

**American  
National  
Standard**

ANSI/AAMI SP10:2002  
& ANSI/AAMI SP10:2002/A1:2003

**Manual, electronic,  
or automated  
sphygmomanometers**

# 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, disclosures 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.

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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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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.

Professional judgment must 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 & SP10:2002/A1:2003  
(Revision of ANSI/AAMI SP9:1994;  
ANSI/AAMI SP10:1992; and  
ANSI/AAMI SP10:1992/A1:1996)

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## **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

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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  
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Rich Walloch, Spacelabs Medical Inc.

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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.

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## In Memoriam

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

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

## Acknowledgements



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

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

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## Foreword

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

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

Blood pressure measured within an artery generally differs from that measured indirectly by techniques that do not require intra-arterial catheters. The efficacy of an indirect blood pressure measurement device can be determined by comparing its measurements with direct intra-arterial measurements. Alternatively, the noninvasive cuff/stethoscope technique, based on Korotkoff sounds identified by an individual trained in auscultation, has been found, however, to produce results directly related to intra-arterially measured blood pressure 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.

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

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# Manual, electronic, or automated sphygmomanometers

## 1 Scope

### 1.1 General

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

### 1.2 Inclusions

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

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

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

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

### 1.3 Exclusions

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