 10 % of subjects below 100 mmHg systolic based on the reading from the reference device, 10 % above 160 mmHg systolic, 10 % below 60 mmHg diastolic, and 10 % above 100 mmHg diastolic, with the remainder distributed between these outer limits.

Ten percent of the subjects should have an arm size of less than 25 cm in circumference and 10 % greater than 35 cm in circumference, with the remainder distributed between these outer limits. The appropriate cuff sizes are determined in 4.6. All cuffs intended for use in the target population shall be utilized.

Different blood pressure ranges and arm-size distributions are acceptable if the device is intended to be used for a special patient population. It is suggested that study populations include any special populations for which performance is known to be compromised (e.g., diabetics, elderly, renal failure patients, arrhythmias).

If the device is designed for use with a single size cuff, at least 40 % of the subjects should have a limb circumference in the upper half of the cuff range, and 40 % should have a circumference in the lower half of the range.

Device intended for use in adult/pediatric populations

This addition to the adult standard shall include children 3 years to 12 years of age. Subjects greater than 12 years of age will be eligible to be included in the adult subject group. Manufacturers validating the device down to 3 years shall include a minimum of 12 subjects greater than or equal to 3 years of age and less than or equal to 12 years of age.

The subject database shall be documented and shall contain no fewer than 85 adult/pediatric subjects with a minimum of 255 paired observations. This standard requires that the total number of acceptable data sets will meet the AAMI minimum requirement of 255 data points, but each subject is not required to contribute 3 data sets. For any subjects not contributing 3 data sets, additional subjects will be tested to reach the minimum number of data points. However, if the manufacturer chooses to use 4.4.5.1.2.B Method 2, each subject shall contribute 3 paired observations.

The device shall be tested over a range of arm sizes and pressures—i.e., at least 10 % below 100 mmHg systolic, 10 % above 160 mmHg systolic, 10 % below 60 mmHg diastolic, and 10 % above 100 mmHg diastolic, with the remainder distributed between these outer limits.

Ten percent of the subjects should have an arm size of less than 25 cm in circumference, and 10 % greater than 35 cm in circumference, with the remainder distributed between these outer limits. The appropriate cuff sizes are determined in 4.6. All cuffs intended for use in the target population shall be utilized.

Different blood pressure ranges and arm-size distributions are acceptable if the device is intended to be used for a special patient population. It is suggested that study populations include any special populations for which performance is known to be compromised (e.g., diabetics, elderly, renal failure patients, arrhythmias).

There is no gender specification.

The manufacturer shall specify in children 12 years of age and younger whether diastole is identified using the 4th or 5th Korotkoff sound.

All cuffs intended for use on adults and children 3 years to 12 years of age shall be utilized.

Children less than 3 years of age shall be tested using the intra-arterial method as the reference standard.

Cuff size for auscultatory measurements shall conform to current ANSI/AAMI bladder dimension requirements (4.6.1.1, 4.6.3.1).

Devices intended for neonate, infant, and pediatric populations (less than 3 years of age)

Children less than 3 years of age shall be tested using the intra-arterial method as the reference standard.

5.4.5.1.2 Reference standard

See 5.4.5.1.1.

5.4.5.1.3.B Measurements

Two trained observers shall make simultaneous, blinded blood pressure determinations on each subject, and the observers' individual values for each reading shall be averaged for purposes of calculations.

One hundred percent of simultaneous measurements of observers shall agree within 10 mmHg, and 90 % or more shall agree within 5 mmHg. Any measurements with observer-to-observer differences greater than 10 mmHg shall not be included in the data set.

Three sets of blood pressure measurements, obtained over a period of 6 min to 30 min, shall be recorded for each subject.

5.4.5.1.4.B Test conditions

Single-arm measurements (using a "Y" connector) are clearly best when possible, allowing for simultaneous, automated, and manual blood pressure measurements.

Sequential single-arm measurements are preferable to simultaneous dual-arm recordings, since interarm variability tends to exceed the variability of repeated single-arm measurements over short time periods. (See Figure B.2.). When sequential measurements are employed, the order of the test and reference measurements should be randomized.

Simultaneous measurements shall be obtained using the same limb for the auscultatory and automated systems unless the cuff sizes and bleed rates for the automated system do not conform to the specifications of 4.5.2.2.

If different limbs are used for simultaneous measurements, additional tests shall be performed for each subject to determine physiologic differences in limb blood pressures. These differences shall be taken into account in calculating agreement. The device should have a test mode to delay emptying the pressure in the cuff until after deflation to a low value (40 mmHg) to permit observer measurement of the diastolic pressure.

For ambulatory devices, testing shall be conducted with subjects in three positions—supine, seated, and standing—and the specified number of subjects shall be met for each condition.

5.4.5.2.B Intra-arterial method as the reference standard

The efficacy of the overall system shall be determined by statistically comparing the blood pressure measurements obtained with the system to those obtained by the intra-arterial method. Technical recommendations for conducting the comparison test are provided in annex C (the intra-arterial method). Annex D provides recommendations on data analysis.

NOTE—Intra-arterial methods are invasive and should not be used for patients or subjects solely for the purpose of validating instrument performance. Annex C suggests situations in which such measurements can be obtained for patients in whom intra-arterial lines have been placed for accomplishing clinical procedures.

5.4.5.2.1.B Reference standard (intra-arterial)

See annex C.

5.4.5.2.2.B Study population

Device intended for use in adult population

The subject database shall be documented and shall contain no fewer than 15 subjects with a minimum of 150 paired observations. A minimum of 5 and a maximum of 10 paired measurements per subject shall be made. The device shall be tested over a range of arm sizes and pressures—i.e., at least 10 % of subjects below 100 mmHg systolic, 10 % above 160 mmHg systolic, 10 % below 60 mmHg diastolic, and 10 % above 90 mmHg diastolic, with the remainder distributed between these outer limits.

Ten percent of the samples should have an arm size of less than 25 cm in circumference, and 10 % greater than 35 cm in circumference, with the remainder distributed between these outer limits. The appropriate cuff sizes are determined in 4.6.

Different blood pressure ranges and arm-size distributions are acceptable if the device is intended to be used for a special patient population. It is suggested that study populations include any special populations for which performance is known to be compromised (e.g., diabetics, elderly, renal failure patients, arrhythmias).

Device intended for use in adult/pediatric populations

The sample size will be at least 20 adult/pediatric subjects with a minimum of 180 paired observations. A minimum of 5 and a maximum of 10 paired measurements per subject shall be made. At least 6 subjects greater than or equal to 3 years of age and less than or equal to 12 years of age are required for testing by manufacturers. Subjects greater than 12 years of age will be eligible to be included in the adult subject group. No additional blood pressure ranges are listed except those already in the adult standard. Cuff size shall conform to the requirements of 4.6. All cuffs intended for use in children (3 years to 12 years of age) shall be utilized. There is no gender specification. Subjects should be selected so that there is no cardiac or vascular malformation that results in an abnormal waveform inappropriate to be considered a reference standard. No arterial site is excluded in the pediatric population, but the manufacturer shall disclose the arterial site used as the reference.

Device intended for use in infant population

The sample size will be at least 15 infant subjects with a minimum of 100 paired observations. A minimum of 5 and a maximum of 10 paired measurements per subject shall be made. The following groups in this infant group are required for testing by manufacturers:

— At least 6 subjects greater than or equal to 29 days and less than 1 year of age; and

— At least 6 subjects greater than or equal to 1 year and less than 3 years of age.

The remaining 3 infants may be from any of the above age groups in order to complete the sample size of 15.

There is no gender specification. There are no requirements for the range of blood pressures measured in the study. Cuff size shall conform to the requirements of 4.6. Subjects should be selected so that there is no cardiac or vascular malformation that results in an abnormal waveform inappropriate to be considered a reference standard. No arterial site is excluded, but the manufacturer shall disclose the arterial site used as the reference. All cuffs intended for use in infants should be utilized. If a cuff size is not utilized, then a statement of how the manufacturer determined the accuracy of the non-invasive blood pressure (NIBP) monitor/cuff system shall be provided.

Device intended for use in neonatal/infant populations

The sample size will be at least 18 neonatal/infant subjects with a minimum of 150 paired observations. A minimum of 5 and a maximum of 10 paired measurements per subject shall be made. The following 5 groups in this neonatal/ infant group are required for testing by manufacturers:

— At least 3 subjects less than 1,000 g;

— At least 3 subjects 1,000 g to 2,000 g;

— At least 3 subjects greater than 2,000 g;

— At least 3 subjects greater than or equal to 29 days and less than 1 year of age; and

— At least 3 subjects greater than or equal to 1 year and less than 3 years of age.

The remaining neonates/infants may be from any of the above weight and/or age groups in order to complete the sample size of 18.

There is no gender specification. There are no requirements for the range of blood pressures measured in the study. Cuff size shall conform to the requirements of 4.6. Subjects should be selected so that there is no cardiac or vascular malformation that results in an abnormal waveform inappropriate to be considered a reference standard. No arterial site is excluded, but the manufacturer shall disclose the arterial site used as the reference. All cuffs intended for use in neonates/infants should be utilized. If a cuff size is not utilized, then a statement of how the manufacturer determined the accuracy of the NIBP monitor/cuff system shall be provided.

Device intended for use in neonatal population

The subject database shall be documented and shall contain no fewer than 15 neonatal subjects. The validation for neonates shall use intra-arterial measurements as the standard since auscultation is not appropriate. A minimum of 5 and a maximum of 10 sets of paired measurements shall be made, with measurements spaced at least 3 min apart. All data shall be used. The minimum number of entries paired values, taking all subjects into consideration, shall be 100. At least 3 neonates in the following 3 groups are required for testing by manufacturers:

— Less than 1,000 g;

— 1,001 g to 2,000 g; and

— Greater than 2,000 g.

There is no gender specification. There are no requirements for the range of blood pressures measured in the study. Cuff size shall conform to the requirements of 4.6. Subjects should be selected so that there is no cardiac or vascular malformation that results in an abnormal waveform inappropriate to be considered a reference standard. No arterial site is excluded, but the manufacturer shall disclose the arterial site used as the reference. All cuffs intended for use in neonates should be utilized. If a cuff size is not utilized, then a statement of how the manufacturer determined the accuracy of the NIBP monitor/cuff system shall be provided.

5.4.5.2.3.B Measurements

For the intra-arterial method, a minimum of 5 and a maximum of 10 paired measurements per subject shall be made, obtained over a period of 10 min to 60 min.

If more than 10 measurements are obtained for any subject, the first 10 paired measurements shall be used for data analysis. Each set of paired values (systolic, mean, and diastolic) shall become part of the database used for computing statistics.

Agreement between the intra-arterial pressure findings and the pressure values obtained by the instrument under test shall be determined according to the procedures of annex C.

5.4.5.2.4.B Test conditions

Due to the inherent risk of movement with an intra-arterial catheter, devices shall be tested with the patient/subject in the supine position. For adult subjects, the intra-arterial catheter can be placed at the axillary or subclavian artery level, proximal to the cuff of the indirect device being tested on the same arm. For neonates and infants, the umbilical artery is the preferred measurement site.

5.5.B Requirements for inflation source and pressure control valves

5.5.1.B Inflation source

See 5.5.1.

For automated sphygmomanometers with manual valves, refer to the requirements in 5.5.

5.5.4 Automated valves

5.5.4.1.B Pressure drop

The system 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 4.5.4.1.B at differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

5.5.4.2.B Valve/cuff exhaust rate

Compliance with 4.5.4.2.B is met by compliance with the requirements of 4.4.B.

5.5.4.3.B 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.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

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

Invasive blood pressure measurements with an indwelling catheter are generally accepted as the "gold standard" for the measurement of blood pressure (Brunner, 1981a, 1981b, 1981c). However, the technique is invasive and carries risks to the patient. Therefore, it is generally used only when the patient's hemodynamic condition justifies the risks associated with the procedure. Accurate measurement of invasive pressures requires an understanding of the requirements for fidelity of the catheter/transducer system (Gardner, Kleinman, and Heimann,), knowledge of the proper placement of the transducer to avoid hydrostatic errors (Berliner and Campbell), and recognition of the variation in blood pressure between the aorta and the peripheral arteries (O'Rourke and Gevers).

Indirect blood pressure measurement devices either can be nonautomated (manual) or electronic/automated. Clinicians use manual sphygmomanometers to assess a patient's vital signs and to monitor and treat hypertension. Measurements made with manual sphygmomanometers and a stethoscope employ the auscultatory method of indirect blood pressure measurement. This method is widely accepted as a clinical standard, and is the basis for the assessment and treatment of hypertension (NIH, 1997). Numerous studies have addressed the differences between manual auscultation and invasive blood pressure measurements (Bruner, Hunyor, and King). The differences can be large (24 mmHg for systolic, 16 mmHg for diastolic), and the errors appear to be random (O'Brien, 1990). Errors associated with this technique include incorrect choice of cuff size, digit preference, and inadequate training of observers (AHA, 1993).

Electronic or automated sphygmomanometers have application in hospitals to provide monitoring of a patient's hemodynamic status, in the home for self-measurement of blood pressure, in physician's offices, and in population screening. Automated sphygmomanometers can be based on any of several techniques (oscillometric is the most common and is replacing the auscultatory technique). Electronic or automated blood pressure measurement techniques might require different sizes or types of cuff for the same patient limb dimensions, and such variation is acceptable provided that overall system performance complies with this standard. Numerous studies have compared the accuracy of automated monitors to either an invasive standard or a manual auscultatory standard. These devices have the advantage of limiting the variable human error in measurement; however, they may have intrinsic errors based on algorithm measurement differences between manufacturers and due to subject rhythm disturbances, variation in a patient's compliance, or patient movement.

Recently, an increasing number of manufacturers have developed home-use devices for application on the wrist. These devices are small and compact (no tube connections) and are easy for consumers to apply and use. The relatively small variation in wrist size when compared to upper arm size allows one cuff size to cover a wide range of subjects.

However, these devices show higher inter-individual scattering than comparable devices for the upper arm (Wessig). Clinical trials have shown that wrist measurement can reach similar accuracy to upper arm measurements of home-use devices. However, about 10 % to 20 % of the patients show a relevant deviation of their wrist-values, compared to the auscultatory reference on the same upper arm. This can be affected by the shape of the wrist, the amount of soft tissue, and even by a third artery (a. *medianis*), which exists in about 3.5 % of the population. Users of wrist-type monitors should check the agreement between the values on the wrist and the auscultatory reference on the upper arm prior to the purchase of such a device. Manufacturers also should be encouraged to develop technical solutions that allow more accurate wrist measurements under extraordinary anatomic conditions.

For devices to be applied on the wrist, the applicable wrist circumference range for adults should include the range of 13.5 cm to 19.5 cm at least, measured around the carpal joint (approximately correlating to an upper arm range of 22 cm to 32 cm circumference). There is no common recommendation for a suitable cuff/bladder size and design for wrist application. Clinical data provided by the manufacturer shall support the claimed wrist circumference range.

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. Blood pressure is routinely measured on all hospitalized patients by either automated or manual sphygmomanometers.

Further, many sphygmomanometers are purchased by individuals on the advice of their physicians or in response to mass advertising. In addition, individuals can make use of automated equipment in pharmacies and other retail stores. Blood pressure measurement in the home and similar unsupervised settings gives the consumer the responsibility of interpreting results and deciding whether further action (i.e., seeing a physician) is necessary. The effectiveness of this unsupervised screening and interpretation in the early detection of hypertension depends on the accuracy and reproducibility of the particular blood pressure measuring device and rests on the assumption that the consumer has adequate information to operate the device correctly and the device is safe for unsupervised use.

A.4 Rationale for the specific provisions of the standard

A.4.1 Labeling requirements

Regulations of the U.S. Food and Drug Administration (FDA) control the general labeling of medical devices. In particular, part 820, chapter 1, title 21 of the *Code of Federal Regulations*, *Good manufacturing practice for medical devices*, establishes requirements for proper handling, legibility, expiration dates, and many other aspects of labeling as they relate to good manufacturing practices. In addition, 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 are comprised in the federal regulations referred to in 4.1.1. All labeling pertaining to electronic or automated sphygmomanometers is controlled by these regulations and should comply with them.

These regulations do not address, however, the information that should accompany particular types of medical devices in order to help ensure that device users can make an appropriate choice for their particular application and use the device correctly. In view of the increasingly widespread use of electronic/automated sphygmomanometers in homes, public places, and other places where medical supervision is not available, the AAMI committee deemed it particularly important to develop labeling requirements that would help minimize the hazards of “possible misinterpretation of results, the establishment or lack of establishment of a diagnosis of hypertension without proper medical evaluation, and possible changes in treatment or lack of treatment without medical supervision” (Berkson, et al., 1979). Provision for this specialized labeling is required in 4.1.2, 4.1.3, and 4.1.4.

A.4.2 Environmental performance and stability

Electronic or automated sphygmomanometers might be exposed to extremes of temperature, humidity, and atmospheric pressure during shipment, storage, and use. Because such exposure is often unavoidable, the device should be designed and manufactured to remain accurate under adverse environmental conditions. No measurement device, however, particularly an electronic one, is completely invulnerable to all conceivable environmental extremes. Therefore, provision has been made in this standard to help ensure that the device will maintain its accuracy (as per 4.4.A and 4.4.B) over defined ranges of temperature, humidity, atmospheric pressure, as well as input voltages and frequencies. Furthermore, the device should withstand defined vibration and shock conditions, as well as a reasonable number of uses, without degradation of performance. All devices also shall meet the requirements for electromagnetic compatibility specified by the FDA.

These requirements were considered by the committee to embrace the 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 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 environmental performance requirements; many of the ECRI proposals were adopted for purposes of this standard, and are noted.

The committee, in this most recent revision, also utilized normative reference 2.7 (ISTA) for additional guidance on appropriate requirements for storage temperature requirements.

A.4.2.1 Storage conditions

Based on substantial documentation, ECRI’s final report proposed that all mobile and portable medical devices be capable of withstanding storage and shipping temperatures in the range of –30 °F (–34 °C) to 149 °F (65 °C). The committee concluded that this range was too wide for many “commercial-grade” electronic components such as liquid crystal displays. The somewhat narrower range specified in 4.2.1 is more reasonable for such components. The specified temperature range, humidity range, and storage time are intended to simulate environmental challenges which electronic sphygmomanometers frequently confront during transport or on-site storage.

The ECRI final report also includes data on 114 devices following 24 hour storage at each of the two extremes of –30 °F (–34 °C) and 151 °F (66 °C). Of 34 brands of sphygmomanometers among these 114 devices, one did not perform satisfactorily after 24 hour exposure to 151 °F (66 °C), and another did not perform satisfactorily after 24 hour storage at 30 °F (–34 °C). In addition to sphygmomanometers, the 114 devices included defibrillators, pacemakers, electrocardiographs, infusion pumps, aspirators, and resuscitators. Of a total of 457 tests conducted, a failure rate of 8.1 % occurred. ECRI concluded that designing to meet these temperature requirements "should not cause significant additional costs to medical device manufacturers and users." The committee judged that the more limited range of storage temperatures specified in 4.2.1 is well within the current state of the art for electronic sphygmomanometers.

In an attempt to harmonize with international standards, a joint working group (JWG) agreed on new requirements that would be incorporated in AAMI SP10 2002 and in EN 1060

A.4.2.2 Operating conditions

Most electronic or automated sphygmomanometers are used in a controlled environment (e.g., hospital, clinic, home, or public place). The operating range specified (50 °F to 104 °F [10 °C to 40 °C]) embraces the range reported by ECRI for this type of protected environment (61 °F to 104 °F [16 °C to 40 °C]).

Some devices, however, are used in the ambient environment by emergency care personnel, and thus might be subjected to greater temperature extremes than are ordinarily encountered in a protected environment. ECRI proposed that all devices be required to withstand operating temperatures of –6 °F (–21 °C) to 115 °F (46 °C), if they are likely to be used in emergency vehicles or in the ambient environment. The committee, in attempting to establish minimum essential performance requirements, decided that an operating range of 50 °F to 104 °F (10 °C to 40 °C) would provide ample assurance of performance under most conditions.

The range for relative humidity is consistent with the one proposed by ECRI for high-temperature conditions. Moreover, a rigorous challenge is presented to the device by the requirement that accuracy be maintained over a relative humidity range of 15 % to 90 %.

In an attempt to harmonize with international standards, a joint working group (JWG) agreed on new requirements that would be incorporated in AAMI SP10 2002 and in EN 1060

A.4.2.3 Vibration and shock

The requirement for packaged devices is intended to help ensure that a device will maintain its performance after sustaining the type of mechanical abuse that often occurs during shipment; the International Safe Transit Association has defined drop and vibration procedures to simulate shipment conditions. The requirement for unpackaged devices helps ensure that devices for home use will either withstand a reasonable level of mechanical abuse or provide an indication to the user that the device is malfunctioning and cannot be relied upon for accurate pressure measurements. Since electronic sphygmomanometers are fragile, the user is responsible for handling the device properly; nevertheless, the device should withstand at least a moderate drop test.

There was concern among committee members that the acceptability of a device would be determined by a single drop test of one unit. Thus, a minimum sample size of 10 has been specified, allowing no more than 2 to fail. Those that do fail should indicate their inability to pass the performance requirements, so that a user will know that an accidental drop has damaged the device.

A.4.2.4 Stability

The accuracy requirement of 4.4 should be met when the device is operating at voltages that deviate from the device's nominal rated voltage. The voltage range specified (104 Vrms to 127 Vrms) is derived from ANSI C84.1, *Voltage ratings for electric power systems and equipment (60 Hz)* (ANSI, 1982). ECRI conducted a study in which line voltages were recorded continuously for 23 hospitals in order to determine the typical variability in line voltages. During a total recording time in excess of 10,000 hours, voltages of less than 108 volts were observed less than 1 % of the time (17 h); no voltages greater than 129 volts were observed. Although electrical failures or power crises could create very unusual line voltages, a required voltage range of 104 Vrms to 127 Vrms is not only consistent with ECRI data, but also presents a rigorous challenge to the accuracy of electronic sphygmomanometers. Furthermore, referencing the ANSI standard is the best means of ensuring that the line voltage requirements of this ANSI/AAMI standard will be appropriately updated over time.

Safety and performance characteristics should be maintained for at least 10,000 full-scale pressure cycles—approximating 5 years of typical device application by the home user. Granted, this number of cycles does not approximate 5 years of use in a hospital setting; in fact, it probably corresponds to 6 months to 12 months of hospital use. However, for purposes of a minimum performance standard, a requirement that the device maintain its accuracy for a minimum of 10,000 full-scale pressure cycles is satisfactory and applicable to both home- and professional-use devices. In addition, industry experience suggests that most device failures are usually evident by

the time 8,000 cycles are reached; a 10,000-cycle requirement provides a reasonable margin for ensuring adequate performance.

A.4.2.4.1 Battery-powered devices

The condition of the battery will affect the reliability of measurements obtained from a battery-powered device, so provision should be made to alert the user when the battery begins to fail. The device should incorporate some means of detecting battery condition or means of protective shutdown in case of battery failure. The four methods given for accomplishing this are intended to be examples only.

A.4.3 Safety requirements

A.4.3.1 Devices incorporating automatic inflation systems

In conventional, manually-operated sphygmomanometers and those electronic devices where the cuff can be inflated by hand, it is difficult to achieve cuff pressures in excess of 330 mmHg; therefore, in such systems there is little risk that the patient will be subjected to prolonged periods of extreme cuff pressure. High-pressure systems are sometimes used in hospitals, however, to inflate the cuff. In addition, some blood pressure measurement devices incorporate automatic inflation systems which can produce cuff pressures far exceeding a safe or comfortable level. This is of particular concern when the patient cannot readily remove the cuff (e.g., unconscious patients not under constant supervision). Recognizing this potential hazard, the committee developed requirements pertaining to cuff pressure for devices incorporating high-pressure, automatic inflation systems.

Inflation pressures and times are particularly significant for neonates. This standard requires lower maximum pressures and shorter determination times for neonates that are in agreement with similar standards accepted by the European Community (IEC 60601-2-30).

The committee discussed the merits of addressing and limiting the rate of inflation for automated-cuff devices. Although a startle response can occur with unusually high inflation rates, there was no hard data available to indicate that harm can result. Therefore, to permit design flexibility, a specification for this parameter is not included in the standard.

A.4.3.1.1 Maximum cuff pressure

The committee chose to refer to the IEC 60601-2-30 standard for the requirements for limits of maximum cuff pressure. The limits outlined in this reference align closely with previous versions of this standard. The committee felt that choosing limits that differed from the IEC standard offered no added benefit to users, yet complicated the approval process for manufacturers.

A.4.3.1.2 Release rate

The device should incorporate manual means by which the subject can deflate the cuff, so that the subject can readily extricate himself or herself from the device in the event of an electrical power failure or if he or she becomes startled or alarmed by the measurement procedure.

A.4.3.2 Electrical safety

Electrical hazards in the use of blood pressure measurement devices in the home or mass screening efforts are rare, because the user is not normally connected to the electrical circuit of the device or attached to other electrical devices at the same time, and is more or less healthy. In the hospital, however, the patient can be electrically susceptible and might have contact with numerous other electrical devices, including the blood pressure measurement device. Therefore, electronic or automated sphygmomanometers intended for hospital use should comply with risk-current requirements and be designed with other electrical safety considerations in mind.

Numerous standards have been promulgated for the safety of electromedical equipment (ANSI, UL, IEC). Since these standards are relatively consistent, IEC 606061-1-1 has been chosen as a reference standard. This document defines maximum risk current for all categories of electromedical apparatus intended for use in the vicinity of patients. Several levels of risk current are specified, depending on the degree of intended contact between the device and the patient and, therefore, on the level of potential electrical hazard. The rationale for the particular risk current limits recommended in safe current limits for electromedical apparatus is provided in that standard.

A.4.3.3 Conductive components

Conductive components of the device should comply with normative reference 2.7 in order to minimize the possible explosion and fire hazard associated with the use of such components in the operating room or wherever flammable anesthetics are employed.

A.4.4 Performance requirements

A.4.4.1 Aneroid manometers

A.4.4.1.1 Range

Many mercury gravity manometers currently being sold and used have a range of 0 mmHg to 260 mmHg. This range has been found to be satisfactory for the measurement of human blood pressure, and has been accepted by the medical profession. If the manometer is not capable of measuring blood pressures up to at least 260 mmHg, 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 of pressure measurement

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 mmHg, 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 mmHg 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 also is an obvious need for proper performance under dynamic conditions. Sections 4.4.1.10.A requires 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 ± 3mmHg, successive readings could differ by as much as 6 mmHg from each other for any given manometer. The committee considered such an excursion excessive. Most available instruments can obtain a repeatability of 4 mmHg, 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 mmHg 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 mmHg error limit (Perlman et al., 1970):

> Of those instruments which did not record properly, 36.5 % (38 of 104) deviated more than ± 7 mmHg 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 mmHg 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 mmHg) than those which do not accurately register zero.

However, McKay, et al. , indicated that only 26 % of devices with an accurate zero produced accurate pressure readings.

The zero reading may be useful 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 also apply to manometers with integral pressure control.

A.4.4.1.10 Pointer-manometer exhaust rate

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 should 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 of pressure measurement

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 exhaust rate

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 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.A 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 degrees 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. The minimum tube dimension of 3.9 mm represents a compromise between the minimum of 4 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 also may 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.4.4.3 Electronic manometers

The electronic manometer performs the same function as the aneroid or mercury manometer and should meet the same performance standards.

A.4.4.4 Pressure transducer accuracy
A.4.4.5 Overall system efficacy—Automated systems

A critical factor in the early detection of hypertension is the accuracy of the blood pressure measurement device, particularly in the case of unsupervised use. While it is important that skilled health care professionals have blood pressure measurement devices that provide accurate and comparable measurements over time, it is equally important, if not more so, that accurate devices are available for nonprofessional or home users. In particular, accurate comparisons shall be made between home readings and those taken in the physician’s office. Comparing measurements is of great value in the long-term management of hypertension because periodic reassessment of the disease state is the basis for changes in the therapeutic regimen. Accuracy and reproducibility are also essential to individuals using coin-operated devices and to the success of mass-screening programs; the blood pressure measurement obtained might be the only criterion by which an individual decides whether to seek professional assistance. For these reasons, no distinction has been made in this standard between accuracy and efficacy requirements for devices intended for use principally by health care professionals and devices intended primarily for nonprofessional use.

Despite the many techniques and devices for the indirect measurement of blood pressure, no reference standard has been found that can accurately model the sounds, pulsations, and flows that occur in the brachial artery as an occluding cuff is deflated or inflated. Therefore, the requirements of this standard are for “efficacy determinations” by

comparison with a known and accepted method, either the manual cuff/stethoscope (auscultatory) technique or the direct intra-arterial technique.

The reading of any blood pressure measurement system is a function of the particular subject, measurement errors, and physiological variation. Measurement errors derive from both the instrument and the observer, the relative contribution of the two being a function of the type of blood pressure measurement system used. For example, electronic systems with digital displays entail little observer interpretation; therefore, the principal sources of measurement error lie in the pressure sensing, transducing, and indicating elements of the device itself and in the algorithm used (that part of the device intended to replace the trained observer). These device-related measurement errors can be limited by specifying the level of accuracy that the transducing/indicating element of the device meets; this standard recommends a maximum allowable error of ± 3 mmHg, or ± 2 % of the reading, whichever is greater, and this level helps ensure that overall system error can consistently be maintained at ± 5 mmHg.

Difficulty can be encountered when attempting to obtain simultaneous readings from the display of the device under test and the reference manometer as described in 5.4. One way of overcoming this difficulty is to videorecord the readouts over the test period so that both values at identical times can be more easily established when the videotape is played back.

Overall system efficacy is influenced by physiological variables such as the physical activity, emotional state, and body position of the subject, and therefore is more difficult to specify. The design of the blood pressure measurement system cannot completely compensate for such variables. This standard provides for a clinical assessment of overall system efficacy by requiring that the manufacturer establish initially, as one aspect of design qualification, that the device meets the requirement of 4.4. Generally speaking, the ± 5 mmHg mean-difference requirement is based on published data on the measurement accuracies obtainable by highly trained blood pressure technicians using manual sphygmomanometers (Berliner, et al., 1960; Rose, Holland, and Crowley, 1964; Wilcox, 1961) and on published comparisons of various blood pressure measurement techniques (Paulus, 1981; Ramsey, 1979; Yelderman and Ream, 1979). More important than the mean error is the error made on individual patients. The upper limit for the standard deviation in Table 1 is such that the estimated probability of erring by 10 mmHg for a given patient is at least 85 % (see annex F). The auscultatory and intra-arterial blood pressure measurement methods represent the best ways of design qualification at the present time, in the absence of a widely accepted, objective bench test that takes into account physiological variation. Annexes B and C provide guidelines for conducting tests of overall system efficacy by comparison with manual cuff/stethoscope measurements and intra-arterial measurements, respectively. Annex D provides guidelines for the interpretation and reporting of test data.

The issue of how to evaluate the accuracy of electronic/automated sphygmomanometers was debated more intensively by the committee than any other single issue. At the crux of these debates are the questions: (a) What should be the reference standard for blood pressure measurements? (b) What are appropriate error tolerances, considering both medical needs and technological capabilities? (c) What are appropriate ways of disclosing test findings? A number of recently published reports reviewed by the committee are relevant to this issue, and are summarized below.

In its early deliberations, the committee recommended that validation be based on either of two techniques: the intra-arterial method or the cuff/stethoscope auscultatory method. Unfortunately, the ideal study comparing the two methods remains to be done. No single study that has been reported has been conducted with subjects of a sufficient number and diversity to be completely convincing. The variability in results from the several studies that have been reported is undoubtedly caused by many factors. A further consideration is the practical problem of acquiring a diverse database with a sufficient number of individuals to achieve statistical confidence.

Reliability of intra-arterial measurements

Borow and Newburger (1982), Colan, et al. (1983), and Van Egmond, et al. (1985) reported on the reliability of intra-arterial measurements. The authors of the first two of these reports measured central aortic pressures simultaneously with noninvasively determined limb pressures, and noted that the differences in measured values were not influenced by cardiac index, systemic vascular resistance, heart rate, or left ventricular ejection fraction, which indicated that intra-arterial measurements were highly stable. Van Egmond made multiple intra-arterial blood pressure measurements in 20 surgical patients, calculated standard errors of estimate of 2.4 mmHg for both diastolic and systolic pressures, and concluded that intra-arterial blood pressure measurement errors are small and that measurements usually can be treated as standards.

Indirect versus intra-arterial measurements

Table A.1 summarizes a number of studies in which comparisons were made between indirect and intra-arterial measurements. Means of differences ranged from 0.8 mmHg to 13.4 mmHg and from 0.8 mmHg to 18 mmHg for systolic and diastolic values, respectively. On the basis of studies such as these, the conclusion can be drawn that directly and indirectly measured blood pressures differ, and that judging the accuracy of direct measurements by

comparing them with indirect measurements is not justified. This is equally true for indirect methods that use the manual cuff/stethoscope technique or any automated measurement techniques.

Intra-arterial measurements as the reference standard

There is almost universal agreement that "true" blood pressure is best determined using a reliable, calibrated transducer directly in an artery. There is also no disagreement that the direct intra-arterial measurement is fraught with its own set of problems, including variability with radial position, the effects of flow-velocity changes, and the frequency response of the transducer and amplifier. These problems are controllable, however, and reproducible results can be obtained under proper circumstances. All known non-intra-arterial methods for determining blood pressure do so by measuring a closely related parameter such as volume changes, diameter changes, or sound changes transmitted to an external transducer through various intervening tissues between arterial blood and body surface.

From the results of the studies listed in Table A.1, it can be concluded that it is difficult to find a sphygmomanometer based on indirect methods that yields both systolic and diastolic blood pressure values that are within ± 5 mmHg (mean) of intra-arterial values. In several instances, however, very good agreement was observed, particularly for systolic values. Thus, the feasibility of obtaining good agreement has been demonstrated. This, coupled with the studies indicating that under proper conditions, highly reliable measurements can be achieved with the intra-arterial method, makes a compelling argument for considering the intra-arterial method as one of two validation methods.

Manual cuff/stethoscope auscultation as the reference standard

In a practical sense, the manual cuff/stethoscope, trained-observer method would be a better reference standard than intra-arterial methods because it is easier and safer. A larger statistical sample can be used in testing than is the case for intra-arterial measurements. The drawback of the cuff/stethoscope method is that the correspondence of the measurements to intra-arterial measurements is not consistently within the desired 3 mmHg band. Means and standard deviations of differences between the two methods ranged widely over five recently published studies. This data can be summarized as follows:

Systolic		Diastolic	
Mean	SD	Mean	SD
0.9–12.3	1.3–13	8.3–18	1.1–9.3

Even so, the cuff/stethoscope method has been the basis for decision making by physicians for many years. Although the procedure is subject to the effects of variations among observers, there is a large body of literature supporting its use and reliability when auscultation is performed by trained individuals.

Table A.2 lists five studies in which various automated or semiautomated instruments were evaluated against a nonautomated cuff/stethoscope method. The subjects studied ranged in age from adolescence to at least 42 years (Sloan, et al. [1984] and Fitzgerald, et al. [1982] did not provide data on age). Across these five studies, the results were as follows for differences between the instrument under test and the cuff/stethoscope, trained-observer method:

Systolic		Diastolic	
Mean	SD	Mean	SD
0.8–5.8	0.4–10.6	0.2–3.3	4.6–8.4

These findings provide additional support for use of the cuff/stethoscope manual method as a reference standard against which other indirect methods can be evaluated.

Error bounds and reporting methods

A large body of literature, including the five studies listed in Table A.2, support the establishment of ± 5 mmHg as the maximum mean allowable difference between simultaneously measured pressures using the manual cuff/stethoscope technique and any automated or semiautomated indirect measurement technique.

This kind of agreement is likely to be much more difficult to achieve when measurements obtained by an electronic, indirect blood pressure measurement device are compared with intra-arterial measurements. Nevertheless, the committee judged that either validation method requires this same level of agreement in order for the user to have confidence in an instrument. This is especially true for an instrument based on the intra-arterial validation method, because its use requires greater skill in obtaining accurate measurements.

To achieve the desirable comparability among studies, the reporting of findings shall be standardized in some respects; minimum requirements for doing so are listed in 4.4.A and 4.4.B of the standard. The necessary statistics are straightforward, requiring no major effort in computation. Adherence to this type of reporting approach will be of considerable value to researchers and users. The committee judged that allowable error bounds for mean and standard deviation were the minimum requirements for which numerical values should be specified. Although no numerical values are specified for other required statistics, the user will have the opportunity to select an instrument that performs most satisfactorily for a certain purpose or population. For example, one system might perform best when applied to young people, while another might perform best at higher blood pressure levels. Such idiosyncrasies might be deduced by examining scatter plots and numbers of measurements outside of 95 % and 85 % limits, as mean values and standard deviations are often insufficient to permit this type of judgment.

The accuracy of blood pressure measurements is affected more by arm size and absolute value of blood pressure than by the age of the subject. Thus, the age distribution specified in the previous edition of this standard has been deleted in favor of the specifications in 4.4.A and 4.4.B of this revised standard.

Statistical justification for study sample size—Auscultatory method

The acceptable limits for the mean and standard deviation of errors in Table 1 were chosen so that the estimated probability of a 10 mmHg error or less is at least 85 %, and they can be used with any sample size. But this estimated probability is itself subject to error; the larger the sample size, the smaller the error. A sample size of 85 participants is sufficient to estimate the probability of erring by 10 mmHg or less to within about ± 7 % (see annex F).

The committee recognized that the validation method can be sensitive to the capabilities and experience of the individual acting as the trained observer. To compensate for this potential bias, a statistically sound procedure is to include observer variability in the design of the study. For this reason, the committee chose to specify that the validation is acceptable only if two different trained observers (rather than one) perform the comparison testing.

Statistical justification for study sample size—Intra-arterial method

The same minimum number of subjects would, under ideal circumstances, be specified for the intra-arterial validation method as for the cuff/stethoscope auscultatory method. The committee recognized, however, that the difficulty and expense associated with obtaining high-quality, intra-arterial blood pressure measurements are considerably greater than for indirect measurements. Thus, fewer subjects were specified.

In arriving at a study population of at least 15 subjects, the committee took into consideration the special problems and expense associated with this number of subjects, which is supported by the experience of some committee members. The committee recognized that confidence levels would be reduced with 15 subjects as compared to 85, but judged that the compromise was reasonable. For a standard deviation of 8 mm and a sample size of 15, the 95 % confidence interval for the mean difference of two measurements is ± 4 mm; that is, if the observed mean is 5 mm, the true mean is between 1 mm and 9 mm. See annex F for further details.

Two of the most important factors contributing to inaccuracies in blood pressure measurements are limb size and absolute value of blood pressure. The relation of cuff size to limb size is known to influence the accuracy of measurements. As only a discrete number of cuffs is ordinarily available, it is appropriate to evaluate sphygmomanometer accuracy over the wide range of limb sizes encountered in the population. At very high blood pressure levels, the effect of cuff size versus limb size is increased, and at very low blood pressure levels, diastolic measurements are often more variable because of the difficulty of detecting sounds. The requirement to have the study population cover a wide range and distribution of limb sizes and blood pressures is a recognition of these influences on accuracy. In the original version of this standard, age ranges were specified. Although subject age might also be an influence on accuracy, the committee now judges that subdividing samples into several age ranges without increasing sample size would not lead to statistically meaningful comparisons. Measurements of blood pressure in special populations such as the elderly, diabetics, and patients in renal failure are often more difficult compared to the general population. However, to specify sufficiently large sample sizes of such subjects would place an undue burden on manufacturers because considerably more than 85 subjects would be required. Nevertheless, this standard does not allow special population subjects to be omitted during patient or subject recruitment. If, in fact, a device cannot achieve the required performance level when applied to special populations, the manufacturer shall disclose this information

Rationale for weight bins in the neonatal population

In the clinical setting, blood pressure (BP) is seldom, if ever, measured in the healthy term newborn. Neonatal intensive care nurseries primarily treat preterm newborns. Technical problems with the accuracy of BP in small preterm newborns (less than 1,000 g) have led to the suggestion of statistically oversampling smaller infants out of proportion of their birth incidence.

Blood pressure ranges for the study populations

For the auscultatory validation method, the systolic and diastolic blood pressure ranges specified for the subject database challenge the device to measure pressure accurately over a range of values normally encountered in both healthy and hypertensive individuals. The specified blood pressure ranges are not so wide, however, as to create extraordinary difficulties in enrolling subjects.

Recording of data/multiple measurements

For any study, it is possible to obtain multiple measurements for comparison of blood pressure data from the instrument under test and the reference standard. A single set of measurements per study should be used. For cuff/stethoscope auscultation, however, it has long been clinical practice to obtain several (usually 3) blood pressure readings from an individual in order to take into account the many factors contributing to variability in readings. For these same reasons, the procedure described in 5.2.5 requires that 3 separate sets of measurements be recorded for each individual. Each measurement set (minimum of 255 for stationary, 765 for ambulatory) is then used to calculate differences in the mean and standard deviation across the entire database.

For the intra-arterial method, it is valuable to use many more measurements per subject, since a total of 15 subjects can satisfy the minimum requirements. During catheterization, variations in blood pressure measurement are not uncommon; there is sufficient time to record at least 10 sets of observations of diastolic and systolic values, and this is what is recommended. Thus, a minimum of 150 observations of systolic and of diastolic paired values will be available for determining mean difference and standard deviation.

Mean values

Diagnoses and judgments on effectiveness of therapy usually have been based on systolic and diastolic blood pressures. Although these measures are unquestionably important in evaluating the health of an individual, the physiologic effectiveness of tissue perfusion can be determined better by mean blood pressure. With nonautomated auscultatory methods, a mean only can be estimated in an individual, often with poor accuracy. Automated measuring methods potentially can determine mean blood pressure at least as accurately as systolic or diastolic values.

The committee therefore recommends that manufacturers disclose, in a form similar to that provided for systolic and diastolic blood pressures, the capabilities of their instruments for determining mean pressures. Following mean pressures in individuals might be a distinguishing and valuable medical contribution of automated sphygmomanometry.

A.4.5 Requirements for inflation source and pressure control valves

Cuff and bladder size affects measurement accuracy when using the nonautomated technique, defined in this document as the reference standard method. (Cuff and bladder dimensions for nonautomated instruments are defined in normative reference 2.1.) The appropriate cuff and/or bladder sizes for electronic or automated sphygmomanometers can differ from those sizes designated in normative reference 2.1, as long as the manufacturer tests these cuffs according to the requirements of this standard. Users of automated monitors should be aware that they should use only cuffs that have been tested with the automated device they are using. Therefore, this standard does not specify cuff and bladder dimensions, but leaves these to the manufacturer.

For safety considerations, it is important to provide for a maximum time during which the cuff is inflated beyond 10 mmHg. There is no evidence to indicate that rate of deflation has a bearing on safety. Thus, the committee determined that deflation rate need not be considered for automated systems, although it is obviously important for the cuff/stethoscope method. If the automated instrument operates with a cuff deflation rate that is incompatible with that required for the cuff/stethoscope method, same-limb measurements are not possible for determining overall system efficacy.

A.4.5.1 Inflation source

Cuff inflation rates that are too low can cause venous congestion, in which case accurate detection of the Korotkoff sounds can be affected and there can be some effect on the diastolic pressure measurement. The minimum cuff inflation rate specified in 4.5.1 is representative of current practice. As a practical matter, it is not possible to inflate a cuff manually at a rate high enough to cause a startle response or serious discomfort to the patient; consequently, a maximum cuff inflation rate has not been specified.

A.4.5.2 Manually adjustable valve

The recommended rate of pressure release established by the American Heart Association is 2 mmHg/s to 3 mmHg/s (AHA, 1981). To ensure that the valve can control this rate, the maximum valve leakage should not exceed one-half (1 mmHg/s) of the minimum acceptable rate, 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 cm^3. The leakage should be measured at 3 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 cm^3. After the diastolic pressure is determined, the compression should be released on the limb as rapidly as possible. Occasional emergencies also necessitate rapid reduction of the bladder pressure to facilitate immediate removal of the cuff. Since the diastolic pressure is usually less than 90 mmHg, a valve meeting the requirements of 4.5.2.3 should function satisfactorily at lower pressures.

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 should 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 strongly favors 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 nonautomated 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 % 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 % 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:
>
> — Optimal length of the bladder to reflect intra-arterial pressure;
>
> — Optimal widths of the bladder; and
>
> — 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 that 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 and 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 still may 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 is available to support a new minimum standard.

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

> The bag shall 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 % wider than the diameter of the limb on which it is to be used. (AHA, 1967)

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* (Task Force, 1987). Prineas (1992) 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, the AHA suggests minimum lengths of 80 % and 100 % of the limb circumference for adults and children, respectively. The AHA recommendations include a table of suggested cuff bladder sizes vis-à-vis limb dimensions.

Although the cleaning and disinfection of cuffs is outside the scope of this document, Stemlicht (1990) and others have published information regarding the risk of cross contamination from blood pressure cuffs.

A.4.6.1.2 Pressure capacity

A range of 0 mmHg to a minimum of 260 mmHg 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 mmHg. 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 hook 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, “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 mmHg/s to 3 mmHg/s. This rate should be controllable by a valve. These criteria can be satisfied if the leakage rate remains below 1 mmHg/s for the entire system.

A.5 Tests

The methods provided in section 4 of the standard are referee tests intended for use in ascertaining device compliance with the requirements of section 4. The methodology specified for design verification of overall system efficacy is not intended for quality assurance purposes, because it is complex and time-consuming. The other methods of section 4 might be suitable for purposes of quality inspection, but it is not intended that these tests shall be used for lot-to-lot quality assurance.

A.5.4.5.2.2.B Study populations—Rationale for weight bins in the neonatal population

In the clinical setting, BP is seldom, if ever, measured in the healthy term newborn. Neonatal intensive care nurseries primarily treat preterm newborns. Technical problems with the accuracy of BP in small preterm newborns (less than 1,000 g) have led to the suggestion of statistically oversampling smaller infants out of proportion of their birth incidence.

Table A.1—Indirect versus intra-arterial blood pressure measurement

				Systolic						Diastolic					
Authors	*Type of instrument*	*Number of patients or subjects*	*Age range*	*Range**	*Mean difference**	*Standard deviation**	*Standard error of estimate**	*Correlation coefficient*	*95% Confidence limit*	*Range**	*Mean difference**	*Standard deviation**	*Standard error of estimate**	*Correlation coefficient*	*95% Confidence limit*
Borow 1982	Oscillometric	30	31–83	98–177	0.8	3.5		0.98		41–97	1.7	2.3		0.97	
Colan 1983	Oscillometric	32	1 day–4 years	41–141	1.8	4.7		0.98		22–73	0.8	4.2		0.94	
Fitzgerald 1982	Semi-automated	23		60–155	13.4			0.78		60–105	8.6			0.4	
	Cuff/stethoscope manual	23			12.3			0.73			8.3			0.51	
Van Egmond 1985	Oscillometric	20		60–170			6.5		10	32–95			6.3		6
	Photoplethysmograph	20		51–162			7.5		13	38–103			7.5		5
	Intra-arterial reliability			60–183			2.4			37–92			2.4		
Nystrom 1985	Oscillometric	20		86–174	0.68	0		0.83		39–103	13.6	2		0.82	
	Ultrasonic	20		81–214	13.3	3		0.83		42–110	7.7	0		0.84	
Nielsen 1983	Standard cuff/stethoscope		17 < 50 32 50–59 11 ≥ 60		8.8	9.0					10.8	6.8			
O'Callaghan 1983	Standard cuff/stethoscope	40 20	60–80 24–43	120–230	4.4 7.0	1.3 1.6		0.97 0.92		60–110	9.2 10.4	1.0 1.1		0.93 0.76	
Vardan 1983	Standard cuff/stethoscope	26	50–81		0.9	3	4				18	2.35	3		
Gould 1984	Semi-automated	28	23–67 mean 50		7 3	12.9 12.8					0 7	10.1 10.2			
	Standard cuff/stethoscope	28	23–67 mean 50		1	13.0					11	9.3			

*mmHg

Table A.2—Automated or semi-automated instrumentation versus manual cuff/stethoscope method

				Systolic					Diastolic				
Authors	*Type of instrument*	*Number of patients or subjects*	*Age range*	*Range**	*Mean difference**	*Standard deviation**	*Standard error of estimate**	*Correlation coefficient*	*Range**	*Mean difference**	*Standard deviation**	*Standard error of estimate**	*Correlation coefficient*
Ellison 1984	Automated oscillometric	35	15–18	95–150	0.8		5	0.90	55–90	2.5		4.1	0.88
Sloan 1984	4 Semi-automated	17 20 20 26	Adults			5 to 7.2		0.896 0.975 0.916 0.968			4.6 to 5.9		0.712 0.887 0.920 0.919
Fitzgerald 1982	Semi-automated	35 35	Adults			0.4 1.1	5 (SEM) 3 (SEM)	0.98 0.98		0.4 0.2		2.8 1.8 (SEM)	0.97 0.97
Doring 1984	Automated	92 92	40–42 40–42	75–180	3.3 2.9	8.7 9.6		0.80	50–105	1.2 0.48	6.2 8.4		0.80
Barker 1984	Automated ultrasonic	24	Adolescents	93–121 82–127	0.5 5.8	7.8 10.6		0.73 0.83	59–82 56–79	0.2 3.3	6.3 5.8		0.07 0.54

*mmHg

Annex B
(informative)

Verification of overall system efficacy by comparison with manual auscultatory measurements

B.1 Introduction

B.1.1 The Korotkoff sounds

The auscultatory sounds by which the arterial blood pressure is determined were first described by Korotkoff in 1905 and are known as the compression sounds of Korotkoff. The sounds heard over the artery below the compression cuff vary in character as the pressure in the cuff is reduced from above systolic toward zero or atmospheric pressure. They are divided into phases (Figure B.1). Phase 1 begins with the sudden appearance of a faint, clear tapping or thumping sound that gradually increases in intensity. Phase 1 ends and Phase 2 begins when the sounds change to a loud "swishing" murmur. Phase 2 ends and Phase 3 begins when the sounds assume a loud, distinct, knocking quality. The sounds of Phase 3 are less intense than those of Phase 1. Phase 4 begins when the sounds suddenly become muffled and have a faint murmur-like or "swishing" quality. Phase 4 ends and Phase 5 begins when silence develops. These distinct phases are difficult to discern in some individuals.

The American Academy of Pediatrics has published a series of Task Force Reports relating to blood pressure measurement in childhood. The 1987 Task Force Report recommended that for auscultatory measurement of BP in children less than 13 years of age, K4 be utilized. It is apparent that this was done for two reasons. First, the only data which existed at that time was from a 1965 article by Moss and Adams (Moss, 1965) that reported comparisons of catheterization laboratory intra-arterial BP versus both K4 and K5 values. Diastolic (D) BP was better represented by K4. Second, there were few studies that had reported K5 values in children.

In 1996, an update on the 1987 Task Force Report appeared. The NIH/American Academy of Pediatrics panel changed the recommendation of DBP estimation to K5 at all ages. In this report, there was no scientific data utilized to make that recommendation; studies had appeared that reported K5 values in large numbers of children, and the committee considered it easier for pediatricians to use K5 rather than have to remember that the age of 13 was the dividing point for the use of K4 versus K5. It is widely recognized that a large percentage of children do not have a K5 in the physiologic range for DBP and, thus, that K5, if it occurred, could not possibly accurately measure DBP. The update authors preferred to use convenience data in preference to accurate data.

The AAMI Pediatrics Sphygmomanometer Subcommittee members recognize that arguments can be made for the use of both K4 and K5 in children less than 13 years of age. In addition, there is no extant data that has demonstrated the age at which K sounds are audible and, more unfortunately, accurate in the estimation of systolic and/or DBP.

The discussion above highlights the need for the manufacturer to reveal the auscultatory reference standard for DBP measurement in any validation study.

B.1.2 The systolic blood pressure

The pressure indicated by the manometer at the moment a Korotkoff sound is first heard over the artery below the compression cuff as the cuff is slowly deflated represents the systolic blood pressure (beginning of Phase 1, Figure B.1). In most instances, the systolic pressure recorded will be higher than that determined by palpation. Some patients can have an "auscultatory gap." This phenomenon is the loss and reappearance of Korotkoff sounds that occur during cuff deflation between systolic and diastolic pressures, in the absence of cardiac arrhythmias. If an auscultatory gap presence is not recognized, it can lead to the registration of spuriously high diastolic pressures or low systolic pressure. Although it is not a requirement that validation studies specifically include subjects with auscultatory gaps, individuals may not be excluded from a study because they have an auscultatory gap.

B.1.3 The diastolic blood pressure

With continued deflation of the compression cuff, the sounds heard over the artery change progressively in the five-phase manner described in Figure B.1. In adults, the diastolic pressure is the value recorded at the moment the sounds finally disappear (beginning of Phase 5).

Arguments against recording the diastolic pressure in adults at the beginning of Phase 4 include the difficulty of recognizing a definite change in the character of the sounds and the fact that, in some patients, muffling of the Phase 4 sounds is not audible.

The onset of muffling is the best index of diastolic pressure for children (according to the *Report of the Second Task Force on Blood Pressure Control in Children* [Task Force, 1987]). Furthermore, in some individuals, the end of Phase 4 (cessation) can be as difficult to determine as its onset (muffling). In a large proportion of children, Phase 5 occurs at a value that is below the clinically apparent diastolic value.

If the stethoscope bell is not pressing upon the artery and sounds are still heard at zero or at very low pressure levels, Phase 4 should be used. If the subject is excluded from the study, a statement should be provided in the instruction manual that the instrument might not be appropriate for use with children.

B.2 General considerations in using the auscultatory technique for verification of overall system efficacy of electronic sphygmomanometers

It is recommended that all automated (electronic) devices that indirectly measure arterial blood pressure be capable of providing simultaneous, same-arm measurements with standard auscultatory equipment (Figure B.2).

Because of individual differences among patients and in the proficiency of operators, testing should incorporate techniques designed to reduce the errors influenced by such variables. Qualified personnel who have undergone training with tapes or other methods on blood pressure measurement techniques should do all testing. As specified in 5.4.5.1.1.B, the nonautomated sphygmomanometer used in the comparison testing should comply with 4.4.A, except that its maximum measurement error should not exceed 1 mmHg at the temperature of the test. Both the measurement design and results should be documented and available for inspection. The results of such testing (on a population of at least 85 subjects) should yield a mean difference in simultaneous measurements no greater than ± 5 mmHg, with a maximum standard deviation of 8 mmHg (4.4.5.B).

Numerous studies have questioned the accuracy of automated monitors in pregnant women. If a manufacturer indicates that its device is intended for use with pregnant women, data should be provided that establishes the accuracy in that patient population.

B.3 Procedure

1) The cuff should be placed on the bare upper arm over the brachial artery of the subject and wrapped snugly so as to eliminate any residual air in the bladder. For auscultatory devices, the microphone should be removed from the cuff and placed over the brachial artery at least 1.5 cm above the antecubital fossa. It is best if the microphone is covered with an adhesive pad to ensure good skin contact and avoid noise artifact from the observer's stethoscope, as long as it doesn't interfere with the manufacturer's recommendations.

2) The cuff should be inflated rapidly to 100 mmHg while the radial pulse is palpated. Stepped inflations of 20 mmHg should continue until the radial pulse has been occluded by the cuff pressure. This occluding pressure should be recorded and the cuff deflated. A sufficient time should elapse (at least 60 s) to allow the return of normal circulation.

3) The cuff should then be inflated to a pressure about 30 mmHg higher than the previously recorded occluding pressure, and the bleed valve should be opened to allow deflation at a rate of 2 mmHg to 4 mmHg per heartbeat or 3 mmHg/s. For automatic devices which do not allow for deflation rates in this range, it might not be possible to perform same-limb measurements simultaneously with cuff/bladder manual auscultation. In such cases, same-limb sequential measurements are preferable to contralateral simultaneous measurements. The manufacturer should describe the method used for appropriate testing to validate the automated device against manual sphygmomanometry.

   NOTE—Check that upon opening the valve at the upper pressure range, the initial escape does not exceed the above deflation rate.

   The valve should be manipulated in such a manner as to continue a linear deflation rate of 2 mmHg to 4 mmHg per heartbeat throughout the measurement period. (As the pressure in the cuff decreases, the valve opening should be changed to ensure this linear rate.)

4) With the stethoscope placed over the brachial artery distally, systolic pressure should be recorded when the first Korotkoff sound is detected. Diastolic pressure is recorded at the onset of either Phase 4 or Phase 5 of the Korotkoff sounds, or under other conditions, depending on the device's principle of operation. Great care should be taken to avoid movement of the stethoscope during the measurement, as the device's microphone or oscillometric sensor (depending on the type of device) can inadvertently sense the movement as noise or Korotkoff sounds.

B.4 Major sources of error

Major sources of error for the auscultatory technique include:

— **Inappropriate cuff/arm relationship.** For most adult upper arms, the correct ratio of bladder width to limb circumference is 0.4 (see normative reference 2.5). If the arm is greater than 35 cm in circumference, this bladder would be too small and the blood pressure would be overestimated. If the arm circumference is less than 25 cm, this bladder would be too large and the blood pressure would be underestimated.

— **Stethoscope or transducer not over the brachial artery.** Too much or too little pressure applied to the head of the stethoscope.

— **Patient's arm and back not supported correctly.** Inadequate time allowed for the patient to relax and the blood pressure to stabilize.

— **Inadequate hearing acuity.** This is a critical point, and all skilled observers should have an audiogram prior to the study.

— **Rapid cuff deflation.** As an example of the problem associated with rapid cuff deflation, assume that a patient's systolic pressure is actually 149 mmHg at a given time and that the heart rate is 60 beats/min. Below are pressure recordings, by two hypothetical operators, that illustrate how the cuff deflation rate can contribute to measurement error:

Deflation rate per second:	10 mmHg	3 mmHg
Cuff pressure 150 mmHg:	No K sound	No K sound
First K sound produced:	140 mmHg	147 mmHg

The first operator, using a 10 mmHg/s deflation rate, recorded a systolic pressure of 140 mmHg (9 mmHg below the actual pressure of 149 mmHg); the second operator, using a correct deflation rate (3 mmHg/s), recorded a systolic pressure of 147 mmHg (2 mmHg below actual).

Measurements made from reference sphygmomanometers should be made to the nearest 1 mmHg. This is intended to limit small differences between test and reference methods on account of conventional rounding to the nearest 2 mmHg and allow controlled deflation at 3 mmHg/s or per heartbeat. Automated devices typically measure to the nearest 1 mmHg.

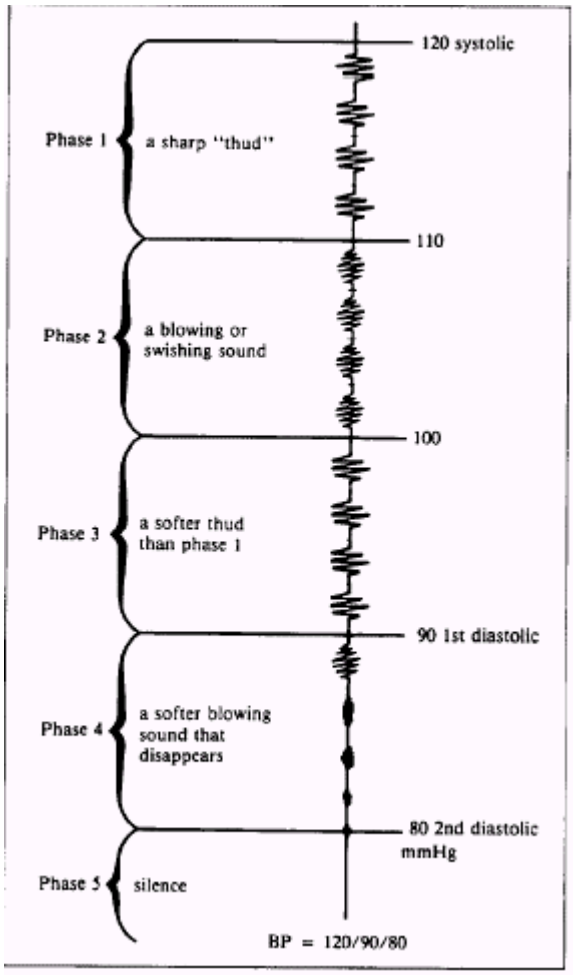

Figure B.1—The various phases of the Korotkoff sounds

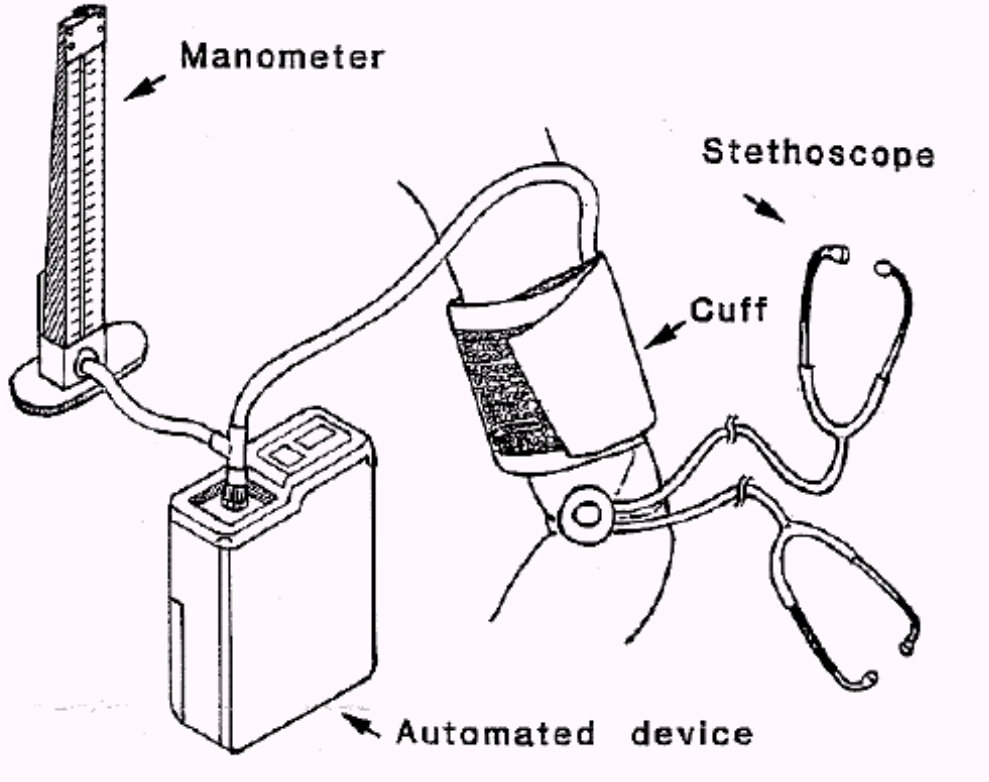

Figure B.2—Method of simultaneous auscultatory validation

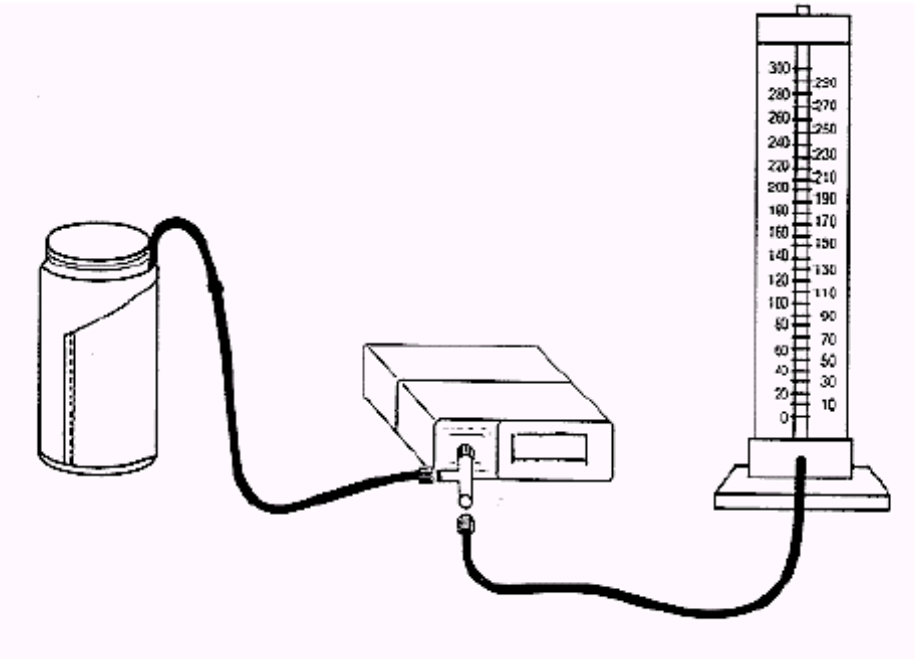

Figure B.3—Method of checking static calibration of unit under test

Annex C
(informative)

Verification of overall system efficacy by comparison with intra-arterial measurements

C.1 Introduction

Verification of sphygmomanometer system efficacy by comparison with direct blood pressure measurements obtained with indwelling arterial catheters is perhaps the more rigorous of the two methods described in 4.4. and 5.4. because in this method (in contrast to the auscultatory method), there is no cancellation of the systematic errors associated with cuff size versus arm size and subject artery stiffness. The following points should be understood.

a) Because this measurement method is invasive, the studies should be conducted on clinical patients in whom an intra-arterial line has already been placed for reasons other than sphygmomanometer verification. This could include patients undergoing carotid arteriography or cardiac catheterization, or patients undergoing clinical research studies approved by an institutional review board that involve intra-arterial blood pressure monitoring (e.g., hemodynamic study of a congestive heart failure drug).

b) Because of the limited availability of these patients, their number will necessarily be smaller, the range of observed blood pressures can be less evenly distributed, and the time required to complete the entire verification will generally be longer than for other verification methods. There are no age range requirements for intra-arterial verification (as in the first edition of the AAMI standard).

c) The intra-arterial instrumentation required for this method is more complex than the manual equipment used for noninvasive verification, and will thus require greater attention to detail on the part of more experienced personnel.

d) The same limb should be used for simultaneous comparison of intra-arterial and indirect blood pressure measurements. The intra-arterial catheter should be proximal to the occluding cuff.

e) The subclavian artery, axillary artery, and brachial artery are the most desirable sites for intra-arterial measurements. The radial artery is not desirable because of the amount of amplification or attenuation of the blood pressure in this artery. Data on optimal sites for intra-arterial measurements in children is not available. Therefore, no arterial site is excluded in the pediatric population, but the manufacturer shall disclose the arterial site used as the reference.

f) The intra-arterial pressure, while highly accurate, might yield a different value than the auscultation (Figure C.1). Generally, the intra-arterial systolic pressure in adults is 3 mmHg to 4 mmHg higher than the systolic pressure by auscultation, while the intra-arterial diastolic pressure is 3 mmHg to 4 mmHg lower than the diastolic pressure by auscultation.

Given the stringent requirements, the invasive method of verifying noninvasive blood pressure measurement devices is potentially the most precise means of verification. If conducted properly, it affords a high degree of assurance that the sphygmomanometer will provide clinically acceptable and useful information. The following suggestions for conducting invasive studies should not be considered definitive or exhaustive.

C.2 Data acquisition

If the comparisons between invasive and noninvasive blood pressure measurements are to be valid, these measurements are best obtained simultaneously. Individuals' blood pressures can vary from moment to moment, and in patients on ventilators or with hypovolemia, these variations can be considerable; hence, the preference for simultaneously measured values. It is important that simultaneous measurements be made in an ipsilateral artery of similar caliber, such as a brachial, axillary, or subclavian artery. The radial artery is not recommended in adults, as correlation might not be obtained consistently. The aortic arch can be used if there is no peripheral vascular disease present. In most instances, a digital subtraction angiogram using minimal amounts of contrast material will confirm the absence of hemodynamically significant vascular lesions.

For blood pressure in neonates, the intra-arterial catheter should be placed in the aorta, as is generally the case when an umbilical artery is used. In any event, the particular catheter site should be specified.

The intra-arterial pressure transducer can be an external or catheter-tip device and should be warmed and both statically and dynamically calibrated before each study. The noninvasive instrument under test should also be

calibrated with the same mercury or digital manometer as the invasive transducer. All calibration records should be kept on a multichannel strip-chart recorder or computerized data collection system with analog or waveform capabilities. The static calibration of both the invasive and noninvasive devices should be within ± 2 mmHg of the reference, and the dynamic calibration (i.e., the frequency-response determination of the invasive device) should be flat (within ± 3 dB) to at least 10 times the fundamental frequency (minimum of 16 Hz), or the frequency response and damping coefficient pair should meet the dynamic requirements proposed by Gardner (1981). In order to achieve this frequency response, the external blood pressure transducer shall be connected to the intra-arterial catheter by stiff tubing, which should be as short as possible, and the entire system shall be completely devoid of air bubbles.

The blood pressure transducer shall be kept at the same level as the blood pressure cuff to avoid hydrostatic effects—for every 1.3 cm of difference in vertical height between the pressure transducer and the arm around which the cuff is wrapped, an offset error of 1 mm difference in measured pressure will result. During each measurement by the noninvasive device, a strip-chart or other computerized recording system should be recording the intra-arterial pressures and analog signals from the noninvasive device (if these are available). Although it is possible to make simultaneous invasive and noninvasive measurements without using a multichannel strip-chart recorder or other computerized recording system, its use is encouraged for the following reasons.

1) The actual intra-arterial systolic and diastolic pressures should be read from the permanent recording, rather than from the display on the intravascular recording device. The accuracy of systolic and diastolic pressure indicators on most monitors is difficult to verify and almost always involves some type of averaging so that the displays will not change too rapidly for clinical use. On some monitors, the selection of systolic and diastolic pressures is accomplished by finding the maximum and minimum pressures over a period of seconds, resulting in very misleading displays if there is much intra-arterial pressure fluctuation. Therefore (and because the chart recorder or computerized system will have been previously calibrated with the system), the reproducibility of readings from the chart recorder or computerized system is better than that for readings from the invasive monitor's digital or analog display.

2) During measurement, it is possible that a gross arrhythmia or artifact due to movement can distort the intra-arterial pressure wave, rendering the determination invalid for comparison purposes. If a continuous, real-time recording of intravascular waveform is used, these artifacts are usually recognized at the time of occurrence, whereas they might never be recognized if only a digital or analog display is used with the invasive system.

3) Electronic signals often associated with the operation of a particular noninvasive device can be recorded simultaneously on other channels of the strip-chart recorder or computerized system. Artifacts caused by patient movement or outside interference usually will become quite obvious upon viewing the chart or computerized record.

4) The permanent record generated by the simultaneous recording of invasive and noninvasive measurements can allow the researcher or manufacturer to devise ways of improving the accuracy of the noninvasive device or enhancing its ability to function in the presence of artifact.

5) In a comparative analysis of the accuracy of the noninvasive and invasive devices, the amount of variability in the patient blood pressure shall be known. This information easily can be obtained from the strip-chart or computerized recordings. The beat-to-beat variability during a noninvasive recording should be calculated. This variability is a source of minor error in the comparisons between the device and the standard.

6) During the study, any deterioration in the waveform recorded by the intra-arterial catheter should be quickly noted and appropriate corrective measures taken immediately (e.g., flushing or adjusting the position of the catheter).

7) The permanent record of each simultaneous determination serves as a source document for further review or inspection.

Multiple readings for each patient should be made as specified in 4.4.5.1.B. At either the beginning or end of each recording session, the following minimum information should be recorded: the patient's identifier, sex, age, height, weight, and arm circumference; the arm on which the occluding cuff was placed; the size of the occluding cuff used; the patient's position, physiologic state, and temperature; and any difficulties encountered.

C.3 Data collection

The most important aspect of data collection is the specification of the intra-arterial pressure during a determination. The measurement obtained from the noninvasive device is subtracted from the intra-arterial measurement to obtain the error for that particular determination. One method of specifying the intra-arterial pressure and computing the error is to obtain from a multichannel strip-chart recorder or computerized system the actual waveforms of the systolic and diastolic pressures at the instant measured by the noninvasive device. The difference between the intra-

arterial pressure recorded and the noninvasive measurement is then calculated. This is only possible if synchronized recordings have been obtained. Another method is to specifically time the period of measurement of the noninvasive device and note this with an event marker on the recording for the intra-arterial pressure. At 3 mmHg/s cuff deflation, the measurement of blood pressure by the noninvasive device ordinarily takes 45 s to 60 s. The intra-arterial beats from the first 15 s of cuff deflation can be averaged to obtain the reference value for systolic pressure, and the last 15 s of cuff deflation can be averaged to obtain the reference value for diastolic pressure. The error of this method has been calculated to be 0.2 ± 3 mmHg for diastolic and 0.6 ± 2 mmHg for systolic. This method is appropriate if the automated device uses markers for systolic and diastpressure that are independent of the mean pressure.

In an alternative method, the highest and lowest values of intra-arterial pressures should be those recorded during the time it takes for the instrument under test to perform a measurement. For example, the systolic (or diastolic) blood pressure reference value obtained by an automated instrument requiring 10 s for measurement should be compared for agreement with the minimum and maximum intra-arterial values over the same 10 s. This method is suggested, particularly for automated monitors that first determine the mean arterial pressure and then determine systolic and diastolic pressure based on the measurement of mean arterial pressure (MAP). Since the measurement of blood pressure is based on the analysis of the oscillometric envelope obtained over the entire determination, the use of the range of reference values of that same time period is indicated.

Of the two methods, the second is far easier to implement and is generally acceptable. Either method requires simultaneous ipsilateral measurements for the greatest level of precision. As pressures can differ in different limbs, simultaneous contralateral measurements are not generally recommended. The need for simultaneous ipsilateral measurements requires the use of a catheter inserted through an artery that is not restricted when the cuff is inflated.

Other methods also might be appropriate. Whichever method is used should be justified as part of the description provided by the manufacturer.

The comparison of intra-arterial blood pressure also should be performed against the mercury column or other accepted means of pressure determination in each subject to obtain an estimate of error between the clinical measurement of blood pressure and intra-arterial blood pressure. This error can be used as a frame of reference for the error obtained by the device. If the device error is in excess of the clinician’s error, then the device might be considered unacceptable for clinical use. If the device error is the same or less than the clinician’s error, then the device would be considered acceptable for clinical use.

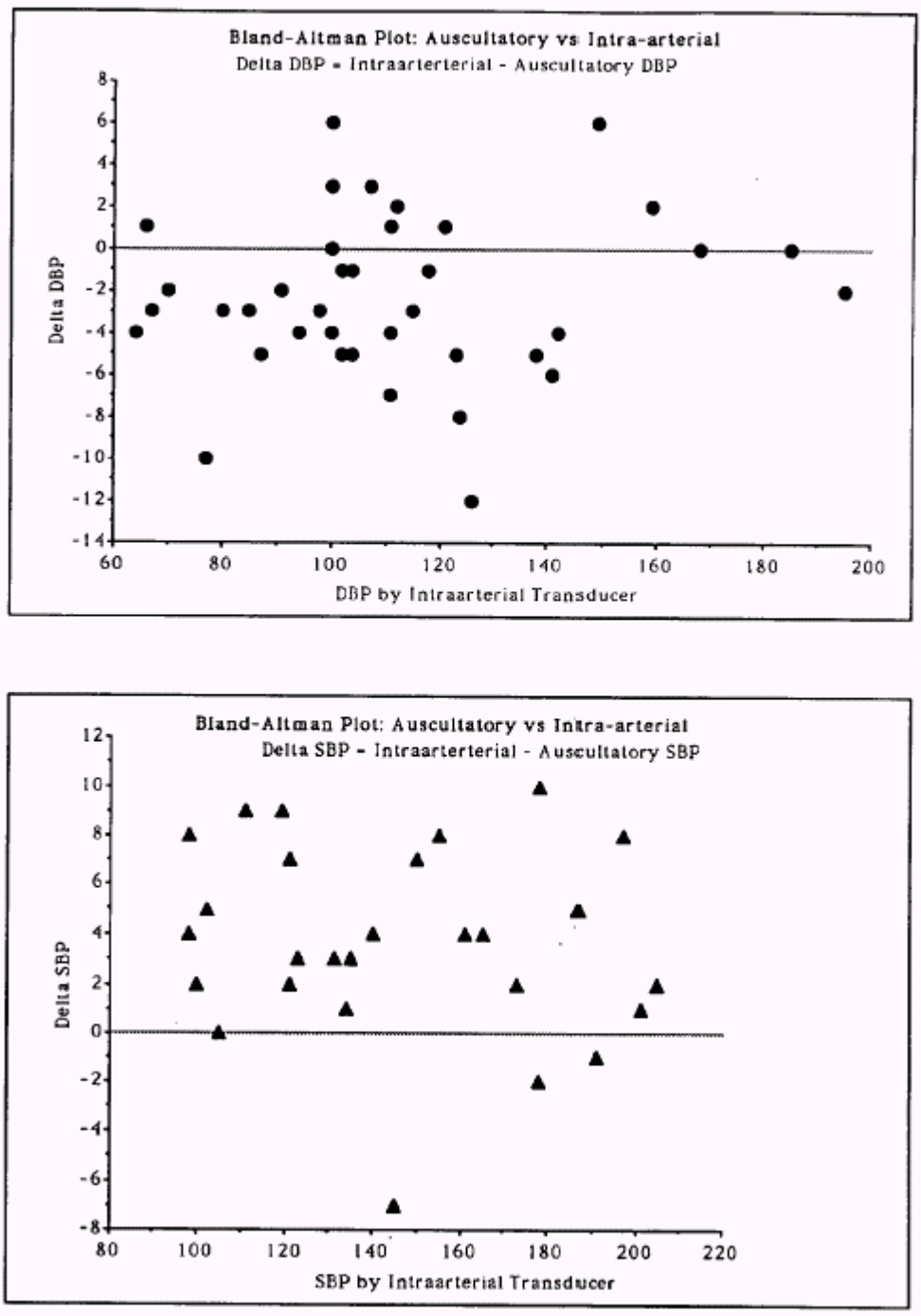

Figure C.1—Bland-Altman plots—Auscultatory versus intra-arterial

Annex D
(informative)

Data analysis and reporting

D.1 Introduction

This annex discusses the rationale for and recommended approaches to the analysis and reporting of data obtained from comparisons of test device(s) and reference method, and for comparisons between observers making simultaneous or sequential auscultatory observations. Changes between the approaches now recommended and those previously suggested (AAMI, 1992) are indicated.

D.2 Data gathering

All data should be recorded in tabular form. Demographic information on the subjects (e.g., subject identifier, age, height, weight, mid-arm circumference, and sex) should be included to verify diversity among subjects. Once a subject has been accepted into the study and before the pressure data has been gathered, the data for that subject should not be excluded from the study if blood pressure values are obtainable. If blood pressure measurements from either the standard method or the automated device are unavailable, data for that individual may be excluded with an accompanying explanation. Additional individuals should then be entered into the study so that the sample size as originally designed is met.

For auscultatory comparisons of devices intended for ambulatory recording, testing should be carried out in all positions of patient and arm in which the device is intended to be used (see annex E).

The final data set should have a minimum N of 85 subjects for the auscultatory method. Systolic and diastolic pressures should be analyzed separately.

The previous recommendation (AAMI, 1992) was that all individual measurements (N = 255) should be analyzed separately against a standard of a mean difference of ± 5 mmHg and a standard deviation of 8 mmHg. The present standard retains this recommendation, but also contains an additional method that uses the average of 3 recordings for each subject (N = 85) as the unit of comparison. This second method does not have a fixed standard for mean and standard deviation of the error between the test and reference. Instead, the allowable standard deviation decreases as the mean error increases. These criteria are based on statistical analysis (see annex F) that requires the overall error to be within ± 10 mmHg with a 95 % level of confidence.

D.3 Data presentation and analysis

D.3.1 Between-observer comparisons

The committee considered the British Hypertension Society's recommendations (O'Brien, et al.,1990) that observer agreement should be quantified before embarking on device testing, and that observers previously shown to agree could share recordings. It was felt, however, that post hoc analysis of simultaneous observer agreement is invaluable in the event of dispute over device performance.

One hundred percent of recordings made simultaneously by observers should agree to within ± 10 mmHg, and 90 % or more should agree to within ± 5 mmHg. Systolic and diastolic pressures should be examined independently. The previous standard (AAMI, 1992) recommended that 95 % or more of recordings made simultaneously by observers should agree to within ± 10 mmHg, and 85 % or more should agree to within ± 5 mmHg. The change was made by the committee in an attempt to reduce apparent test device errors that might be due to observer disagreements.

A draft standard being prepared by the CEN committee (prEN1060-4, 08/2001) recommends that, during training, 90 % of the readings by two observers should agree to within 5 mmHg, and 96 % should agree to within 10 mmHg. The standard also states that, during testing, any readings that have an observer-to-observer difference of greater than 4 mmHg should be discarded.

An earlier version of this standard (AAMI, 1987) recommended that between-observer agreement should be verified by a test of the difference between means. However, the present committee agreed that a measure of clinically acceptable disagreement between observers was more meaningful than hypothesis testing. Furthermore, with the sample sizes advocated, even small differences (on the order of 1 mmHg to 2 mmHg) are likely to be statistically significant at the 5 % level, so that a comparison might be considered to be flawed despite reasonable agreement.

If observer agreement meets the above criteria, then the average of each pair of recordings made simultaneously by the observers should be used for comparison against the test device. If observer agreement fails to meet these criteria, it cannot be used to validate the instrument.

D.3.2 Test-reference method comparisons

The preferred method is analysis of agreement (Bland and Altman, 1986). For each comparison of observers against device, in each position, a scatter plot of average versus difference should be drawn (Figure D.1). Systolic and diastolic values should be plotted separately. “Average” represents the average of the test and reference method, a reasonable estimate of the (unknown) true blood pressure at each point. “Difference” is the difference between the test and reference observations at each point. It is also recommended that horizontal lines showing the mean, ± 1, and ± 2 standard deviations should be superimposed. Similar plots should be drawn to illustrate the between-observer comparison. The data should be summarized in tabular form, as in Table D.1.

The standard recommends either simultaneous, same-arm determinations or sequential determinations. During sequential comparisons, temporal variation in blood pressure can create apparent test-reference differences, which would artificially increase the error of the test device. Some members of the committee suggested discarding individual measurements where the reference blood pressure varied by more than 8 mmHg. The CEN committee (prN1060-4, 08/2001) recommends that a subject should be included in the study only if “the diastolic reference values of the entire series of measurements do not deviate from one another by more than 8 mmHg and the systolic reference value by not more than 12 mmHg.” If a manufacturer chooses to use one of these methodologies to reduce error due to temporal variation, it should clearly indicate this in its report.

D.3.3 Effect of arm circumference and cuff bladder width on agreement

The committee was concerned that the known effect of arm circumference on measurement error has not adequately been taken into account in previous evaluations. The source of measurement error is particularly important when only a single cuff size is supplied with a particular device. The committee wished to ensure that:

a) If only one size of cuff bladder is supplied, it should provide reasonably accurate measurements with all adult arm sizes; otherwise, the device labeling should clearly indicate the restricted range of arm sizes over which the device can be used; and

b) If several cuff sizes are provided, the differences in cuff volume should not in themselves impair the accuracy of the device.

Where a device is supplied with cuffs of one size only, a scatter plot should be drawn to show the relationship between arm size and measurement error (i.e., the differences between test and reference methods [Figure D.2]). The differences should be expressed in percentage terms:

$$\text{percent difference} = \frac{\text{difference between test \& reference methods}}{\text{average of test \& reference methods}}$$

As arm circumference is likely to be positively correlated with blood pressure, a straightforward plot of arm size versus difference can wrongly suggest that arm size determines error, when in fact error simply increases with increasing blood pressure. Plotting (percent difference) will limit this confounding effect, but nevertheless, the arm size versus percent difference plot should be interpreted carefully in the light of the plots in Figure D.1. Where cuffs of more than one width are provided, a scatter plot should be drawn for each of the cuff sizes individually (Figure D.3). Systolic and diastolic pressures should be plotted separately.

D.3.4 Mean and standard deviation

The previous edition of this standard (AAMI, 1992) recommended that a mean difference of ± 5 mmHg, with standard deviation of differences of 8 mmHg between test device and reference method, should be taken as the upper limits of clinically acceptable disagreement. The rationale for the choice of these figures was presented at that time.

These figures have become widely accepted. Experience to date suggests that they are realistic targets for manufacturers. Until further experience is gained with the present protocols, the clinical evaluation protocol recommended by the British Hypertension Society (O’Brien, et al., 1990), and equivalent protocols, the committee saw no compelling reason to revise these figures. However, some cautionary notes should apply.

This standard discusses minimum requirements. Manufacturers should strive to obtain a degree of agreement such as that seen between competent, trained observers performing simultaneous auscultatory measurements. Trained observers typically agree to within ± 2 mmHg with standard deviation of 4 mmHg.

In the previous standard (AAMI, 1992), the figures for mean difference and standard deviation (SD) of differences derived from 255 values, which represented 3 individual recordings from 85 subjects. Some concern was expressed that a device that was at the outer edge of these limits (μ = 5 mmHg, SD = 8 mmHg) might have an error that was clinically unacceptable.

As a result of these concerns, an additional method was developed with the goal of providing a 95 % confidence that readings from the device would agree with the reference to within 10 mmHg. The method (annex F) uses the average of 3 recordings for each subject (N = 85) as the unit of comparison. The decision to use the average of these measurements was based on comments from some clinicians that at least 3 readings should be made on patients being diagnosed for hypertension. If the sequential method is used, averaging also will reduce apparent device errors due to temporal blood pressure variations. This method does not have a fixed standard for mean and standard deviation of the error between the test and reference. Instead, the allowable standard deviation decreases as the mean error increases. While the maximum mean error is still ± 5 mmHg, the SD at that level is only 4.8 mmHg. The maximum allowable SD is 6.95 mmHg, if the mean error is zero.

The committee decided to retain both methods after considerable debate. While the second method addressed the concern of devices with a high mean and SD, some members felt that the averaging of 3 readings would discriminate against some devices. The first method (N = 255) would tend to reject a device that had little offset (low mean error) but was imprecise (high variability). This method would be more favorable to a device that had an offset but was more precise (low variability). The opposite is true for the second method (N = 85). The committee determined that keeping both methods of analysis would provide a better means to evaluate the test device.

Parametric descriptors such as the mean and standard deviation can be unduly influenced by outlying values, so that two methods that are generally in agreement can fail to achieve the above targets due to a relatively small proportion of large differences. Users might find it more meaningful clinically to express agreement in terms of the percentage of differences that fall within certain thresholds (e.g., 5, 10, 15 mmHg). The latter approach is influenced less by occasional outlying values, but can be misleading where there are large systematic differences.

Neither approach can effectively portray complex distributions of differences across the range of measurement (e.g., when differences increase with increasing blood pressure, as shown in Figure D.5). In such a circumstance, log transformation of the original data might be useful (Bland and Altman, 1986).

D.4 Sample size

As discussed in D.3.1, even small mean differences (on the order of 1 mmHg to 2 mmHg) are likely to be significantly different statistically with high degrees of probability, given the recommended sample size (N = 255). For the reference-test comparisons, however, the committee is not principally interested in the ability of the comparisons to detect mean differences. (In fact, as discussed in A.4.4.5, only about 85 observations are needed to detect a mean difference as large as 5 mmHg, given an expected 8 mmHg standard deviation of differences, with 98 % power (ß = 0.02) at the 5 % significance level [a = 0.05]).

Instead, the committee is more concerned with the sample size needed to estimate the standard deviation of differences (s.d.d.) with confidence. Small samples will, by chance, frequently produce values for the s.d.d. that are unrepresentatively high or low in comparison to the true s.d.d. device. This might lead to the test device unfairly failing or inappropriately passing the 8 mmHg criterion.

Clearly, the larger the sample, the better in this respect, but equally clearly, there are logistic considerations. Hypothetical data derived from random number sampling (Figure D.6) tends to support the choice of N = 255 over N = 150, but shows greater precision of estimates of the s.d.d. with larger sample sizes. The choice of N = 255 remains somewhat arbitrary.

Table D.1—Sample data summary

	Number of observations	Range[+]	mean difference (mmHg)	SD of differences (mmHg)	% exceeding 5	10	15
observer 1 — observer 2							
systolic	255	88-211	0.8	2.5	6	2	0
diastolic	255	47-123	-0.5	2.2	6	0	0
*test device — observers**							
systolic	255	90-221	-4.9	5.2	38	12	2
diastolic	255	48-122	-4.0	7.5	42	28	4

[+]Corresponding to the range of x values in a plot of difference vs. average (for example in figure D.1).
*Average of each simultaneous pair of recordings by the observers.

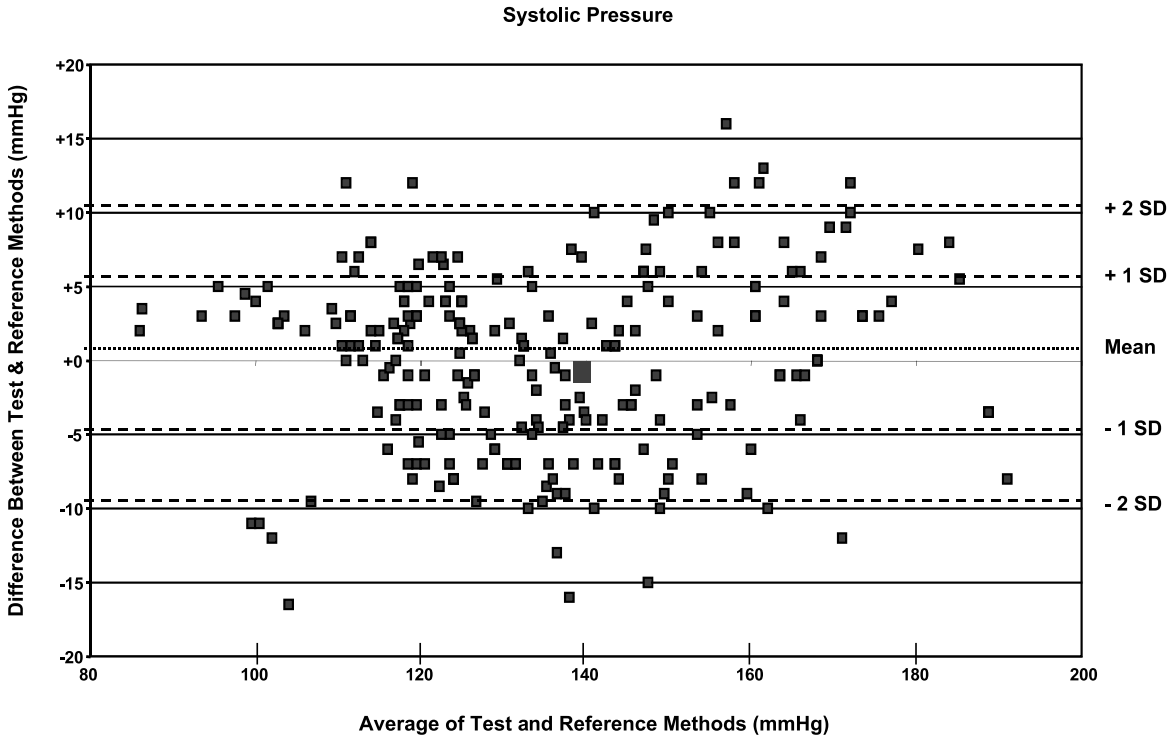

Figure D.1—Agreement between test and reference methods for systolic pressure

Hypothetical data, N = 255, mean = 0 mmHg, and standard deviation = 6 mmHg

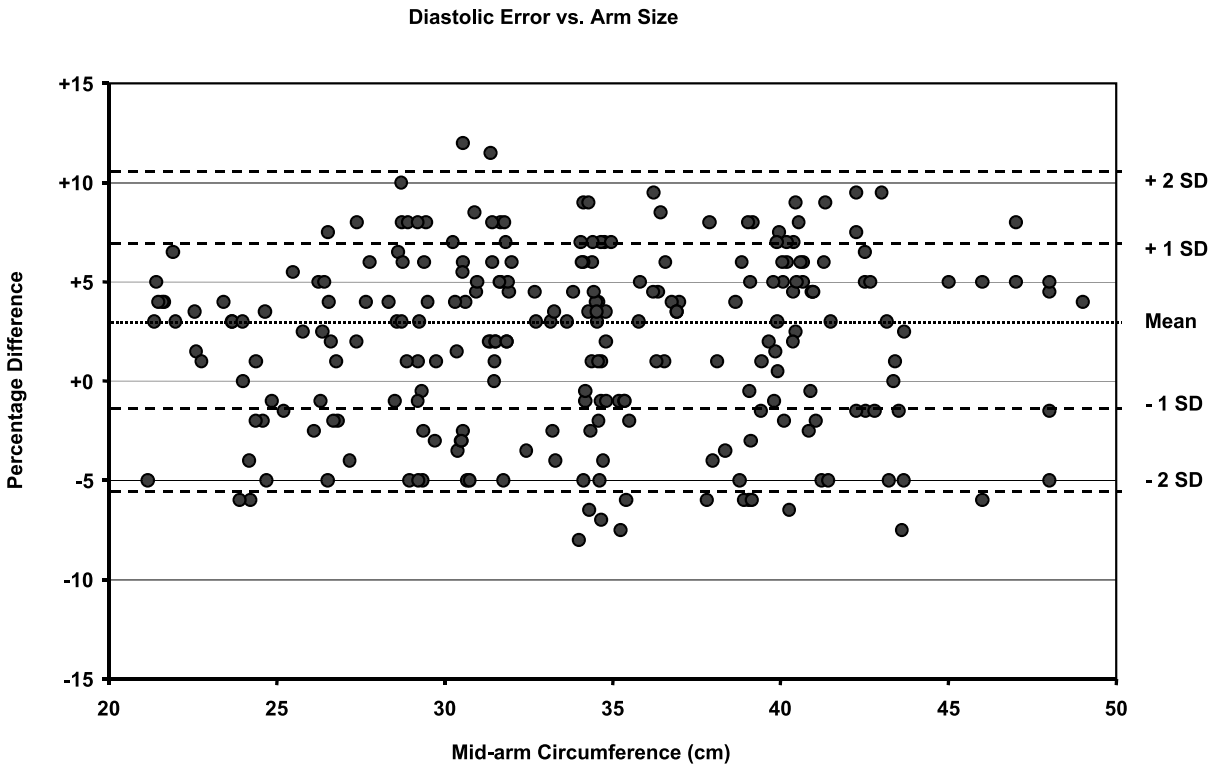

Figure D.2—Scatter plot of arm circumference versus error (expressed as percentage difference between test and reference methods)

Hypothetical data, N = 255

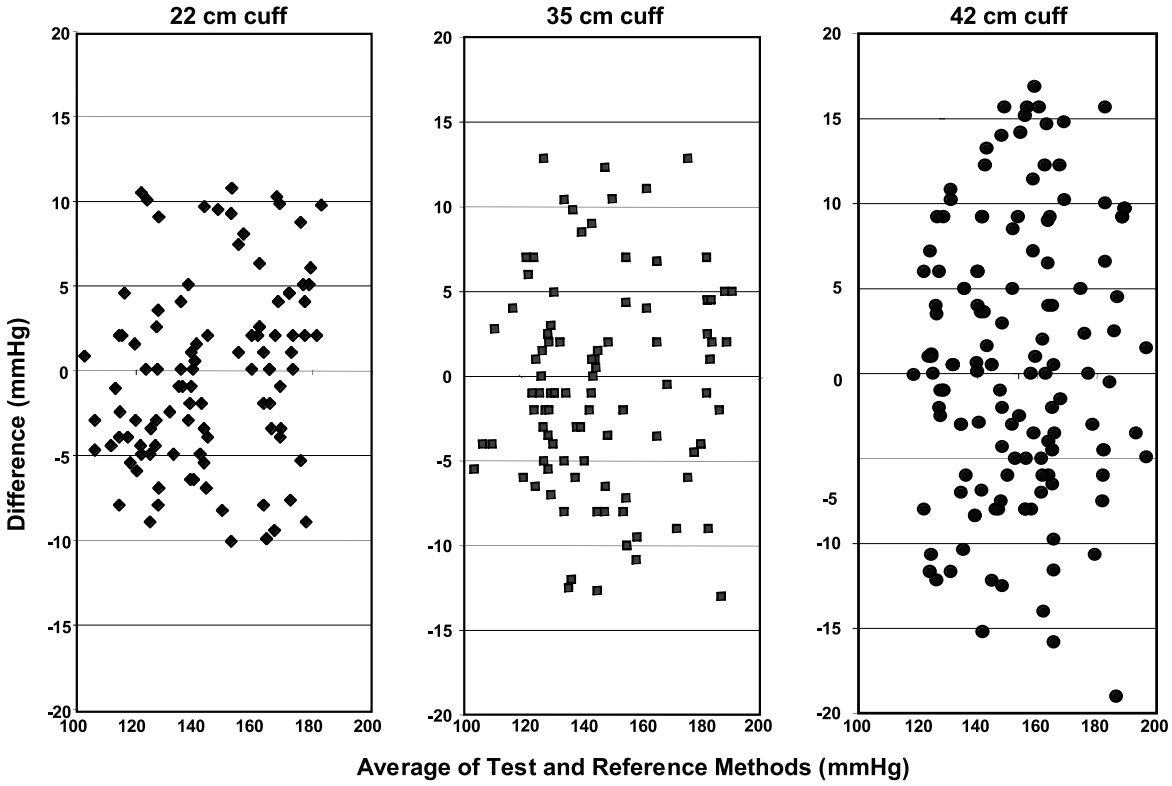

Figure D.3—Scatter plots illustrating the effects of cuff bladder width on measurement error (expressed as absolute differences between test and reference methods)

Horizontal lines represent mean, ± 1, ± 2 standard deviations for the overall comparison.
Hypothetical data, N = 255.

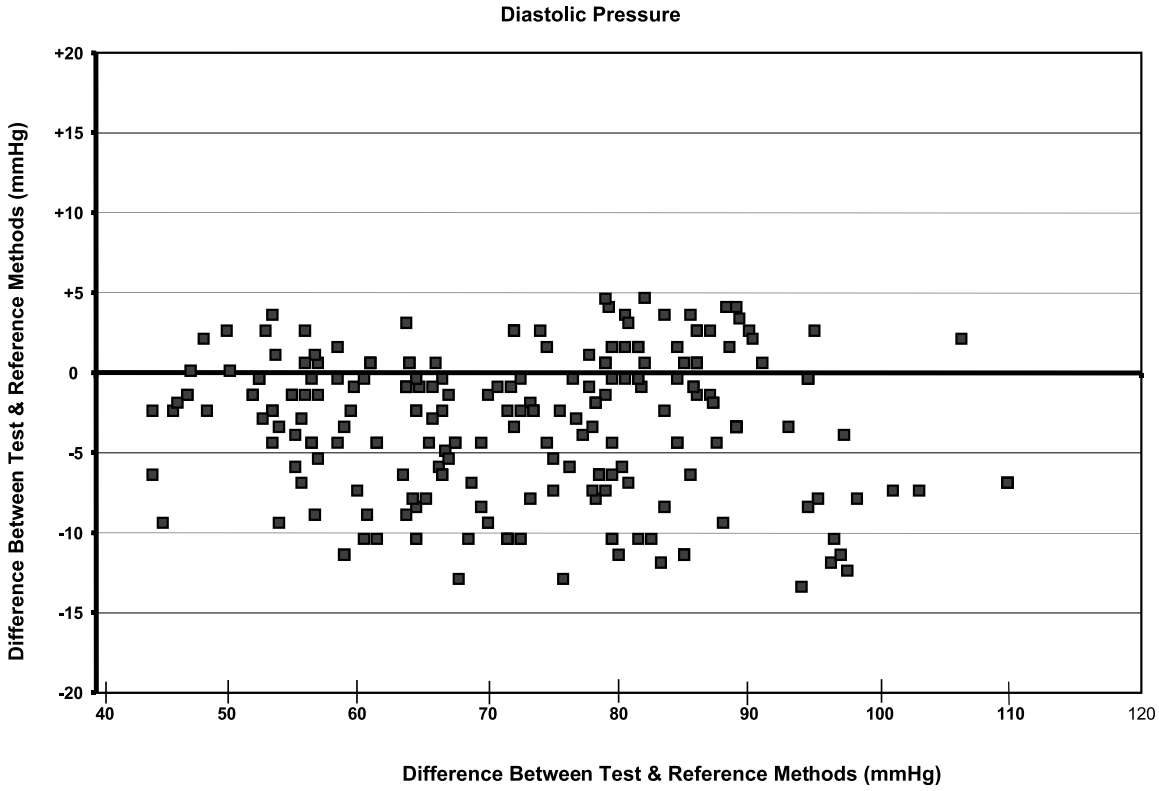

Figure D.4—Scatter plot illustrating how agreement can be misrepresented by expressing differences in percentage terms

About 11 % of measurements exceed 10 mmHg, but this principally reflects an average systematic error of –5 mmHg.

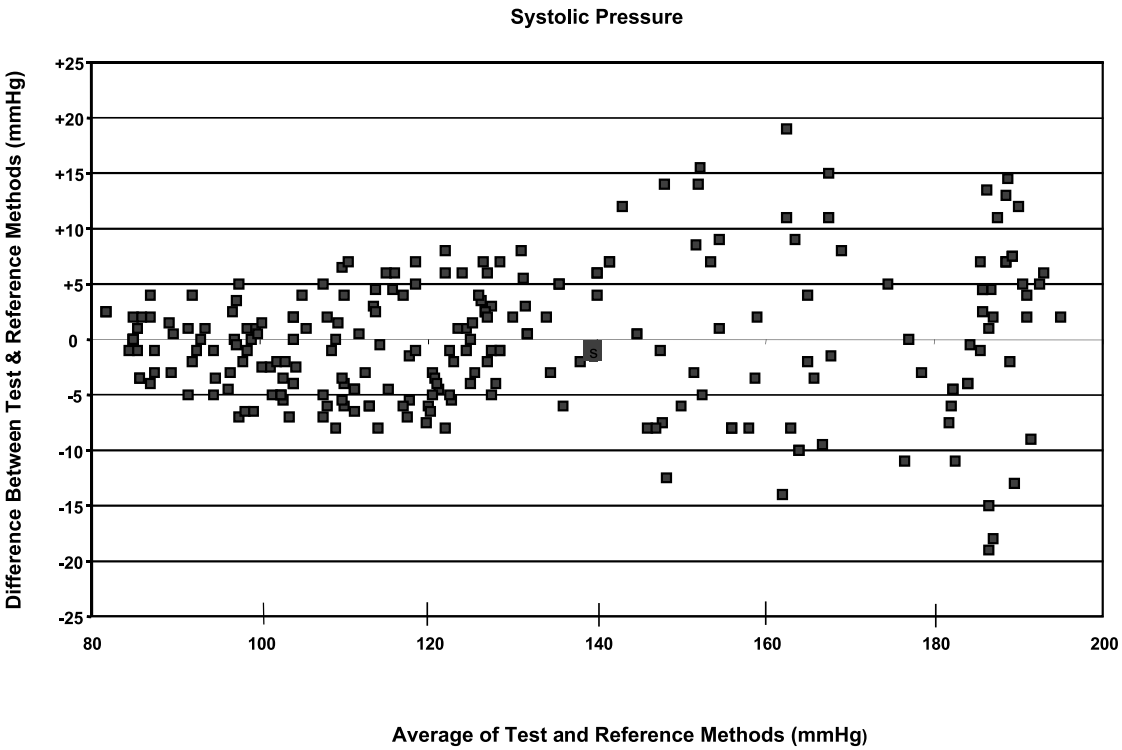

Figure D.5—Average of test and reference methods for systolic pressure

Compare with Figure D.1. The accuracy of this hypothetical device decreases with increasing pressure. Nevertheless, the mean and SD are still 0 and 6 mmHg. In such a case, it might be helpful to log transform the original data and replot the log values (see text).

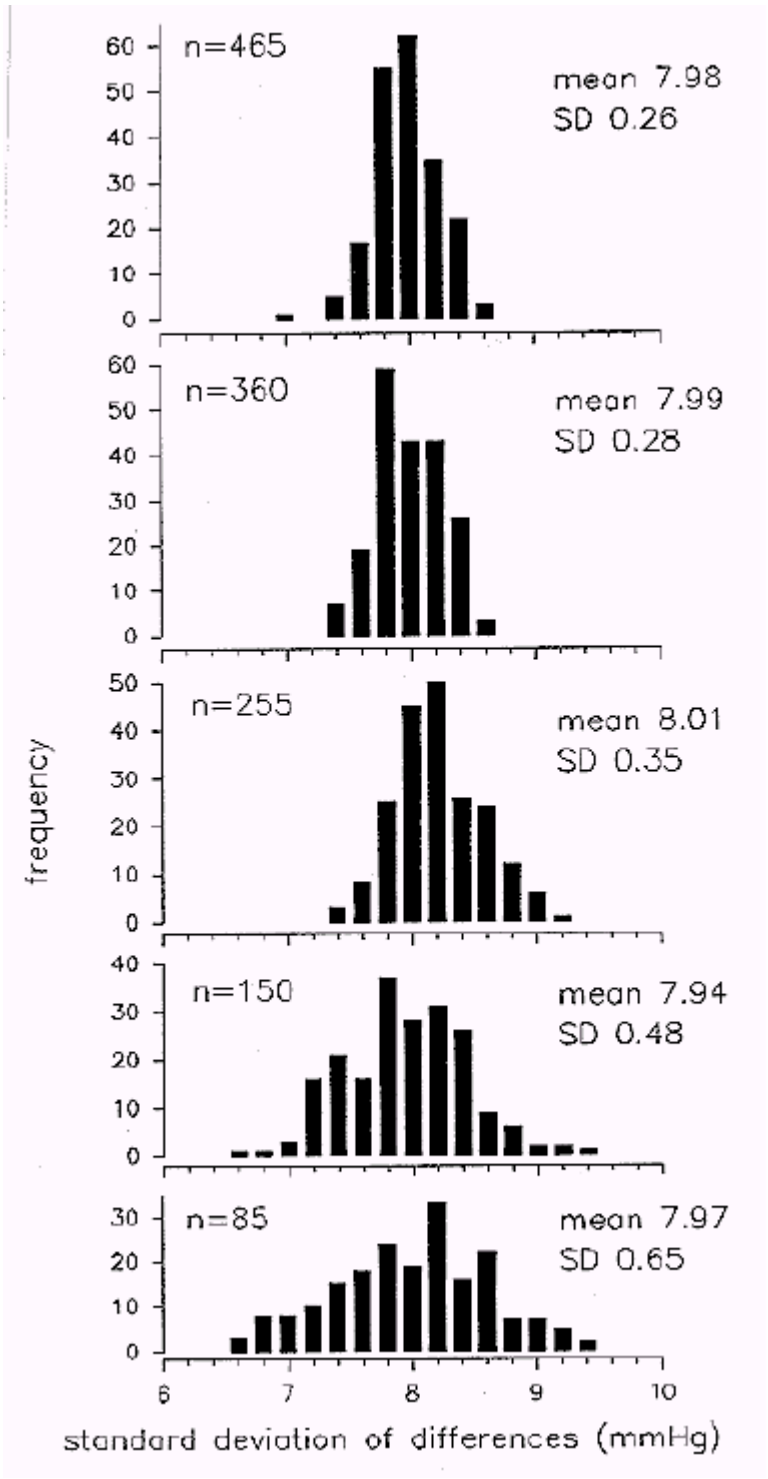

Figure D.6—Effect of sample size on the precision of estimates of the standard deviation of differences (s.d.d.) between observers and test device

Annex E
(informative)

Special considerations for the assessment of ambulatory blood pressure monitoring systems

E.1 Introduction

Ambulatory blood pressure recorders 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. While one aspect of testing these devices is essentially the same as the controlled laboratory conditions that have been described in this standard, two additional testing issues include assessment of the validity of the device during motion and reliability during clinical use in the field.

An oversimplified way of viewing an ambulatory blood pressure recorder is that it is a device capable of obtaining repeated measurements of pressure over the day and night in the absence of motion. Therefore, if the manufacturer only wishes the device to be labeled as one that is accurate and reliable during clinical use when both the arm and subject are still, only comparisons of the device with auscultatory measurements (as described in annex B) and field testing (see E.4) need be performed. However, if the manufacturer desires labeling stating that the device is precise during repeated ambulatory determinations, then verification of the accuracy of the device during motion should be obtained.

E.2 Special considerations for resting measurements of ambulatory blood pressure recorders

Unlike nonportable recording devices, ambulatory blood pressure monitors record pressure readings in supine, seated, and standing positions. Thus, the validation procedure should include equal numbers of measurements in these three positions. Separate analyses of agreement should be performed, and the limits of agreement should be compared among the different posture groups to assess whether error is increased in a particular position.

Another special consideration for ambulatory blood pressure monitors is the potential loss of precision during clinical use. For example, some ambulatory recorders have microphones that have been sewn within the cuff sleeve. The microphone may be displaced with ordinary ambulation or arm motion; hence, the device can become imprecise. Ambulatory blood pressure recorders are also subject to greater wear and tear during clinical use than are nonportable pressure recorders. Thus, part of the resting measurements to assess an ambulatory blood pressure recorder should include testing before and after 24 h study. The disparity between the reference manometer and the device at the beginning and end of the study should be compared. The disparity should not exceed 5 mmHg in 75 % of the paired simultaneous test samples.

E.3 Measurements during motion

Because ambulatory blood pressure recorders are worn during a variety of activities including walking, jogging, and light exercise, it is important to assess the accuracy of these devices during motion. This is exceedingly difficult, however, as the only precise standard measurement of blood pressure during exercise is intra-arterial recording. Furthermore, assessment of a device during motion requires the use of contralateral arms. During motion studies, the intra-arterial catheter should be inserted into the brachial artery. Placing a blood pressure cuff over this catheter site dampens the intra-arterial waveform, rendering it inaccurate. Requisite to using contralateral arms in motion testing is assurance, by either simultaneous or sequential measurements with a reference sphygmomanometer, that the blood pressures in the two arms are within 5 mmHg of each other.

As shown in Figure E.1, ambulatory blood pressure recorders can be assessed during bicycle exercise and compared in contralateral arms with intra-arterial pressures. In general, both clinician and recorder error are greater during physical exercise than during resting conditions. The amount of recorder variability with motion can be so great that it is unacceptable and the device should be restricted for resting measurements only.

Another method useful for verification of ambulatory blood pressure recorders during ambulation of motion is continuous ambulatory intra-arterial blood pressure recordings (e.g., Oxford medilog system). This device requires an indwelling brachial artery catheter infused continuously with sodium heparin for a period of 24 h. (An external transducer is located at heart level and measures beat-to-beat blood pressure, and complex software programs have been developed to calculate 2 min averaged blood pressures.) Recently, it also has been possible to obtain simultaneous analog output from the noninvasive device and intra-arterial device. The intra-arterial blood pressure monitors have aided in assessment of 24 h blood pressure variability by noninvasive devices during all forms of activities. While the continuous measurement of intra-arterial pressure is the most precise method of assessing a noninvasive ambulatory blood pressure recorder during ambulation, its use is highly restricted to a few centers in the

world. Furthermore, about 15 % of patients undergoing ambulatory intra-arterial recordings develop complications, including ecchymoses, hematoma, arterial occlusion, and arterial dissection. Therefore, obtaining data with this method only could be justified if the procedure was already being performed for a reason other than the validation study.

If the opportunity exists to assess an ambulatory blood pressure recorder during motion against intra-arterial recordings, the method of data collection and analysis should be the same as previously described (annexes C and D).

E.4 Field testing of ambulatory blood pressure monitoring devices

E.4.1 Assessment of precision over 24 h

Ambulatory blood pressure recorders were developed to assess blood pressure changes in the patient's own environment over a prolonged period of time (usually 24 h). Thus, it is necessary to establish whether the recorder is easy to use and how well it stands up to the rigorous conditions of the field. Testing the recorder for reproducibility from one study to another poses a problem: blood pressure variability can be marked in an individual from one day to the next.

A recent study of 73 patients by Prisant, et al. (1992) concluded that intrapatient variability might limit the usefulness of a single 24 h ambulatory recording. Figure E.2 (taken from the Prisant, et al. study) is a histogram of variability occurring between two separate 24 h studies.

E.4.2 Clinical performance

It is, however, appropriate to assess the clinical performance of a recorder. Ease of recorder application should be tested, including programming, reliability with repeated clinical use, and data return in "ambulatory" studies. Three different devices should be assessed on a minimum of 10 patients for a total of 30 24 h studies. A minimum of 75 blood pressure readings in 24 h should be obtained, with intervals of 15 min during the awake period (e.g., 0600 to 2300 hours) and 30 min during sleep (e.g., 2300 to 0600 hours). Most devices have a set of error codes that are associated with motion artifact, extraneous noise, etc. The number of satisfactory readings in 24 h should exceed 80 % of the number programmed for the 24 h (e.g., 60/75). The types and frequencies of error codes/aborted readings should include a comparison of data return rates at the beginning and end of the 30 studies. The data should be disclosed to users in writing.

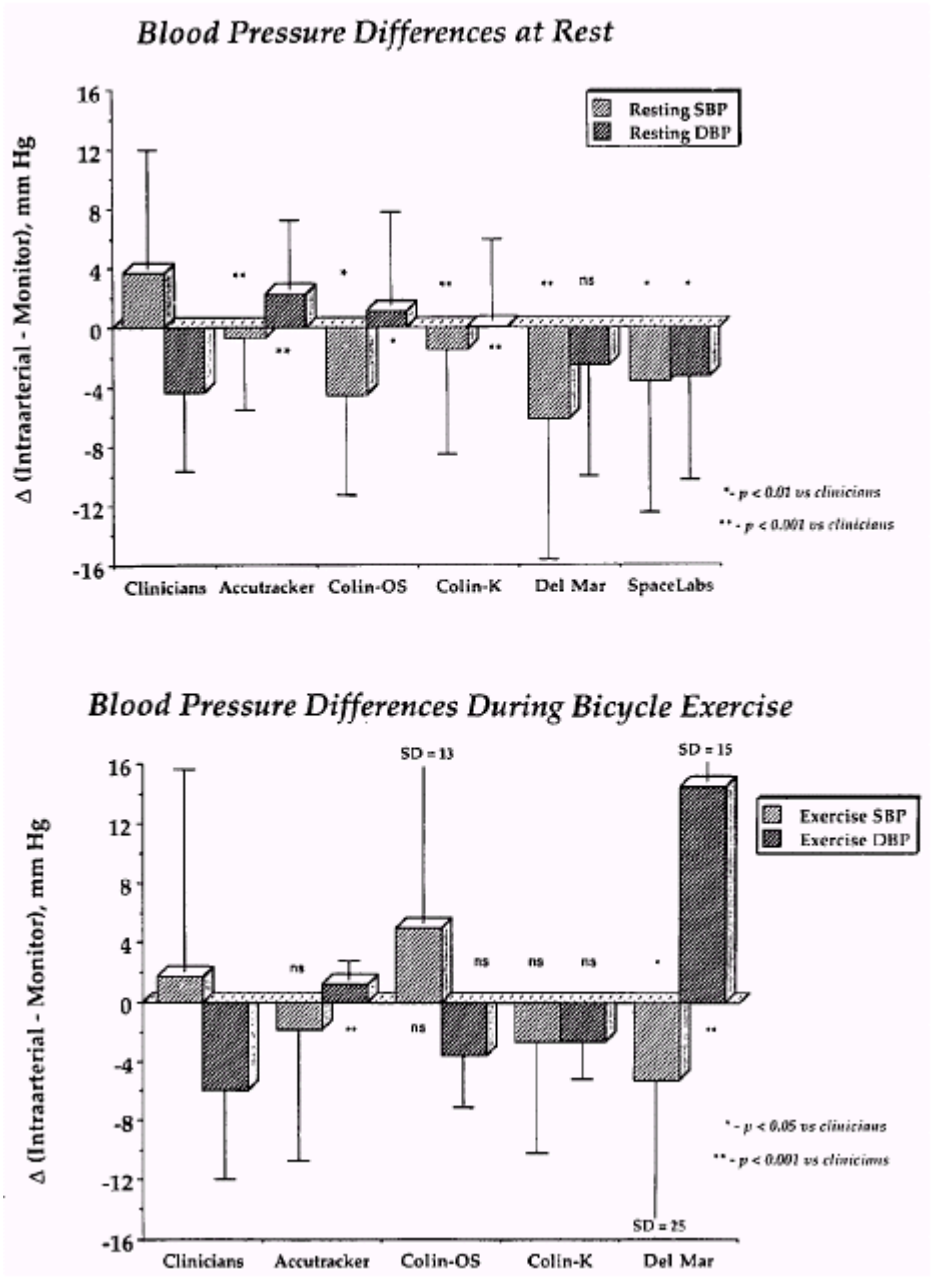

Figure E.1—Comparison of mean differences

a) Comparison of mean differences in intra-arterial blood pressure and clinicians; and b) intra-arterial blood pressure and four different ambulatory blood pressure monitors at rest and during bicycle exercise.

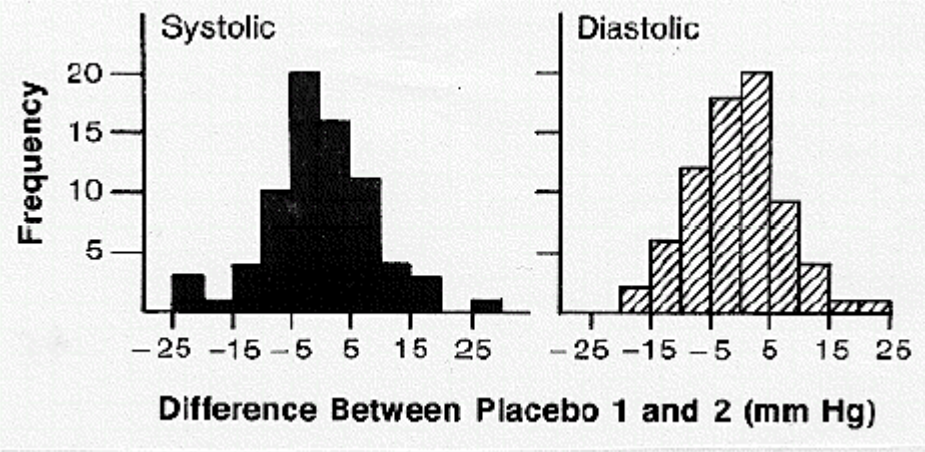

Figure E.2—Histogram of variability in two studies

Frequency histogram of difference between set 1 and set 2 (placebo 1 and placebo 2) mean 24 hour systolic and diastolic blood pressures of 73 hypertensive patients.

Annex F
(informative)

Statistical considerations

F.1 Background and notation

There are 3 pairs of blood pressure measurements on each person, one member of each pair corresponding to the reference auscultatory method and the other to the device being evaluated. The difference between the device and reference readings is an error, and the average error for a given person is used for analysis. Thus, if the device is evaluated on 85 people, the *sample mean error, sample variance of errors,* and *sample standard deviation of errors* refers to the mean, variance, and standard deviation of 85 numbers, each being the average of 3 errors on the same person. (This represents a change from the most recent previous version of this document, in which the sample standard deviation of errors using an auscultatory reference referred to the standard deviation of all 85 x 3 = 255 errors.) These sample statistics are only estimates of the *true mean error* (also called *bias*), *true variance of errors*, and *true standard deviation of errors*, which could be determined by testing the device on an unlimited number of people. A *tolerable error* is an error of 10 mmHg or less for a given person (using the average of that person's readings). Here is a summary of notations used throughout this annex:

n is the number of people on whom the device is evaluated.

A *tolerable error* is an error of 10 mmHg or less on a single person using the average of that person's readings.

δ, σ^2, and σ are the true mean (also called the *bias*), variance, and standard deviation of people's errors, each person's being an average of 3 readings; δ, σ^2, and σ are conceptual quantities corresponding to testing the device on an unlimited number of people.

D, V, and $V^{½}$ are the sample mean, variance, and standard deviation of *n* people's errors. These are estimates of the bias, true variance, and true standard deviation.

The most recent previous version of this document set a static upper limit for the sample standard deviation of errors, irrespective of the sample mean error. But a standard deviation of 7 mmHg, for example, is worse if the mean error is 5 mmHg than if it is 0 mmHg. The probability of a tolerable error for a device with a true standard deviation of 7 mmHg is about 85 % if the bias is 0 mmHg, but only 75 % if the bias is ± 5 mmHg (see Figure F.1). For a device with a bias of ± 5 mmHg to maintain an 85 % probability of a tolerable error, its true standard deviation shall be 4.81 mmHg (see Figure F.2).

F.2 Acceptance criterion

A device is considered acceptable if its estimated probability of a tolerable error is at least 85 %. This rule makes the upper limit for an acceptable sample standard deviation depend on the sample mean error. Table F.1 gives the upper standard deviation limit for different values of the sample mean error.

Table F.1—Upper limit on the sample standard deviation to yield at least 85 % probability of a tolerable error

Sample mean error	0	± 0.5	± 1.0	± 1.5	± 2.0	± 2.5	± 3.0	± 3.5	± 4.0	± 4.5	± 5.0
St dev ≤	6.95	6.93	6.87	6.78	6.65	6.47	6.25	5.97	5.64	5.24	4.81

The sample standard deviation is allowed to be as high as 6.95 mmHg to accept the device if the sample mean error is 0 mmHg, but shall be 4.81 mmHg or less to accept the device if the sample mean error is ± 5 mmHg. The device is automatically rejected if the sample mean error is greater than 5 mmHg or less than –5 mmHg.

Linear interpolation is used when the sample mean error is between two values of the table. For example, suppose the mean is 2.2 mmHg. This is (2.2 – 2.0)/(2.5 – 2.0) = .40 = 40 % of the distance between 2.0 and 2.5, so one uses .40 x 6.47 + (1 – .40) x 6.65 = 6.58. The sample standard deviation would have to be 6.58 or less to accept the device.

F.3 Sample size determination

Table F.1 can be used with any number of participants, but the procedure becomes more accurate as the sample size becomes larger. The estimated probability of a tolerable error is just that—an estimate. How far off it is depends on the sample size. A sample size of n = 85 yields a 90 % chance that the estimated probability of a tolerable error will not differ by more than about .07 from its true probability. Thus, if the estimated probability of a tolerable error is 85 %, one can be confident that the true probability of a tolerable error is at least 78 %.

F.4 Evaluation of the procedure

This section evaluates the probability of accepting a device for different values of the true mean and standard deviation of errors and a sample size of 85. Results are summarized in Table F.2.

Table F.2—Probability of accepting the device for different values of the true mean and standard deviation of errors and a sample size of n = 85

In parentheses is the true probability of a tolerable error.

Bias	σ = 5	σ = 6	σ = 7	σ = 8
0	(.95) 1.0	(.90) .98	(.85) .45	(.79) .04
1	(.95) 1.0	(.90) .96	(.84) .40	(.79) .03
2	(.94) 1.0	(.89) .89	(.83) .26	(.77) .02
3	(.91) .99	(.86) .66	(.81) .11	(.76) .01
4	(.88) .86	(.83) .28	(.78) .03	(.73) .00
5	(.84) .33	(.79) .05	(.75) .00	(.70) .00
6	(.79) .02	(.74) .00	(.71) .00	(.67) .00
7	(.73) .00	(.69) .00	(.66) .00	(.63) .00

For example, consider the three numbers corresponding to a bias of 3 mmHg and a true standard deviation of σ = 5. The true probability of a tolerable error is 91 %. This is above the threshold of 85 %, so we would like to accept the device. With a sample size of n = 85 people, the device has a 99 % chance of being accepted. On the other hand, if the bias is 3 mmHg and the true standard deviation is 7 mmHg, the true probability of a tolerable error is only 81 %, which is below the threshold of 85 %. Thus, we would like to reject the device. Table F.2 shows that with a sample size of n = 85 people, the probability of accepting the device is 11 %.

F.5 Details of calculations

F.5.1 Determination of Table F.1

Denote the sample mean and variance of the errors by D and V, respectively. The estimated probability of a tolerable error, assuming normally distributed errors, is

$$f(D,V) = \Phi\left(\frac{10 - \overline{D}}{\sqrt{V}}\right) - \Phi\left(\frac{-10 - \overline{D}}{\sqrt{V}}\right) \qquad \text{(F1)}$$

Table F.1 was obtained by equating (F1) to .85 and solving for the sample standard deviation $V^{1/2}$ for given values of the sample mean error D.

F.5.2 Determination of sample size

A Taylor series expansion of (F1) about the true mean σ and variance σ^2 yields

$$f\left(\overline{D},V\right) \approx f\left(\delta,\sigma^2\right) + f_{\overline{D}}\left(\delta,\sigma^2\right)\left(\overline{D} - \delta\right) + f_V\left(\delta,\sigma^2\right)\left(V - \sigma^2\right) \tag{F1a}$$

where f_D and f_V denote partial derivatives of $f(D,V)$ with respect to D and V, respectively:

$f_{\overline{D}}\left(\delta,\sigma^2\right) = (1/\sigma)\{\phi(y) - \phi(x)\}$ and

$f_V\left(\delta,\sigma^2\right) = -\frac{1}{2\sigma^2}\{x\phi(x) + y\phi y\}$

where $\chi = (10 - \delta)/\sigma$, $\gamma = (10 + \delta)/\sigma$, and $\phi(.)$ denotes the standard normal density function.

Thus, $f(D,V)$ is asymptotically normally distributed with mean $f(\delta, \sigma^2)$ and standard deviation.

$$\phi_f = \sqrt{\left(f_{\overline{D}}\right)^2 \operatorname{var}\left(\overline{D}\right) + \left(f_V\right)^2 \operatorname{var}(V)} \tag{F2}$$

Substituting $2\sigma 2/n$ and $2\sigma 4/(n - 1)$ for var(D) and var(V) and simplifying (2) yields

$$\operatorname{var}\left\{f\left(\overline{D},V\right)\right\} \approx \sqrt{\frac{\{\phi(x) - \phi(y)\}^2}{n} + \frac{\{x(\phi) + y\phi(y)\}^2}{2(n-1)}} \tag{F3}$$

$$\leq \sqrt{\frac{\{\phi(x) - \phi(y)\}^2 + (1/2)\{x\phi(x) + y\phi(y)\}^2}{n-1}} \tag{F4}$$

The inequality (F4), obtained by replacing n by $n - 1$ in the first term of (F3), is a very close approximation for reasonably large n. Because χ and γ will differ for different devices, to be conservative we shall maximize (F4) over all possible values of χ and γ. The maximum value is $\{2\pi(n - 1)\}^{-1/2}$, occurring when one of χ and γ is 0 and the other approaches $\pm\infty$. We can be 90 % confident that the difference between the estimated and actual probabilities of a tolerable error is no more than 1.645 $\{2\pi(n - 1)\}^{-1/2}$. Substitution of n = 85 yields .07 as the largest reasonable discrepancy between the estimated and actual probabilities of a tolerable error.

F.5.3 Determination of properties of the procedure

The sample mean *D* and variance *V* from a sample of size *n* from a normal population are independent; *D* is normally distributed with mean.

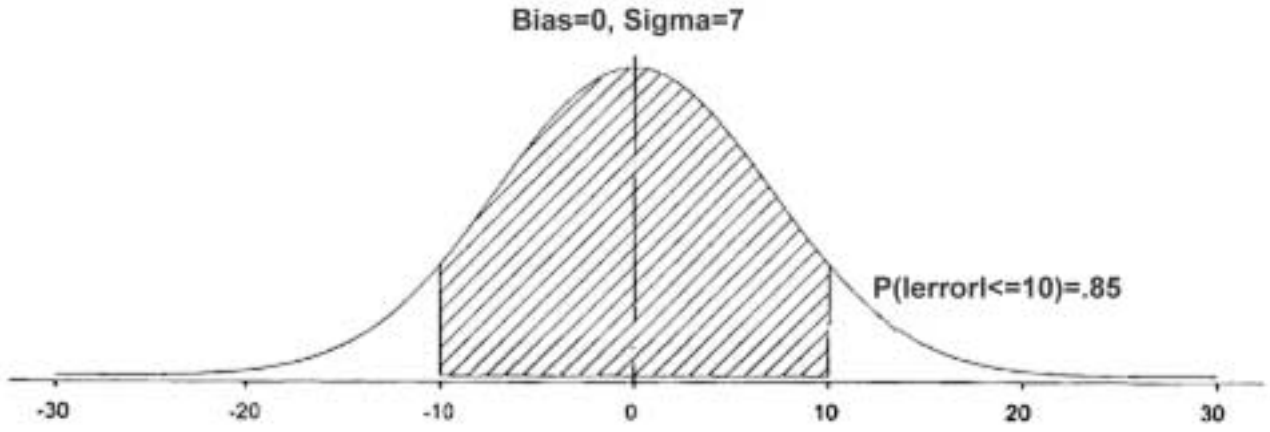

Figure F.1—Distribution of errors

Figure F.1 shows the distribution of errors when the device has bias 0 and true standard deviation 7. The shaded area, 85 % of the total, is the probability of a tolerable error. Figure F.2 shows the distribution for a device whose bias is 5 mmHg and standard is 7 mmHg. Now the probability of a tolerable error is only 75 %.

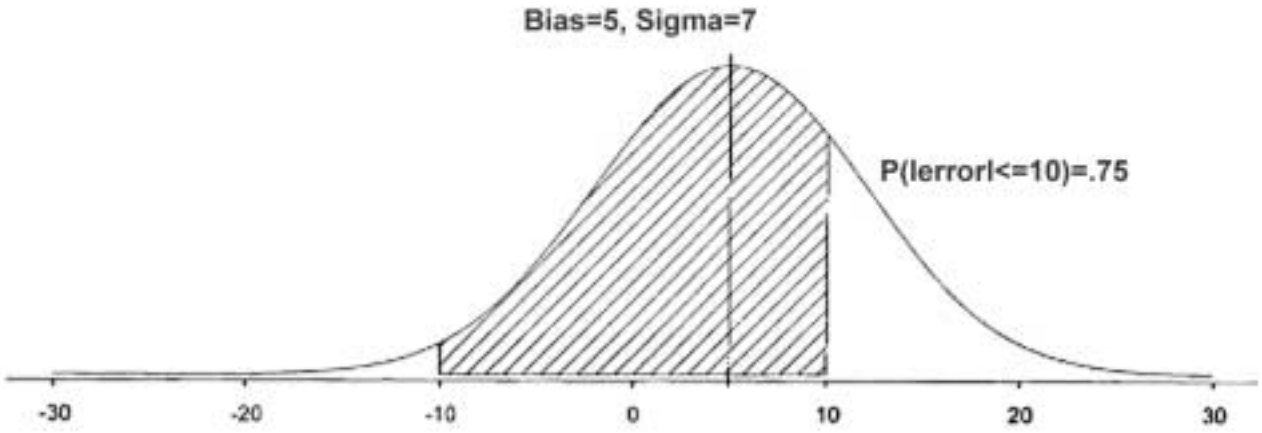

Figure F.2—Standard deviation of errors

Figure F.2 shows how much the true standard deviation of errors for a device with bias 5 mmHg has to decrease to maintain an 85 % probability of a tolerable error. It has to decrease from 7 mmHg (Figure F.1) to 4.81 mmHg (Figure F.2).

Annex G
(informative)

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