

American National Standard



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ANSI/AAMI/ ISO 81060- 2:2013

Non-invasive sphygmomanometers —
Part 2: Clinical investigation of automated
measurement type

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 frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare 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.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

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 decision-making.

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.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.



Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type

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Approved 19 March 2013 by
Association for the Advancement of Medical Instrumentation

Approved 26 June 2013 by
American National Standards Institute, Inc.

Abstract: This standard specifies the requirements and methods for the clinical validation of medical electrical equipment used for the intermittent non-invasive automatic estimation of the arterial blood pressure by utilizing a cuff. It is applicable to all sphygmomanometers that sense or display pulsations, flow, or sounds for the estimation, display, or recording of blood pressure. These sphygmomanometers need not have automatic cuff inflation. This standard covers sphygmomanometers intended for use in all patient populations (i.e. all age and weight ranges, and all conditions of use, e.g., ambulatory blood pressure monitoring, stress testing blood pressure monitoring). It is also applicable to the validation of electronically-controlled intermittent non-invasive blood pressure measurement medical electrical equipment, including blood pressure monitors for the home healthcare environment or self-measurement.

Keywords: non-invasive blood pressure monitor, electromedical equipment, automated sphygmomanometer

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI, or by visiting the AAMI website at www.aami.org.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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Contents

Page

Glossary of equivalent standards	iv
Committee representation	v
Background of AAMI adoption of IEC 81060-2:2013	vi
Foreword	vii
Introduction	ix
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements for CLINICAL INVESTIGATIONS	2
5 CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER	3
6 CLINICAL INVESTIGATION with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT	18
7 * Pregnant (including pre-eclamptic) PATIENT populations	24
Annex A (informative) Rationale and guidance	25
Annex B (normative) Target heart rates for exercise stress testing	38
Annex C (informative) Reference to the essential principles	39



Advancing Safety in Medical Technology

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf



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Committee representation

Association for the Advancement of Medical Instrumentation

Sphygmomanometer Committee

The adoption of ISO 81060-02 as a revision of ANSI/AAMI/ISO 81060-02:2009 was initiated by the AAMI Sphygmomanometer Committee, which serves as the U.S. TAG (technical advisory group) for IEC/SC 62D and ISO/TC 121 Joint Working Group. U.S. representatives played an active role in developing the ISO standard. 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:

<i>Cochairs</i>	John W. Graves, MD David Quinn
<i>Members</i>	Bruce Stephen Alpert, MD, University of Tennessee Health Sciences Center Michael Joseph Bernstein, BS, Physio Monitor Jim Brown, Colder Products Company Richard A. Dart, MD, Marshfield Clinic Gerhard Frick, Microlife Services AG Bruce A Friedman, D.Eng, GE Healthcare Jeff Gilham, Spacelabs Medical Inc. John W. Graves, MD, Mayo Clinic Clarence E. Grim, MS MD, Medical College of Wisconsin Michael Gutkin, MD FACP, Michael Gutkin MD LLC Charles S. Ho, PhD, FDA/CDRH Tsutomu Ichikawa, Omron Healthcare Co Ltd Jiri Jilek, Carditech Jack M. Millay, Accurate Blood Pressure Charles C. Monroe, Philips Electronics North America Bruce Z. Morgenstern, MD, Phoenix Childrens Hospital Yechiam Ostchega, PhD, RN, National Center for Health Statistics David Quinn, Welch Allyn Inc. Robert Smith, Robert M. Smith, MD, LLC. Leonard Steinfeld, MD, Mount Sinai Hospital William B. White, MD, University of Connecticut Health Center J.S. Wiley, Draeger Medical Systems Inc. Colin Wu, Ph.D., National Heart Lung & Blood Institute Ruomei Zhang, Midmark Corp
<i>Alternates</i>	Greg Downs, Spacelabs Medical Inc. James Li, Omron Healthcare Co Ltd David G. Osborn, Philips Electronics North America Sandy Weininger, PhD, FDA/CDRH Donna Williams, Welch Allyn Inc.

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

Background of ANSI/AAMI adoption of ISO 81060-2:2013

This standard was developed by the International Organization for Standardization (ISO)/TC 121/SC 3 and International Electrotechnical Commission (IEC)/SC 62D Joint Working Group (JWG) 7 on Non-invasive blood pressure monitoring equipment and has been adopted by the AAMI Sphygmomanometer Committee. The objective of this standard is to provide minimum labeling, performance, and safety requirements for the clinical validation of medical electrical equipment use for the intermittent non-invasive automatic estimation of the arterial blood pressure by utilizing a cuff. It is applicable to all sphygmomanometers that sense or display pulsations, flow, or sounds for the estimation, display, or recording of blood pressure.

This is a revision of the American National Standard AAMI/ISO 81060-2:2009, which revised ANSI/AAMI SP10:2002. During the course of this international standard undergoing U.S. review, the U.S. Technical Advisory Group for the ISO and IEC JWG 7 decided to adopt this revision. Serving as the U.S. sub-TAG for the ISO/IEC JWG, the AAMI Sphygmomanometer Committee was responsible for developing the U.S. consensus on the international standard and otherwise participated in the drafting of this document.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of IEC and ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the IEC and ISO standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed 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 standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

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 Standards Department, AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

NOTE—Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 81060-2:2013.

NOTE—This background does not contain provisions of the American National Standard, *Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type* (ANSI/AAMI/ISO 81060-2:2013), but it does provide important information about the development and intended use of the document.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

This second edition cancels and replaces the first edition (ISO 81060-2:2009), subclauses 5.2.4.3.1 and 6.2.4 of which have been technically revised. Numerous clarifications have been added and kPa equivalent values for the mmHg values have been included in the standard, including the Criterion 2 requirements of 5.2.4.1.2. It also incorporates the Technical Corrigendum ISO 81060-2:2009/Cor 1:2011.

ISO 81060-2 was prepared by Technical Committee ISO/TC 121, *Anesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee 62D, *Electromedical equipment*, in accordance with ISO/IEC mode of cooperation 5.

ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

- *Part 1: Requirements and test methods for non-automated measurement type*
- *Part 2: Clinical investigation of automated measurement type*

In this document, the following print types are used:

- requirements, compliance with which can be verified, and definitions: roman type;
- notes and examples: smaller roman type;
- test methods: *italic type*;
- terms defined in this document: SMALL CAPITALS TYPE.

Throughout this document, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new

requirements and to equip themselves for conducting new or revised tests. It is the recommendation of ISO/TC 121 and IEC/TC 62 that the content of this part of ISO 81060 not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed, and not earlier than 5 years from the date of publication for equipment already in production.



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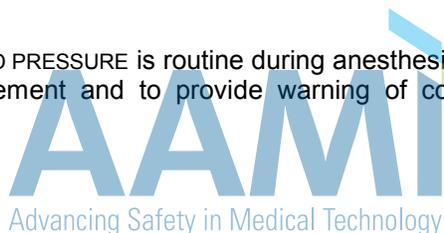
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Introduction

Determination of BLOOD PRESSURE is an important procedure that is clinically used to assess the status of a PATIENT.

Frequent determination of BLOOD PRESSURE is routine during anesthesia. BLOOD PRESSURE serves to aid in drug titration and fluid management and to provide warning of conditions that could affect PATIENT morbidity and mortality.



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Non-invasive sphygmomanometers — Part 2: Clinical investigation of the automated measurement type

1 Scope

This part of ISO 81060 specifies the requirements and methods for the CLINICAL INVESTIGATION OF ME EQUIPMENT used for the intermittent non-invasive automated estimation of the arterial BLOOD PRESSURE by utilizing a CUFF.

This part of ISO 81060 is applicable to all SPHYGMOMANOMETERS that sense or display pulsations, flow or sounds for the estimation, display or recording of BLOOD PRESSURE. These SPHYGMOMANOMETERS need not have automatic CUFF inflation.

This part of ISO 81060 covers SPHYGMOMANOMETERS intended for use in all PATIENT populations (e.g. all age and weight ranges), and all conditions of use (e.g. ambulatory BLOOD PRESSURE monitoring, stress testing BLOOD PRESSURE monitoring and BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT for self-measurement as well as use in a professional healthcare facility).

EXAMPLE AUTOMATED SPHYGMOMANOMETER as given in IEC 60601-2-30 undergoing CLINICAL INVESTIGATION according to this part of ISO 81060.

This part of ISO 81060 specifies additional disclosure requirements for the ACCOMPANYING DOCUMENTS of SPHYGMOMANOMETERS that have undergone CLINICAL INVESTIGATION according to this part of ISO 81060.

This part of ISO 81060 is not applicable to CLINICAL INVESTIGATIONS of NON-AUTOMATED SPHYGMOMANOMETERS as given in ISO 81060-1 or INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as given in IEC 60601-2-34.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 81060-1, *Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type*

IEC 60601-2-30:2009, *Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012