Sphygmomanometer Guidance Collection 2010

Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type (ANSI/AAMI/ISO 81060-1:2007)

Non-invasive sphygmomanometers —Part 2: Clinical validation of automated measurement type (ANSI/AAMI/ISO 81060-2:2009)

Medical electrical equipment— Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers (ANSI/AAMI/IEC 80601-2-30:2009)

American National Standard

ANSI/AAMI/ISO 81060-1:2007

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

AAMI
Association for the Advancement of Medical Instrumentation

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.

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

Approved 18 March 2008 by
Association for the Advancement of Medical Instrumentation

Approved 1 May 2008 by
American National Standards Institute, Inc.

Abstract: This standard specifies requirements for mechanical sphygmomanometers and their accessories that, by means of an inflatable cuff, are used for the non-invasive measurement of blood pressure. This standard also specifies requirements for the safety, essential performance, effectiveness, and labeling, for these instruments and their accessories, including test methods to determine the accuracy of their measurements. The standard covers non-invasive blood pressure measuring devices with a mechanical pressure sensing element and display used in conjunction with a stethoscope or other manual methods for detecting Korotkoff sounds.

Keywords: sphygmomanometer, blood pressure

AAMI Standard

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

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 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical

International designation	U.S. designation	Equivalency
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	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/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007	ANSI/AAMI/ISO 15223-1:2007	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Sphygmomanometer Committee

This standard was adopted with minor U.S. inclusion by the Sphygmomanometer Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of this document does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the committee had the following members.

Cochairs:	Bruce Stephen Alpert, MD
	Bruce A Friedman
Members:	Bruce Stephen Alpert, MD, University of Tennessee @ Memphis College of Graduate Health Sciences
	Donald J. Fournier, Draeger Medical
	Gerhard Frick, Microlife Services AG
	Bruce A Friedman, GE Healthcare
	David Gallick, Sun Tech Medical
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	Dayn C. McBee, Sun Tech Medical
	David Osborn, Philips Medical Systems
	John Seller, Welch Allyn Inc
	Andrea D. Stebor, PhD, GE Healthcare

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 AAMI Adoption of ISO 81060-1:2007

This standard was developed by the International Organization for Standardization (ISO)/TC 121/SC3 and International Electrotechnical Commission (IEC)/SC 62D Joint Working Group 7 on Non-Invasive Blood Pressure Monitoring Equipment and has been adopted by the AAMI Sphygmomanometer Committee, with one minor U.S. inclusion. The objective of this standard is to provide minimum labeling, performance, and safety requirements for non-automated type non-invasive sphygmomanometers.

This is a new American National Standard. During the course of this international standard undergoing U.S. review, the U.S. Technical Advisory sub-Group (sub-TAG) for the ISO and IEC Joint Working Group (JWG) 7 (AAMI Sphygmomanometer Committee) decided to adopt this then proposed international standard as an American National Standard. During the national balloting process, the committee decided to include one minor U.S. inclusion in Annex A, subclause 6.4.2, which does not change any technical content of ISO/IEC 81060-1:2007, but provides clarification of the section. Serving as the U.S. sub-TAG for the ISO/IEC JWG, the AAMI Sphygmomanometer Committee was responsible for developing U.S. consensus on the international standard and otherwise participated in the drafting of that 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.

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 Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This background does not contain provisions of the American National Standard, *Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type* (ANSI/AAMI/ISO 81060-1:2007), but it does provide important information about the development and intended use of the document.

NOTE—Beginning with the ISO foreword on page “x”, this American National Standard is identical to ISO 81060-1:2007, except for the minor inclusion to Annex A, subclause 6.4.2.

AAMI inclusion to ISO 81060-1:2007

6.4.2 * Non-automated sphygmomanometers for transport

Add the following:

Note: See last paragraph of the Annex A, Subclause 6.4.2 for U.S. inclusion.

Annex A

Subclause 6.4.2 Non-automated sphygmomanometers for transport

Add at the end of section, the following paragraph**:**

Note: Since clause 6.4.2 of this standard requires functional testing before and after vibrations, but not during vibrations, the U.S. believes that there is no proof that the device can indeed perform within specifications during vibrations, such as enabling the user to accurately measure the blood pressure of a patient who is being transported in a moving ambulance. Thus, this standard cannot be used in the U.S. to substantiate a claim of functionality within the manufacturer's specifications during transport.

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.

ISO 81060-1 was prepared by Technical Committee ISO/TC 121, *Anesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

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*

The preparation of a second part covering clinical evaluation for the automated measurement type is planned.

For automated measurement type non-invasive sphygmomanometers, see IEC 60601-2-30 [7].

Introduction

The minimum safety requirements specified in this part of ISO 81060 are considered to provide a practical degree of safety in the operation of non-automated sphygmomanometers.

The requirements are followed by specifications for the relevant tests.

A “rationale and guidance” section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex A.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this part of ISO 81060 but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex A does not form part of the requirements of this part of ISO 81060.

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

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

1 * Scope

This part of ISO 81060 specifies requirements for non-automated sphygmomanometers, as defined in 3.11, and their accessories, which, by means of inflatable cuffs, are used for the non-invasive blood pressure measurement by operator observation.

This part of ISO 81060 specifies requirements for the safety and essential performance, including effectiveness and labeling, for non-automated sphygmomanometers and their accessories, including test methods to determine the accuracy of non-invasive blood pressure measurement.

The part of ISO 81060 covers non-invasive blood pressure measurement devices with a pressure-sensing element and display used in conjunction with means of detecting blood flow.

EXAMPLE 1 A stethoscope for detecting Korotkoff sounds, Doppler ultrasound or other manual methods.

Requirements for non-invasive blood pressure measurement equipment with electrically-powered pressure sensing elements and/or displays used in conjunction with other automatic methods determining blood pressure are specified in IEC 60601-2-30 [7].

Requirements for invasive blood pressure measurement equipment that directly measure blood pressure are specified in document IEC 60601-2-34 [8].

EXAMPLE 2 Measuring equipment, including associated transducers, that is used for the invasive measurement of circulatory system pressures.

2 Normative references

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

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7010:2003, *Graphical symbols — Safety colors and safety signs — Safety signs used in workplaces and public areas*

ISO 10993-1[1)], *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of sterilization process for medical devices*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. For convenience, an alphabetized list of the sources of all defined terms used in this document is given in Annex E.

3.1
accompanying document
document accompanying a **non-automated sphygmomanometer** or accessory and containing information for those accountable for the installation, use and maintenance of the **non-automated sphygmomanometer** or accessory, the **operator** or the **responsible organization**, particularly regarding safety

[Modified from ISO 14971:2007, definition 2.1]

3.2
bladder
that part of the **cuff** that is inflatable

3.3
blood pressure
pressure in the systemic arterial system of the body

3.4
clearly legible
capable of being read by a person with normal vision

[IEC 60601-1:2005, definition 3.15]

3.5
cuff
part of the **non-automated sphygmomanometer** that is wrapped around the limb of the **patient**

NOTE A cuff might comprise a bladder and an inelastic part that encloses the bladder, or have an integral bladder (i.e., the cuff including the bladder are fixed together or are one piece).

1) To be published. (Revision of ISO 10993-1:2003)

3.6
expected service life
maximum period of useful life as defined by the **manufacturer**

[IEC 60601-1:2005, definition 3.28]

3.7
intended use
use of a product, process or service in accordance with the specifications, instructions and information provided by the **manufacturer**

NOTE Intended use should not be confused with normal use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but also maintenance, service, transport, etc.

[IEC 60601-1:2005, definition 3.44]

3.8
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging or labeling of **non-automated sphygmomanometers**, or adapting **non-automated sphygmomanometers**, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 [2] defines “labeling” as written, printed or graphic matter

– affixed to a medical device or any of its containers or wrappers

or

– accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this part of ISO 81060, that material is described as markings and the accompanying document.

NOTE 2 “Adapting” includes making substantial modifications to a non-automated sphygmomanometer already in use.

NOTE 3 In some jurisdictions, the responsible organization can be considered a manufacturer when involved in the activities described.

[Modified from IEC 60601-1:2005, definition 3.55]

3.9
*** model or type reference**
combination of figures, letters or both used to identify a particular model of **non-automated sphygmomanometer** or accessory

[Modified from IEC 60601-1:2005, definition 3.66]

3.10
nominal
value quoted for reference purposes that is subject to agreed tolerances

[IEC 60601-1:2005, definition 3.69]

3.11
non-automated sphygmomanometer
instrument used for the non-invasive measurement of the **blood pressure** by utilizing an inflatable **cuff** with a pressure-sensing element, a valve for deflation, and a display used in conjunction with a stethoscope or other manual methods for estimating **blood pressure**

NOTE Components of these instruments include manometer, cuff, valve for deflation (often in combination with the valve for rapidly exhausting the pneumatic system), hand pump or electro-mechanical pump for inflation of the bladder, and connection hoses. A non-automated sphygmomanometer can also contain electro-mechanical components for pressure control.

3.12
non-invasive blood pressure measurement
indirect measurement of the **blood pressure** without arterial puncture

3.13
normal use
operation, including routine inspection and adjustments by any **operator**, and stand-by, according to the instructions for use

NOTE Normal use should not be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, service, transport, etc., as well.

[IEC 60601-1:2005, definition 3.71]

3.14
operator
person handling equipment

[IEC 60601-1:2005, definition 3.73]

3.15
patient
living being (person or animal) undergoing a medical, surgical or dental procedure

[IEC 60601-1:2005, definition 3.76]

3.16
pneumatic system
part of the **non-automated sphygmomanometer** that includes all pressurized and pressure-controlling components

EXAMPLES Cuff, tubing, connectors, valves, transducer and pump.

3.17
portable
term referring to transportable equipment intended to be moved from one location to another while being carried by one or more persons

[IEC 60601-1:2005, definition 3.85]

3.18
responsible organization
entity accountable for the use and maintenance of a **non-automated sphygmomanometer**

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the patient, operator and responsible organization can be one and the same person.

NOTE 2 Education and training is included in "use."

[Modified from IEC 60601-1:2005, definition 3.101]

3.19
stationary
term referring to equipment that is not intended to be moved from one place to another

[IEC 60601-1:2005, definition 3.118]

3.20
type test
test on a representative sample of the **non-automated sphygmomanometer** with the objective of determining if the **non-automated sphygmomanometer**, as designed and manufactured, can meet the requirements of this document

[Modified from IEC 60601-1:2005, definition 3.135]

4 Identification and marking

4.1 * Units of measurement

The cuff pressure shall be indicated in either millimeters of mercury (mmHg) or kilopascals (kPa).

Check compliance by inspection.

4.2 * Legibility of markings

The markings required by 4.4, 4.6, and 4.7 shall be clearly legible under the following conditions:

a) for warning statements, instructive statements, safety signs and drawings on the outside of the non-automated sphygmomanometer, from the intended position of the person performing the related function;

b) for markings on the inside of the non-automated sphygmomanometer or non-automated sphygmomanometer parts, from the intended position of the person performing the related function.

Check compliance for a clearly legible marking by the following test.

1) Position the non-automated sphygmomanometer or its part so that the viewpoint is the intended position of the operator; or the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

2) Ensure that the ambient luminance is the least favorable level in the range of 100 lx to 1,500 lx.

3) Ensure that the observer has a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), corrected if necessary.

4) The observer correctly reads the marking from the viewpoint.

4.3 * Durability of markings

The markings required by 4.4 and 4.6 shall be removable only with a tool or by appreciable force and shall be sufficiently durable to remain clearly legible during the expected service life of the non-automated sphygmomanometer. In considering the durability of the markings, the effect of normal use shall be taken into account.

Check compliance by inspection and the following tests.

After all the other tests of this document have been performed:

a) markings are rubbed by hand, without undue pressure, first for 15 s with a cloth soaked with distilled water, then for 15 s with a cloth soaked with methylated spirits and then for 15 s with a cloth soaked with isopropyl alcohol.

b) legibility of markings are tested to the requirements of 4.2;

c) adhesive labels shall not have worked loose or become curled at the edges.

4.4 * Marking of non-automated sphygmomanometer

The non-automated sphygmomanometer, the cuff and/or their components shall be marked clearly and legibly with the following:

a) the name or trademark and address of the manufacturer;

b) model or type reference;

c) * where appropriate, an identification reference to the serial or batch number, or Symbol 5.16 or 5.14 from ISO 15223-1:2007;

d) the non-automated sphygmomanometer and its parts shall be marked with regard to proper disposal, as appropriate;

e) * the numbering on the scale or digital display shall not exceed the measurement range as determined in 7.1.2.

The following is additionally required for a non-automated sphygmomanometer containing a mercury manometer:

f) * safety sign for mandatory action “Refer to instruction manual/booklet” in accordance with M002 of ISO 7010:2003 and safety sign for warning “General warning” in accordance with W-001 of ISO 7010:2003;

g) an indication that the tube contains mercury.

Check compliance by inspection.

4.5 * Usability of reading

Means shall be provided to address legibility and parallax error of reading the scale of a non-automated sphygmomanometer in normal use by ensuring that there is an indication to the operator when the parallax error results in a reading error that exceeds ± 2 mmHg (0.3 kPa).

Check compliance by the tests of 4.2.

The observer reads the scale with an error of less than ± 2 mmHg (0.3 kPa) from the viewpoint.

4.6 Marking of the cuff

The cuff shall additionally be marked with the following information:

a) indication of the correct positioning for the cuff over the artery;

b) indication the limb circumference for which it is appropriate (see 7.2.4).

Check compliance by inspection.

4.7 Marking of the non-automated sphygmomanometer packaging

The packaging of a non-automated sphygmomanometer, the cuff or their components shall be marked with the following:

a) details to enable the responsible organization to identify the contents of the packaging;

b) for a sterile non-automated sphygmomanometer, cuff or component, the appropriate Symbol 5.20. 5.21, 5.22, 5.23 or 5.24 from ISO 15223-1:2007;

c) for a non-automated sphygmomanometer, cuff or component with an expiry date, Symbol 5.12 from ISO 15223-1:2007;

d) for a single use non-automated sphygmomanometer, cuff or component, the words “single use only” or “do not re-use” or Symbol 5.2 from ISO 15223-1:2007;

e) any special storage and/or handling instructions;

f) the intended use of the cuff.

Check compliance by inspection.

5 General requirements for testing non-automated sphygmomanometers

5.1 * Type tests

The tests described in this standard are type tests.

5.2 * Representative sample

Type tests are performed on a representative sample of the item being tested.

NOTE Multiple samples can be utilized simultaneously if the validity of the results is not significantly affected.

5.3 Environmental conditions

General conditions of normal use shall include the following.

a) Unless otherwise specified in this part of ISO 81060, the non-automated sphygmomanometer complies with this part of ISO 8106 under the least favorable working conditions within the environmental temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing).

b) The non-automated sphygmomanometer is shielded from other influences (for example, draught), which might affect the validity of the tests.

5.4 Repairs and modifications

In the event of the necessity for repairs or modifications after a failure or a probability of future failure during the sequence of tests, the testing laboratory and the supplier of the non-automated sphygmomanometer for the test can agree, either upon the presentation of a new sample on which all tests influencing the result are performed again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests are repeated.

5.5 * Humidity preconditioning treatment

Prior to the tests described in Clause 7, the non-automated sphygmomanometer or its parts shall be subjected to a humidity preconditioning treatment.

Set up the complete non-automated sphygmomanometer or its parts. Detach covers used during transport and storage.

Perform the humidity preconditioning treatment in a humidity cabinet containing air with a relative humidity of 85 % $\pm$ 5 %. Maintain the temperature of the air in the cabinet, at all places where a non-automated sphygmomanometer can be located, within 2 °C of any convenient temperature, T, in the range of + 20 °C to + 32 °C. Before being placed in the humidity cabinet, bring the non-automated sphygmomanometer to a temperature between T and T + 4 °C, and maintain this temperature for at least 4 h before the humidity treatment.

Keep the non-automated sphygmomanometer and its parts in the humidity cabinet for 48 h.

Where the risk management process suggests that the non-automated sphygmomanometer can be exposed to high humidity for extended periods (such as a non-automated sphygmomanometer intended for outdoor use), extend the period appropriately.

After the treatment, re-assemble the non-automated sphygmomanometer, if necessary.

6 General requirements

6.1 General

Equipment or parts thereof using materials or having forms of construction different from those detailed in this part of ISO 81060, shall be accepted as equivalent if it can be demonstrated that an equivalent degree of safety and performance is obtained.

Planning and design of products applying this part of ISO 81060 should consider the environmental impact from the product during its life cycle. See also Annex B. Environmental aspects are addressed in Annex C.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

Check compliance by inspection of the risk management file.

6.2 Electrical safety

Non-automated sphygmomanometers that utilize electrical power shall meet the applicable requirements in IEC 60601-1, in addition to the requirements in this part of ISO 81060.

Check compliance by application of the tests of IEC 60601-1.

6.3 Mechanical safety

Rough surfaces, sharp corners and edges that can cause injury or damage shall be avoided or covered. Particular attention shall be paid to flange or frame edges and the removal of burrs.

Check compliance by inspection.

6.4 Mechanical strength

6.4.1 * Non-automated sphygmomanometers

Non-automated sphygmomanometers or their parts shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling. Stationary non-automated sphygmomanometers are exempt from the requirements of this subclause.

The non-automated sphygmomanometer shall function normally following a free fall from a distance, d, of 25 cm.

A non-automated sphygmomanometer that is marked “Shock Resistant” shall function normally following a free fall from a distance, d, of 1 m.

Check compliance by the following test.

Allow the non-automated sphygmomanometer to fall freely six times (once on each side) from a height = d on to a 50 mm $\pm$ 5 mm thick hardwood (hardwood density $>$ 600 kg/m^3) board lying flat on a concrete or a similar rigid base.

After the test, check that the non-automated sphygmomanometer functions normally by performing the tests described in 7.1.1.

6.4.2 * Non-automated sphygmomanometers for transport

Non-automated sphygmomanometers or their parts, intended for use during patient transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling.

After the following tests, the non-automated sphygmomanometer shall function normally.

a) Shock (according to IEC 60068-2-27):

— peak acceleration: 1,000 m/s^2 (102 g);

— duration: 6 ms;

— pulse shape: half sine;

— number of shocks: 3 shocks per direction per axis (18 in total).

b) Broad-band random vibration (according to IEC 60068-2-64):

— frequency range: 10 Hz to 2,000 Hz;

— resolution: 10 Hz;

— acceleration amplitude:

— 10 Hz to 100 Hz: 5.0 (m/s^2)^2/Hz;

— 100 Hz to 200 Hz: – 7 db/octave;

— 200 Hz to 2,000 Hz: 1.0 (m/s^2)^2/Hz;

— duration: 30 min per each perpendicular axis (3 in total).

After the test, check that the non-automated sphygmomanometer functions normally by performing the tests described in 7.1.1.

U.S. inclusion:
Note: See last paragraph of the Annex A, Subclause 6.4.2 for U.S. inclusion.

6.4.3 * Non-automated sphygmomanometers containing a mercury manometer

A non-automated sphygmomanometer containing a mercury manometer shall not leak mercury following a free fall from a distance, d, of 1 m under conditions of normal use.

Check compliance by the following test.

Allow the non-automated sphygmomanometer to fall freely six times (once on each side) from a height = d on to a 50 mm $\pm$ 5 mm thick hardwood (hardwood density $>$ 600 kg/m^3) board lying flat on a concrete or a similar rigid base. Care should be taken while testing to ensure that there is no escape of mercury into the environment should the non-automated sphygmomanometer under test fail.

After the test, visually inspect to check that there is no leakage of mercury from the manometer of the non-automated sphygmomanometer.

After the test, check that the non-automated sphygmomanometer functions normally by performing the tests described in 7.1.1.

7 Requirements

7.1 Pressure indicating means

7.1.1 * Limits of the error of the cuff pressure indication

Over the temperature range of 15 °C to 25 °C and the relative humidity range of 15 % to 85 % (non-condensing), for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to ± 3 mmHg (± 0.4 kPa).

Over the temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing), for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to ± 3 mmHg (± 0.4 kPa) or 2 % whichever is greater.

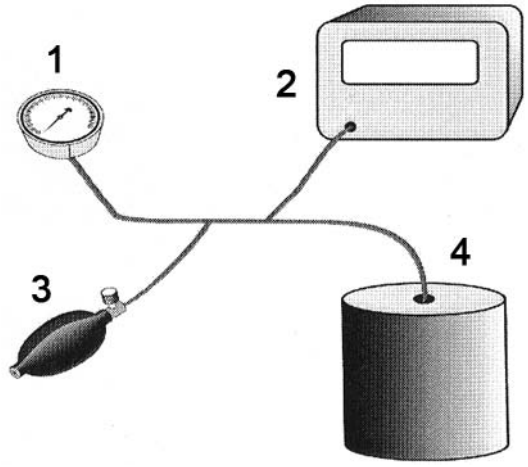
Check compliance by means of the following test.

a) Replace the cuff of the non-automated sphygmomanometer with a vessel (see Figure 1).

   Connect the calibrated reference manometer to the pneumatic system by means of a T-piece connector and hoses. After disabling the electromechanical pump (if fitted), connect the additional pressure generator to the pneumatic system by means of another T-piece connector.

b) Perform the test in pressure steps of not more than 50 mmHg between 0 mmHg and the maximum pressure on the scale.

c) Express the results as the difference between the indicated pressure of the non-automated sphygmomanometer being tested and the corresponding reading of the reference manometer.



Key

1 calibrated reference manometer with a maximum error of 0.8 mmHg (0.1 kPa)
2 non-automated sphygmomanometer to be tested
3 rigid metal vessel with a capacity of 500 ml ± 5 %
4 pressure generator

EXAMPLE Ball pump (hand pump) with a deflation valve.

Figure 1 — Test set-up for determining the limits of error of the cuff pressure indication

7.1.2 * Nominal range and measuring range

The nominal range for the cuff pressure measurement shall be disclosed in the accompanying document [see 12.2.1 l)]. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of cuff pressure measurement outside the nominal range of cuff pressure shall be clearly indicated as out of range.

For a non-automated sphygmomanometer, the nominal range for the cuff gauge pressure shall extend from 0 mmHg (0 kPa) to at least 260 mmHg (35 kPa).

Check compliance by inspection.

7.2 Pneumatic system

7.2.1 * Air leakage

Air leakage shall not cause a pressure drop that exceeds 4 mmHg/min (0.5 kPa/min).

Check compliance by means of the following test. (If, because of technical reasons, this test cannot be performed, use an alternative test procedure specified by the manufacturer.)

a) Use the following apparatus:

   1) rigid metal cylinder;

   2) pressure generator;

EXAMPLE Ball pump (hand pump) with deflation valve.

   3) time-measuring device.

EXAMPLE Stopwatch.

b) Wrap the cuff around a cylinder of an appropriate size, such that the internal circumference of the applied cuff exceeds the circumference cylinder by (7 ± 2) %.

NOTE 1 Electro-mechanical pumps that are a part of the system can be used for this test. Valves that are permanently opened can be disconnected for this test.

NOTE 2 For this test, no calibrated reference manometer is required because the cuff pressure display of the non-automated sphygmomanometer under test can be used when the error of the cuff pressure indication is taken into account. The advantage of this test is that the non-automated sphygmomanometer under test is in its original configuration. Additional connections can increase the leakage.

c) Because decreasing or increasing the pressure when changing to the next pressure step influences the thermodynamic equilibrium, wait at least 60 s before reading the values. Perform the measurement at least five pressure steps (e.g. 50 mmHg (7 kPa), 100 mmHg (14 kPa), 150 mmHg (20 kPa), 200 mmHg (27 kPa) and 250 mmHg (33 kPa)) over the whole measuring range. Test the air leakage over a period of 5 min, and determine the measured value from this. If the air leakage results in a pressure drop significantly different than 4 mmHg/min (0.5 kPa/min), the test period of 5 min can be reduced.

d) Express the air leakage as the pressure reduction per minute.

7.2.2 * Pressure reduction rate

Manually-operated and self-linearizing deflation valves shall be capable of adjustment to a deflation rate of 2 mmHg/s (0.3 kPa/s) to 3 mmHg/s (0.4 kPa/s). Deflation valves that control the deflation rate per pulse shall be capable of adjustment to a deflation rate of 2 mmHg/pulse (0.3 kPa/pulse) to 3 mmHg/pulse (0.4 kPa/pulse).

Check compliance of manually-operated deflation valves by functional testing. Check compliance of self-linearizing valves by means of the following test.

a) Use the following apparatus:

   1) T-piece;

   2) calibrated reference manometer with signal output port and an error less than 0.8 mmHg (0.1 kPa);

   3) human subjects;

   4) recording unit.

b) Select a subject whose limb size is approximately equal to the upper limit of limb circumferences for the cuff.

c) Connect the calibrated reference manometer to the cuff by means of a T-piece.

d) Connect the output port of the calibrated reference manometer to the recording unit.

e) Apply the cuff to the subject according to the accompanying document for the cuff.

f) Inflate the cuff to at least 200 mmHg (27 kPa).

g) Adjust the rate of deflation accordingly.

h) Remove the cuff.

i) Repeat steps e) to h) nine times.

j) Select a subject whose limb size is approximately equal to the lower limit of limb circumferences for the cuff.

k) Repeat steps e) to i).

l) Determine the rate of the pressure reduction (e.g. by graphical evaluation and drawing tangents) at the pressure of 60 mmHg (8 kPa), 120 mmHg (16 kPa) and 180 mmHg (24 kPa). Calculate the pressure reduction rate as the mean value calculated separately for the pressures of 60 mmHg (8 kPa), 120 mmHg (16 kPa) and 180 mmHg (24 kPa) and for the various limb circumferences. If the pressure reduction rates are dependent on the pulse rate, record the pulse rate. In this case, express the result as pressure reduction per pulse.

7.2.3 * Rapid exhaust

During the rapid exhaust of the pneumatic system with the deflation valve fully open, the time for the pressure reduction from 260 mmHg (35 kPa) to 15 mmHg (2 kPa) shall not exceed 10 s.

Check compliance by means of the following test.

a) Use the following apparatus:

   1) rigid metal vessel, with a volume of 500 ml ± 5 %;

   2) calibrated reference manometer, with an error less than 0.8 mmHg (0.1 kPa);

   3) T-piece connector;

   4) time-measuring device.

EXAMPLE Stopwatch.

b) Perform the test with the metal vessel in place of the cuff.

c) Connect the calibrated reference manometer by means of a T-piece to the pneumatic system.

d) Inflate to the maximum pressure and open the valve for rapidly exhausting the pneumatic system.

e) Measure the time between 260 mmHg (35 kPa) to 15 mmHg (2 kPa) using the time-measuring device.

f) Ensure that the time is less than or equal to 10 s.

7.2.4 Cuff

The bladder length should be approximately 0.80 × the circumference of the limb at the midpoint of the intended range of the cuff. The width of the bladder should be at least 0.40 × the circumference of the limb at the midpoint of the intended range of the cuff.

NOTE These recommended dimensions are subject to ongoing consideration.

7.2.5 Cuff and bladder

The cuff and bladder and integral tubing shall maintain their integrity and be capable of withstanding an internal pressure equal to the maximum pressure intended for the cuff in normal use. For cuffs with removable bladder, the bladder shall be completely retained in the cuff during pressurization to the maximum pressure intended for the cuff in normal use.

Check compliance by means of the following test. (If, because of technical reasons, this test cannot be performed, use an alternative test procedure specified by the manufacturer.)

a) Use the following apparatus:

   1) rigid metal cylinder;

   2) pressure generator;

EXAMPLE Ball pump (hand pump) with deflation valve.

   3) time-measuring device.

EXAMPLE Stopwatch.

b) Wrap the cuff around a cylinder of an appropriate size, such that the internal circumference of the applied cuff exceeds the circumference of the cylinder by (7 ± 2) %.

NOTE 1 Electro-mechanical pumps that are a part of the system can be used for this test. Valves that are permanently opened can be disconnected for this test.

NOTE 2 For this test, no calibrated reference manometer is required because the cuff pressure display of the non-automated sphygmomanometer under test can be used when the error of the cuff pressure indication is taken into account. The advantage of this test is that the non-automated sphygmomanometer under test is in its original configuration. Additional connections can increase the leakage.

c) Pump the cuff pressure to the maximum pressure as stated in the accompanying document for its use or the maximum indication on the non-automated sphygmomanometer, whichever is greater.

d) Hold the pressure for 5 min.

e) During these 5 min, ensure that the cuff does not open and the bladder does not creep out of the cuff.

7.2.6 * Tubing connectors

Tubing connectors, if provided, shall incorporate a means of preventing accidental disconnection. Tubing connectors shall not be equipped with a connector that connects with a connector complying with ISO 594-1 or ISO 594-2.

Check compliance by inspection.

7.3 * Tamper proofing or unauthorized access

Means shall be provided to prevent tampering or unauthorized access:

— for all non-automated sphygmomanometers, any adjustment or function that affects accuracy;

— for mercury non-automated sphygmomanometers, the separation of reservoir and scale.

EXAMPLE Requiring a tool for opening or seal breakage.

It shall be clear to an operator if tampering or unauthorized access has occurred.

Check compliance by inspection.

7.4 Dynamic response in normal use

The delay in the settling of the cuff pressure indication shall not exceed 1.5 s for the change in indication from 200 mmHg to 50 mmHg or from 25 kPa to 5 kPa when the pressure in the system drops from 200 mmHg to 0 mmHg or from 25 kPa to 0 kPa.

Check compliance with the following test.

a) Use the following apparatus:

1) time-measuring device;

EXAMPLE Stopwatch.

2) pressure generator.

EXAMPLE Ball pump (hand pump), with deflation valve.

b) Connect the pressure generator directly (without a cuff) to the hose leading to the manometer of the non-automated sphygmomanometer.

c) When a gauge pressure of more than 200 mmHg or 25 kPa has been reached, occlude the tube and remove the pressure generator.

d) After removing the occlusion from the tube, measure the time between the change in indication from 200 mmHg to 50 mmHg or 25 kPa to 5 kPa.

e) Check that the time does not exceed 1.5 s.

8 Additional requirements for non-automated sphygmomanometer with mercury manometer

8.1 * Internal diameter of the tube containing mercury

The nominal internal diameter of the tube containing mercury shall be at least 3.9 mm. The tolerance on the diameter shall not exceed ± 0.2 mm. See also 12.2.1 q).

Check compliance by means of the following test.

a) Use limit plug gauges or similar devices, with a tolerance of less than 0.05 mm.

b) Check the nominal internal diameter of the tube at each end using the limit plug gauge.

8.2 * Portable non-automated sphygmomanometer

A portable non-automated sphygmomanometer shall be provided with an adjusting or locking mechanism to secure it in the position for use as indicated in the accompanying document.

Check compliance by inspection.

8.3 * Prevention of mercury spillage during transport

To prevent the spillage of mercury during transport, a means shall be provided of keeping the mercury in its reservoir.

Check compliance by inspection.

8.4 * Prevention of mercury spillage in normal use

A mercury gravity **non-automated sphygmomanometer** shall incorporate a means (stopping device) at the top of the tube that both permits the inward and outward flow of air and prevents the passage of liquid mercury. The reservoir itself shall be fitted with a means (stopping device) to prevent mercury from flowing out of the reservoir neck and into the attached tubing and permits the inward and outward flow of air.

Check compliance by means of the following test.

a) Use the following apparatus:

   1) collecting vessel of adequate size to contain the non-automated sphygmomanometer under test;

   2) calibrated reference manometer, with an error of less than 0.8 mmHg (0.1 kPa);

   3) T-piece connector;

   4) pressure generator.

EXAMPLE Ball pump (hand pump) with a deflation valve.

b) Place the non-automated sphygmomanometer to be tested in the collecting vessel.

c) Connect the pressure generator and a T-piece connector attached to a calibrated reference manometer directly to the hose leading to the mercury reservoir.

d) Use the pressure generator to raise the pressure in the non-automated sphygmomanometer to 100 mmHg (13.3 kPa) greater than the maximum scale reading on the test manometer.

e) Maintain this pressure for 5 s and then release the pressure in the system.

f) Check that no mercury has been spilt.

8.5 Quality of the mercury

The mercury shall have a purity of not less than 99.99 %.

Check compliance by testing or by inspection of the declaration of the supplier of the mercury.

9 Non-automated sphygmomanometers with aneroid manometer

9.1 * Scale mark at zero

If a tolerance zone is shown at zero, it shall not exceed ± 3 mmHg (± 0.4 kPa) and shall be clearly indicated. Graduations within the tolerance zone may be used.

Check compliance by inspection.

9.2 * Zero

The movement of the elastic sensing element, including the pointer, shall not be obstructed within 6 mmHg (0.8 kPa) below zero.

Neither the dial nor the pointer shall be adjustable by the operator.

Check compliance by inspection.

9.3 Hysteresis error

The hysteresis error throughout the pressure range shall not exceed 4 mmHg (0.5 kPa).

Check compliance by means of the following test.

a) Use the following apparatus:

   1) rigid metal vessel, with a capacity of 500 ml ± 5 %;

   2) calibrated reference manometer, with an error less than 0.8 mmHg (0.1 kPa);

   3) pressure generator;

EXAMPLE Ball pump (hand pump) with a deflation valve.

   4) T-piece connectors.

b) Replace the cuff with the rigid metal vessel.

c) Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system.

d) After disabling the electro-mechanical pump (if fitted) connect the additional pressure generator to the pneumatic system by means of another T-piece connector.

e) Test the non-automated sphygmomanometer with increasing pressure steps of not more than 50 mmHg or 7 kPa to the scale maximum; hold the pressure for 5 min and then decrease it by the same steps.

f) Do not tap on the manometer housing to reduce the friction to move the pointer.

g) Disconnect the calibrated reference manometer during the 5 min at maximum pressure.

h) Express the results as the difference between the indicated values on the non-automated sphygmomanometer at the same test pressure steps when decreasing the pressure and when increasing the pressure.

9.4 * Construction and materials

The construction of the **non-automated sphygmomanometer** and the material for the elastic sensing elements shall ensure adequate stability of the measurement. The elastic sensing elements shall be aged with respect to pressure and temperature.

The difference in the pressure indication of the **non-automated sphygmomanometer** before and after 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) shall be not more than 3 mmHg (0.4 kPa) throughout the pressure range.

Check compliance by means of the following test.

a) Use the following apparatus:

1) alternating pressure generator, which generates a sinusoidal pressure variation below 20 mmHg (3 kPa) and above 220 mmHg (30 kPa) at a maximum rate of 1 Hz.

b) Start the procedure specified in 7.1.1.

c) Connect the non-automated sphygmomanometer directly to the alternating pressure generator and perform 10,000 alternating pressure cycles.

d) One hour after the stress test, perform the procedure as specified in 7.1.1 at the same pressure levels as before the stress test.

e) Express the results as differences between the indicated values on the reference manometer and non-automated sphygmomanometer at the same test pressure steps before and after the stress test.

10 Cleaning, sterilization and disinfection

10.1 Reusable non-automated sphygmomanometer and parts

All components specified for re-use in the accompanying documents, and which come into contact with the patient shall be capable of being either cleaned and disinfected or cleaned and sterilized.

Check compliance by a review of the accompanying documents for methods of cleaning and disinfection or cleaning and sterilization (see 12.2.2) and by inspection of the relevant validation reports.

10.2 Non-automated sphygmomanometer and parts requiring processing before use

All components specified in the accompanying documents to be cleaned and disinfected or cleaned and sterilized before use and which come into contact with the patient shall be capable of being cleaned and disinfected or cleaned and sterilized.

Check compliance by a review of the accompanying documents for methods of cleaning and disinfection or cleaning and sterilization (see 12.2.2) and by inspection of the relevant validation reports.

10.3 Non-automated sphygmomanometer and parts delivered sterile

Non-automated sphygmomanometers or accessories labeled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937.

Check compliance by inspection of the relevant validation reports.

11 Biocompatibility

Non-automated sphygmomanometers and parts thereof intended to come into contact with biological tissues, cells, body fluids, or breathing gases shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Check compliance by inspection of the relevant validation reports.

12 Information supplied by the manufacturer

12.1 Accompanying document

The non-automated sphygmomanometer and accessories shall have accompanying document(s) containing at least the instructions for use and a technical description. The accompanying document shall be regarded as a part of the non-automated sphygmomanometer.

NOTE The purpose of the accompanying document is to promote the safe use of the non-automated sphygmomanometer during its expected service life.

The accompanying document shall identify the non-automated sphygmomanometer by including, as applicable, the following:

— name or trade-name of the manufacturer, and an address to which the responsible organization can refer;

— model or type reference.

The accompanying document shall specify any special skills, training and knowledge required of the intended operator or the responsible organization and any restrictions on locations or environments in which the non-automated sphygmomanometer can be used.

The accompanying document(s) shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Check compliance by inspection.

12.2 Instructions for use

12.2.1 General

The instructions for use shall include:

a) the intended use of the non-automated sphygmomanometer, in particular:

— intended medical indication;

EXAMPLE 1 Conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.

— any known restrictions on use or contra-indication(s) to the use of the non-automated sphygmomanometer;

— intended patient population;

EXAMPLE 2 Age, weight, health, condition.

— intended part of the body or type of tissue applied to or interacted with;

— intended conditions of use;

EXAMPLE 3 Environment including hygienic requirements, frequency of use, location, mobility.

b) a brief description of the non-automated sphygmomanometer, including its significant physical and performance characteristics;

c) all information necessary to operate the non-automated sphygmomanometer in accordance with its specification;

EXAMPLE Explanations of the functions of controls, displays and signals, the sequence of operation, and connection and disconnection of detachable parts and accessories, and replacement of material that is consumed during operation.

d) how the non-automated sphygmomanometer functions;

e) an explanation of the selection of a suitable cuff size and application to the patient;

f) an explanation of operating steps of the non-automated sphygmomanometer including:

- adjustment of the pressure reduction rate;
- patient position in normal use (see Bibliography [18]), including:
  - comfortably seated,
  - legs uncrossed,
  - back and arm supported,
  - middle of cuff on the upper arm at the level of the right atrium,
  - a recommendation that the patient relax as much as possible and not talk or move during the measurement procedure,
  - a recommendation that 5 min should elapse before the first reading is taken;
- operator position in normal use;
- a recommendation for the use of K5 in auscultation of adults;

NOTE 1 K5 is the point at which the Korotkoff sounds can no longer be heard.

- * a recommendation for the use of K4 in auscultation of children aged 3 to 12.

NOTE 2 K4 is the change in the tones heard through a stethoscope from a clear tapping sound to a muffled sound.

- * a recommendation for the use of K5 in auscultation of pregnant female patients, unless sounds are audible with the cuff deflated, in which case K4 should be used (see Bibliography [18]);

g) the information required in 4.4;

h) a description of all markings on the non-automated sphygmomanometer;

EXAMPLE Figures, symbols, warning statements, abbreviations and indicator lights.

i) for cuffs, the information required in 4.6;

j) * the nature and frequency of the maintenance needed to ensure that the non-automated sphygmomanometer operates accurately and safely at all times;

k) if installation of the non-automated sphygmomanometer or its parts is required, a reference to where the installation instructions are to be found (e.g. the technical description);

l) the nominal range of cuff pressure measurement (see 7.1.2);

m) a statement, if applicable, that the performance of the non-automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude;

n) for non-automated sphygmomanometers intended for use in environmental conditions beyond those specified in this part of ISO 81060, the limits of the error of the cuff pressure indication over those environmental conditions;

o) if the non-automated sphygmomanometer is intended to be dismantled by the operator, the correct method of reassembly;

p) recommended storage conditions.

The following additional information is required for a non-automated sphygmomanometer containing a mercury manometer:

q) internal nominal diameter and tolerance of the tube containing mercury;

r) detailed instructions for the safe handling of mercury (see Annex B);

s) for portable non-automated sphygmomanometers, a caution regarding the necessity to maintain the verticality of the mercury column to perform a valid measurement;

t) information concerning the disposal of the non-automated sphygmomanometer or components thereof.

NOTE The instructions for use are intended for the operator and the responsible organization and should contain only the information most likely to be useful to the operator or responsible organization. Additional details can be contained in the technical description. See also 12.3.

The instructions for use shall be in a language that is acceptable to the intended operator.

12.2.2 Cleaning, disinfection and sterilization

For non-automated sphygmomanometer parts or accessories that can become contaminated through contact with the patient or with body fluids or expired gases during normal use, the instructions for use shall contain:

a) the details about cleaning and disinfection or cleaning and sterilization methods that may be used;

b) a list of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such non-automated sphygmomanometer parts or accessories can tolerate.

See also 10.1 and 10.2.

This requirement does not apply to any material, component, accessory or non-automated sphygmomanometer that is marked as intended for single use, unless the manufacturer specifies that the

material, component, accessory or non-automated sphygmomanometer is to be cleaned and disinfected or cleaned and sterilized before use (see 10.2).

12.2.3 Maintenance

The instructions for use shall inform the operator or responsible organization that the reference manometer used for calibration should be traceable against international or national measurement standards.

The instructions for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the non-automated sphygmomanometer.

Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by service personnel, including the recommended frequency to be applied, but not necessarily including details about the actual performance of such maintenance.

For non-automated sphygmomanometers containing rechargeable batteries that are intended to be maintained by anyone other than service personnel, the instructions for use shall contain instructions to ensure adequate maintenance.

12.2.4 Accessories, supplementary equipment, used material

The instructions for use shall include a list of accessories, detachable parts and materials that the manufacturer has indicated are intended for use with the non-automated sphygmomanometer.

12.2.5 Environmental protection

The instructions for use shall:

a) identify any risks associated with the disposal of waste products, residues, etc., and of the non-automated sphygmomanometer and accessories at the end of their expected service life;

b) provide advice on minimizing these risks;

c) provide a caution to comply with regional law when non-automated sphygmomanometer or accessory is discarded;

d) provide a warning to comply with regional law when a mercury sphygmomanometer is discarded.

12.2.6 Reference to the technical description

The instructions for use shall contain the information specified in 12.3 or a reference to where the material specified in 12.3 is to be found (e.g. in a service manual).

Compliance with the requirements of 12.2 is checked by inspection of the instructions for use in the language of an intended operator.

12.3 Technical description

The technical description shall provide all data that is essential for safe operation, transport and storage, and measures or conditions necessary for installing the non-automated sphygmomanometer, and preparing it for use.

This shall include:

a) the permissible environmental conditions of use including conditions for transport and storage;

b) all characteristics of the non-automated sphygmomanometer, including range(s) and accuracy of the displayed values or an indication where they can be found;

c) any correction factors to be applied for changes in ambient conditions;

d) a warning statement that addresses the hazards that can result from unauthorized modification of the non-automated sphygmomanometer, e.g. a statement to the effect:

   — "WARNING: No modification of this equipment is allowed."

   — "WARNING: Do not modify this equipment without authorization of the manufacturer."

   — "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure its continued safe use."

If the technical description is separable from the instructions for use, it shall contain:

e) the information required in 4.4;

f) for cuffs, the information required in 4.6;

g) a brief description of the non-automated sphygmomanometer, how the non-automated sphygmomanometer functions and its significant physical and performance characteristics;

h) instructions for correct replacement of interchangeable or detachable parts that the manufacturer specifies as replaceable by service personnel;

i) for a non-automated sphygmomanometer containing a mercury manometer:

   — the nominal internal diameter and tolerance of the tube containing mercury (see 8.1),

   — the material of the tube containing mercury;

j) where replacement of a component could result in an unacceptable risk, appropriate warnings that identify the nature of the hazard and, if the manufacturer specifies the component as replaceable by service personnel, all information necessary to safely replace the component;

k) a statement that the manufacturer will make available on request, circuit diagrams, component part lists, descriptions, calibration instructions or other information that will assist service personnel to repair those parts of the non-automated sphygmomanometer that are designated by the manufacturer as repairable by service personnel;

l) instructions for the operator or responsible organization in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.

NOTE 1 The technical description is intended for the responsible organization and service personnel.

The manufacturer may designate the minimum qualifications for service personnel. If present, these requirements shall be documented in the technical description.

NOTE 2 Some authorities with jurisdiction impose additional requirements for qualification of service personnel.

Compliance with the requirements of 12.3 is checked by inspection of the technical description.

Annex A
(informative)

Rationale and guidance

General

This annex provides a rationale for some requirements of this part of ISO 81060 and is intended for those who are familiar with the subject of this part of ISO 81060 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 81060. The numbering is, therefore, not consecutive.

Clause 1 Scope

Because the significance of blood pressure measurement with non-automated sphygmomanometers has been recognized and the number of professional operators is growing rapidly, care should be taken to ensure that the available non-automated sphygmomanometers are as safe and accurate as possible. Blood pressure is routinely measured by either automated sphygmomanometers or non-automated sphygmomanometers.

Many sphygmomanometers are purchased by individuals on the advice of their physicians or in response to mass advertising. In addition, individuals can use automated equipment in pharmacies and other retail stores. Blood pressure measurement in the home and in 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 detection of hypertension depends on the accuracy and reproducibility of the particular sphygmomanometer and rests on the assumption that the consumer has adequate information to operate the sphygmomanometer correctly and that the sphygmomanometer is safe for unsupervised use. Non-automated sphygmomanometers are not generally acceptable for these unsupervised uses because a non-automated sphygmomanometer requires extensive training for proper operation.

Subclause 3.9 Model or type reference

The model or type reference is intended to establish the relationship of the non-automated sphygmomanometer to commercial and technical publications, to accompanying documents, and that between separable parts of the non-automated sphygmomanometer. It is also important for identifying a non-automated sphygmomanometer or accessories in case of a safety alert or other required corrective action.

Subclause 4.1 Units of measurement

Parallel or dual scales of mmHg and kPa are not acceptable as this represents a potential source of reading error. The numbering of the two scales is relatively close if the factor of 10 is disregarded (see Figure A.1). In critical, stressful situations a correct reading cannot be guaranteed, e.g. a reading for the systolic blood pressure of 150 mmHg (20 kPa) will be recorded as 200 mmHg. Single scales require less concentration than dual scales to ensure correct readings.

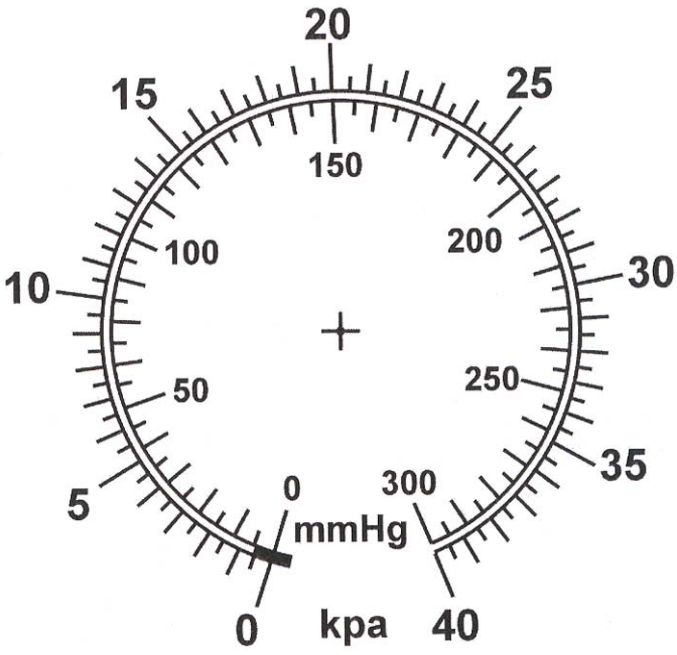


Figure A.1 — Example of a dual scale units of measure

Subclause 4.2 Legibility of markings

Markings on non-automated sphygmomanometers, cuffs or their components are expected to be clearly legible by an operator over the range of normal illumination levels where the non-automated sphygmomanometer is typically operated. The levels used in this test are derived from the following recommended illumination levels for use in interior lighting design (see Bibliography [18]:

— 100 lx to 200 lx is recommended for working spaces where visual tasks are performed only occasionally;

— 500 lx to 1,000 lx is recommended for visual tasks of small size or reading medium-pencil handwriting;

— 1,000 lx to 2,000 lx is recommended for visual tasks of low contrast or very small size: e.g. reading handwriting in hard-pencil on poor-quality paper.

If markings are not legible to the operator under the expected conditions of use, there would be an unacceptable risk.

The Minimum Angle of Resolution (MAR) is a visual acuity measurement method developed as an improvement on the long-used Snellen scale. The values are express as a logarithm of the Minimum Angle of Resolution. Log MAR can be calculated from the Snellen scale, i.e. log MAR = log(6/6) = 0 for normal vision.

Subclause 4.3 Durability of markings

The rubbing test is performed with distilled water, methylated spirits and isopropyl alcohol. Methylated spirits or ethanol 96 % is defined in the European Pharmacopoeia as a reagent in the following terms:

C_2H_6O (MW46.07). Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms: C_3H_8O (MW60.1).

Subclause 4.4 Marking of non-automated sphygmomanometer

c)

Although the non-automated sphygmomanometers should have a serial number, the cuffs can have a batch number instead because they are manufactured in lots.

e)

The numbering of the scale cannot exceed the measurement range because the operator needs to have confidence in the reading. If the numbering exceeds the measurement range, it can lead to confusion. When all displayed values or possible readings on the scale are within the specified limits of error, there should be no doubt about the accuracy of any reading.

f)

Two safety signs are required because of the hazards associated with mercury. It is a “mandatory action” for operators to read the instructions for use so that they are aware of chemical hazards associated with mercury. In addition, the general warning informs the operator that a hazard is present.

Subclause 4.5 Usability of reading

Operators need to be able to reliably, repeatably and accurately read the scale of a non-automated sphygmomanometer. Since the operator is interpreting the changing indication of the manometer to determine the patient's blood pressure, it is vital that the non-automated sphygmomanometer provide adequate control of the rate of pressure reduction in combination with the reading the scale. Errors caused by parallax or illegible scales can cause measurement error. Manufacturers should consider performing this test as a usability test and not just relying on a single observer.

Subclause 5.1 Type tests

In order to ensure that all non-automated sphygmomanometers conform to this part of ISO 81060, the manufacturer or installer should take measures during manufacture, installation and assembly to ensure that each item satisfies all requirements, even if they are not completely tested individually during manufacture, installation or assembly.

Such measures could take the form of:

a) production methods (to ensure good manufacturing output and constant quality) where such quality would be related to safety or performance;

b) production tests (routine tests) performed on every produced item;

c) production tests performed on a production sample where results would justify a sufficient confidence level.

Production tests need not be identical with type tests, but can be adapted to manufacturing conditions.

Production tests would, of course, be restricted to conditions (possibly derived from type tests) that would simulate the worst-case situation.

Subclause 5.2 Representative sample

The type test sample or samples need to be representative of the units intended for the responsible organization.

Subclause 5.5 Humidity preconditioning treatment

To prevent condensation when the non-automated sphygmomanometer is placed in the humidity cabinet, the temperature of such a cabinet should be equal to or slightly lower than the temperature of the non-automated sphygmomanometer when it is introduced. To avoid the need for a temperature stabilization system for the air in the room outside the cabinet, the cabinet air temperature during the treatment is adapted to that of the outside air within the limits of the range of + 20 °C to + 32 °C and then “stabilized” at the initial value. Although the effect of the cabinet temperature on the absorption of humidity is recognized, it was felt that the reproducibility of test results would not be substantially impaired and the cost-reducing effect would be considerable.

Subclause 6.4.1 Non-automated sphygmomanometers

Non-automated sphygmomanometers in normal use will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, a non-automated sphygmomanometer needs to be robust enough to withstand the vibration, shock, bumps and drops that it will encounter in normal use.

These tests were chosen by first reviewing the results of the work published in other patient monitoring standards where those committees (see Bibliography [1] [3]) qualitatively assessed the relative severity of the scenarios within various environments, home, healthcare facilities and transport (wings and wheels), by various sizes and types of equipment (i.e. hand-held, portable and mobile).

After that qualitative assessment, those committees assessed the relevant particular standards for environmental testing in the IEC 60068 series[6] and their respective rationales, as well as the IEC 60721 series[9] of guidance documents. In selecting the requirements, those committees reviewed other sources for material related to these tests (e.g. FDA Reviewers Guidance for premarket notification submissions, Mil Std 810, etc.) but found the best fit was with the standard IEC 60721-3-7[11]. There is also a guidance document, IEC/TR 60721-4-7[12], that helps to correlate environmental condition classes of IEC 60721-3-7 to environmental tests according the IEC 60068 series. The aforementioned standards specify three classes of mechanical conditions, 7M1, 7M2 and 7M3. Those committees found the classes 7M1 and 7M3 to best represent the conditions seen during patient transport within healthcare facilities and patient transport outside healthcare facilities, respectively. Those committees agreed different tests and test levels should be applied to instruments intended for use in a healthcare facility than instruments intended for use during patient transport outside the healthcare facility.

Verifying that the instrument is functioning within the manufacturer's specifications while the vibration (random and sinusoidal) tests are being conducted is not believed necessary. This line of thought was considered and it was decided that the test done in this manner would be overly burdensome and would only add a minimum additional level of safety that would not justify the costs. Verifying proper functioning after completion of the tests was believed adequate.

Subclause 6.4.2 Non-automated sphygmomanometers for transport

Non-automated sphygmomanometers in normal use, used for patient transport outside a healthcare facility, will be subjected to mechanical stresses (e.g. vibration, shock, bump and drop) and could randomly be subjected to additional stresses. Therefore, instruments intended to be used for patient transport outside a healthcare facility need to be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7 level 7M3. IEC 60721-3-7 indicates that in addition to the conditions

covered by class 7M2, the class 7M3 applies to use at, and direct transfer between, locations with significant vibrations, or with high level shocks. Rough handling and transfer of instruments is expected in these environments.

An additional shock test for this class of instrument is added even though there are no established generalized test programs that exactly reproduce the range of vibration and shock conditions that instruments might meet when installed in a range of land vehicles and aircraft. Therefore the dynamic tests specified in this clause have been chosen on the basis that instruments tested to these levels are likely to withstand the normal dynamic disturbances that they will meet when used in the range of vehicles and aircraft (including helicopters) likely to be used for transporting patients.

The use of instruments in road ambulance, fixed wing and rotary wing aircraft, naval vessels, etc., can require additional tests and verification of safety when used in these environments.

U.S. inclusion:

Note: Since clause 6.4.2 of this standard requires functional testing before and after vibrations, but not during vibrations, the U.S. believes that there is no proof that the device can indeed perform within specifications during vibrations, such as enabling the user to accurately measure the blood pressure of a patient who is being transported in a moving ambulance. Thus, this standard cannot be used in the U.S. to substantiate a claim of functionality within the manufacturer's specifications during transport.

Subclause 6.4.3 Non-automated sphygmomanometers containing a mercury manometer

To protect against the harmful effects that can be caused by the spillage of mercury, an additional drop test is required for a non-automated sphygmomanometer that contains mercury. The sphygmomanometer is expected to be dropped in a condition of normal use, i.e. open. The chosen acceptance criterion does not relate to the functioning of the instrument, but the prevention of environmental contamination.

Subclause 7.1.1 Limits of the error of the cuff pressure indication

Many national and international organizations recommended an accuracy of $\pm$ 3 mmHg (0.4 kPa). 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 $\pm$ 3 mmHg (0.4 kPa) 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.

Subclause 7.1.2 Nominal range and measuring range

Many non-automated sphygmomanometers utilizing mercury gravity manometers currently being sold and used have a cuff pressure range of 0 mmHg to 260 mmHg (0 kPa to 35 kPa). 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 non-automated sphygmomanometer is not capable of measuring cuff pressures up to at least 260 mmHg (35 kPa), the systolic pressure of a hypertensive individual might not be adequately determined. For purposes of comparison, this range is stipulated for non-automated sphygmomanometers utilizing either aneroid or mercury gravity manometers.

Non-automated sphygmomanometers can be exposed to extremes of temperature, humidity and atmospheric pressure during shipment, storage and use. Because such exposure is often unavoidable, the non-automated sphygmomanometer 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. Provision has therefore been made in this part of ISO 81060 to help ensure that the non-automated sphygmomanometer maintains its accuracy over defined ranges of temperature, humidity and atmospheric pressure. Furthermore, the non-automated

sphygmomanometer is expected to withstand defined vibration and shock conditions, as well as a reasonable number of uses without degradation of performance.

Subclauses 7.2.1 Air leakage and **7.2.2 Pressure reduction rate**

The standard method of estimating blood pressure using the Korotkoff sounds specifies that the deflation rate should be between 2 mmHg/s and 3 mmHg/s (0.3 kPa/s and 0.4 kPa/s). This is the accepted practice for use in both normal and hypertensive patients.

Non-automated sphygmomanometers are commonly used for other purposes, including estimating pressure in patients in shock and as a venous tourniquet for inserting intravenous cannulae. Much lower leak rates are required for these applications.

Non-automated sphygmomanometers also have to be calibrated and leak tested. Excessive leak rates can make this difficult.

With patients in shock it is often necessary to “hover” around the systolic pressure to hear whether the much quieter sounds that occur in shock are present or not. This is not possible with a leak rate of 1 mmHg/s (0.13 kPa/s). It should be possible with a leak rate of 6 mmHg/min or 0.8 kPa/min (value used in the AAMI standard), 4 mmHg/min or 0.5 kPa/min (value used in the European standard) and 2 mmHg/min or 0.3 kPa/min (value used in Japanese standards). The value of 4 mmHg/min (0.5 kPa/min) was chosen as a practical compromise for this part of ISO 81060 as 2 mmHg/min (0.3 kPa/min) is difficult to measure.

For use as a venous tourniquet, a pressure of 40 mmHg to 80 mmHg (5 kPa to 11 kPa) is appropriate. This could be maintained for 40 s, 6 min, 10 min and 20 min at each of the above rates. All but 1 mmHg/s (0.13 kPa/s) allow sufficient time for venous access.

Calibration is difficult with a leak, but should be possible at 6 mmHg/min (0.8 kPa/min).

To perform a leak test, the adiabatic effect on pressure caused by inflation have to be allowed to reach equilibrium. The test specifies that 60 s should elapse before the test is performed, and that it should last for a further 5 min after which time the pressure in the device will have fallen by 300 mmHg (40 kPa), 36 mmHg (5 kPa), 24 mmHg (3 kPa) and 12 mmHg (1.6 kPa) at the various leak rates, and none of them will be at the pressures specified for the test. Only a leak rate of 2 mmHg/min (0.3 kPa/s) will have the pressure reasonably close to the specified pressure at the end of the test, although the rate of 4 mmHg/min (0.5 kPa/s) could be acceptable.

The rate of pressure release recommended by the American Heart Association is 2 mmHg/s to 3 mmHg/s (0.3 kPa/s to 0.4 kPa/s). To ensure that the valve can control this rate, the maximum valve leakage should not exceed one-half (1.0 mmHg/s or 0.13 kPa/s) of the minimum acceptable rate, as determined in the total pneumatic system under operating conditions. The volume of the smallest bladder in normal use (excluding the neonatal cuff) is approximately 80 ml. The leakage should be measured at three pressures throughout the range to verify proper functioning of the check valve within the adjustable valve, particularly at the lower pressures.

A standard adult cuff has an in-use bladder volume of approximately 200 ml. After the diastolic pressure is determined, the compression should be released 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 (12 kPa), a valve meeting the requirements of this subclause should function satisfactorily at lower pressures.

The volume of air in the bladder directly affects the measurement of the air leakage. It has to be standardized. In tests intended to replicate the recommended application of a cuff to a human upper arm,

it was found that a rigid cylinder provided a satisfactory phantom. This showed that the inner circumference of the cuff had to be approximately 7 % more than the circumference of the cylinder for optimal results (unpublished tests performed by Physikalisch-Technische Bundesanstalt).

Subclause 7.2.3 Rapid exhaust

In an emergency situation, it can be necessary to deflate the cuff rapidly. Rapid exhaust also assists more rapid repetitive measurements.

Subclause 7.2.6 Tubing connectors

This requirement addresses the known hazards associated with cross-connections. There is a demonstrated unacceptable risk associated with the use of Luer connectors with patients, including neonatal patients, in the cuffs and tubing. Three-way adaptors are readily available in the clinical environment, so that a reverse Luer connector affords very little protection from this risk.

The manufacturer is free to choose any other appropriate connector.

Subclause 7.3 Tamper proofing or unauthorized access

Tamper proofing is a safety feature. It is intended to prevent the non-automated sphygmomanometer from being adjusted by unauthorized and untrained persons or from an accidentally performed adjustment. In the risk assessment performed during the development of this part of ISO 81060, the security of settings was identified as a potential risk, which the committee determined should be minimized by tamper proofing.

The need for and complexity of security of settings depends on the complexity of the non-automated sphygmomanometer and the importance of the settings to patient safety. The effectiveness of any security system depends critically on its implementation by the responsible organization. Only the responsible organization can adequately control the security system so that operators cannot compromise it. In some legacy equipment, access to configuration of settings has not been restricted. In such instances, operators have, intentionally or unintentionally, changed settings. Patient safety can be compromised if the non-automated sphygmomanometer calibration is improperly changed.

Subclause 8.1 Internal diameter of the tube containing mercury

Too narrow tubing can result in measurement errors due to, for example, poor visibility, mercury separation, and excessive meniscus. The minimum tube dimension specified 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 centre of the tube. The angle of contact at the edge of the liquid surface is about 132° between mercury and glass but varies with the cleanliness of the glass surface and the purity of the mercury. It is therefore good practice to use the level of the mercury column in the centre of the tube for obtaining more accurate pressure values.

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

Subclause 8.2 Portable non-automated sphygmomanometer

Since the accuracy of a mercury manometer is affected by the inclination relative to gravity, means need to be provided to ensure the correct positioning of the reservoir and the tube containing mercury relative to the position of operation. Otherwise, inaccurate readings can occur.

Subclause 8.3 Prevention of mercury spillage during transport

Leakage of dangerous materials (e.g. mercury) is a potential hazard. During transport, it is necessary to keep the mercury in the reservoir to minimize the risk of spillage.

Subclause 8.4 Prevention of mercury spillage in normal use

Mercury spillage is unacceptable because 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 non-automated sphygmomanometer. Prevention of mercury spillage is also necessary because the loss of a large quantity will make the non-automated sphygmomanometer unusable at the higher end of its scale if insufficient mercury to cover the entire range remains in the non-automated sphygmomanometer. Mercury spillage is also a hazard to the operator. For these reasons, it is essential that manometers of a non-automated sphygmomanometer 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.

Subclause 9.1 Scale mark at zero

For the aneroid gauge, a tolerance zone at zero is a good indication that the gauge movement has not been damaged. When the pointer leaves the tolerance zone at zero, the operator should suspect that the cuff pressure measurement might be inaccurate.

Subclause 9.2 Zero

The indication at zero is important for non-automated sphygmomanometers that contain an aneroid manometer because the pointer can indicate that the manometer has become inaccurate. A positive or negative pressure indication outside the given tolerance zone is strong evidence that the manometer has become inaccurate. Thus an adjustable dial can conceal the malfunction of a non-automated sphygmomanometer.

Subclause 9.4 Construction and materials

Aneroid transducers are subject to measurement drift when they are first used. The purpose of this test is to ensure that the manufacturer has appropriately aged the transducer prior to shipment. If the transducers are not aged prior to incorporation into the non-automated sphygmomanometer, it will drift out of its initial calibration after a limited number of usage cycles. This test requires that additional ageing cycles be performed. Checking the accuracy before and after this additional ageing ensures that the transducer has been aged prior to calibration.

The 10,000 cycles also help ensure that the non-automated sphygmomanometer has sufficient stability to be useful in clinical practice.

Subclause 12.2.1 General

f)

The examination of diastolic blood pressure by auscultation can be made by the detection of the 4th and/or 5th Korotkoff (K) sounds. K4 is the change in the tones heard through the stethoscope from a clear tapping sound to a muffled sound. K5 is the point at which the K sounds can no longer be heard. Current practice guidelines suggest that K5 should be used for adults and K4 for children aged 3 to 12.

j)

It is recommended that the performance should be checked at regular intervals and after maintenance and repair, by re-testing at least the requirements in 7.1.1, 7.2.1 (testing at least at 50 mmHg and 200 mmHg or 7 kPa and 27 kPa), and for a non-automated sphygmomanometer with a mercury manometer, the requirements in 8.4.

Annex B
(informative)

Advice regarding non-automated sphygmomanometers with a mercury manometer

B.1 Guidelines and precautions

A mercury-type non-automated sphygmomanometer should be handled with care. In particular, care should be taken to avoid dropping the non-automated sphygmomanometer or treating it in any way that could result in damage to its manometer. Regular checks should be made to ensure that there are no leaks from the inflation system and to ensure that the manometer has not been damaged so as to cause a loss of mercury.

B.2 Health and safety when handling mercury

Exposure to mercury can have serious toxicological effects.

Only a specialized service centre should perform maintenance of a mercury non-automated sphygmomanometer. Refer to national regulations for the handling and shipping of hazardous materials.

B.3 Mercury spillage

When dealing with spilled mercury, wear protective gloves. Avoid inhalation of mercury vapor or ingestion of mercury. Do not use an open vacuum system to aid collection.

Collect all the small droplets of spilled mercury into one globule and immediately transfer all the mercury into a sealed container.

After removal of as much of the mercury as practicable, treat the contaminated surfaces with a wash composed of equal parts of calcium hydroxide and powdered sulfur mixed with water to form a thin paste. Apply this paste to all the contaminated surfaces and allow it to dry. After 24 h, remove the paste and wash the surfaces with clean water. Allow the surfaces to dry, then ventilate the area.

B.4 Cleaning the manometer tube

To obtain the best results from a mercury-type non-automated sphygmomanometer, the manometer tube should be cleaned at regular intervals (e.g. under the recommended maintenance schedule). This will ensure that the mercury can move up and down the tube freely, and respond quickly to changes in pressure in the cuff.

During cleaning, care should be taken to avoid the contamination of clothing. Any material contaminated with mercury should be placed in a sealed container and disposed of according to national regulations for hazardous materials.

Annex C
(informative)

Environmental aspects

The environmental impact generated by a non-automated sphygmomanometer measuring the blood pressure is mainly limited to the following:

— impact at local environment during normal use;

— use, cleaning and disposal of consumables during testing and normal use;

— for mercury manometers, the disposal of supplies and consumables during maintenance;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this document addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the non-automated sphygmomanometer.

See Table C.1 for a mapping of the life cycle of a non-automated sphygmomanometer to aspects of the environment.

Table C.1 — Environmental aspects addressed by clauses of this document

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction	Distribution (including packaging)	Use	End of life
		Stage A	Stage B	Stage C	Stage D
		Addressed in subclause/annex			
1	Resource use	6.1	6.1	6.1, 6.2	6.1
2	Energy consumption	6.1	6.1	6.1	—
3	Emission to air	6.1, 6.4.3, Annex B	6.1, 8.3	4.4, 6.1, 6.2, 6.4.3, 7.3, 8.4, 10, Annex B	4.4, 6.1, 12.2.1
4	Emission to water	6.1, 6.4.3, Annex B	6.1, 8.3	4.4, 6.1, 6.4.3, 7.3, 8.4, 10, Annex B	4.4, 6.1, 12.2.1
5	Waste	6.1, Annex B	6.1	4.4, 6.1, 6.2, 12.2.1, Annex B	4.4, 6.1, 12.2.1
6	Noise	6.1	–	6.1, 6.2	—
7	Migration of hazardous substances	6.1, 6.4.3, Annex B	8.3	4.4, 6.1, 6.2, 6.4.3, 7.3, 8.4, 10, 11, 12.2.1, Annex B	4.4, 6.1, 12.2.1
8	Impacts on soil	6.1, 6.4.3, Annex B	8.3	4.4, 6.1, 6.4.3, 7.3, 8.4, Annex B	4.4, 6.1, 12.2.1
9	Risks to the environment from accidents or misuse	6.1, 6.4.3, Annex B	8.3	4.4, 6.1, 6.2, 6.4.3, 7.3, 8.4, Annex B	4.4, 6.1, 12.2.1

Annex D
(informative)

Reference to the essential principals

This part of ISO 81060 has been prepared to support the essential principles of safety and performance of non-automated sphygmomanometers as medical devices according to ISO/TR 16142 [4]. This part of ISO 81060 is intended to be acceptable for conformity assessment purposes.

Compliance with this part of ISO 81060 provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible. See Table D.1.

Table D.1 — Correspondence between this part of ISO 81060 and the essential principles

Corresponding essential principle of document ISO/TR 16142:2006, Table A.1, Clause A	Clause(s)/sub-clause(s) of this part of ISO 81060	Qualifying remarks/Notes
1	All, 4.1, 4.6, 7.24	
2	All, 4.6, 7.2.3, 7.2.4, 7.3	
3	All	
4	5, 6, 7, 8, 9, 10, 11, 12	And via IEC 60601-1
5	5.3, 5.5, 6.4.2, 7.2.1, 7.2.2, 12.2.1 p)	And via IEC 60601-1
6	5, 6, 7	And via IEC 60601-1
7.1	8.3, 8.4, 8.5, 9, 10, 11	Annex B and via IEC 60601-1
7.2	4.4 f), 4.4 g), 8.3, 8.4, 8.5	Annex B and via IEC 60601-1
7.3	—	Via IEC 60601-1
7.4	—	
7.5	8.3, 8.4, 8.5	Via IEC 60601-1
7.6	6.4.3, 8	And via IEC 60601-1
8.1	10, 12.2.2	And via IEC 60601-1
8.1.1	—	
8.1.2	—	
8.2	4.7 b)	
8.3	10.3	
8.4	10.2	
8.5	10.2	
8.6	4.7	
9.1	7.1.2, 7.2, 12.2.1 c)	And via IEC 60601-1
9.2	6.3, 6.4, 7.1.1, 7.2	And via IEC 60601-1

Table D.1 (*continued*)

Corresponding essential principle of document ISO/TR 16142:2006, Table A.1, Clause A	Clause(s)/sub-clause(s) of this part of ISO 81060	Qualifying remarks/Notes
9.3	—	Via IEC 60601-1
10.1	7, 8.1, 9	And via IEC 60601-1
10.2	4.1, 4.5	And via IEC 60601-1
10.3	4.1	And via IEC 60601-1
11.1.1	–	
11.2.1	–	
11.2.2	–	
11.3	—	Via IEC 60601-1
11.4	—	
11.5.1	—	
11.5.2	—	
11.5.3	—	
12.1	—	
12.2	—	Via IEC 60601-1
12.3	—	
12.4	—	
12.5	—	Via IEC 60601-1
12.6	6.2	
12.7.1	—	Via IEC 60601-1
12.7.2	—	Via IEC 60601-1
12.7.3	—	Via IEC 60601-1
12.7.4	—	Via IEC 60601-1
12.7.5	—	Via IEC 60601-1
12.8.1	—	
12.8.2	—	
12.8.3	12.2.1 f)	
13.1	4, 12	And via IEC 60601-1
14.1	—	

Annex E
(informative)

Terminology — Alphabetized index of defined terms

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[2] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[3] ISO 14971, *Medical devices — Application of risk management to medical devices*

[4] ISO/TR 16142:2006, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[5] ISO 21647:2004, *Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors*

[6] IEC 60068 (series), *Environmental testing*

[7] IEC 60601-2-30, *Medical electrical equipment — Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment*

[8] IEC 60601-2-34, *Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment*

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[11] IEC 60721-3-7, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities— Portable and non-stationary use*

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American National Standard

ANSI/AAMI/ISO 81060-2:2009

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

Association for the Advancement of Medical Instrumentation

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.

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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 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.

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American National Standard

ANSI/AAMI/ISO 81060-2:2009
(Revision of SP10:2002 and
Amendment 1:2003 and Amendment 2:2006)

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

Approved 18 June 2009 by
Association for the Advancement of Medical Instrumentation

Approved 11 August 2009 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. This standard is not applicable to the validation of non-automated sphygmomanometers as given in ANSI/AAMI/ISO 81060-1:2007.

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

AAMI Standard

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

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 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009	ANSI/AAMI/IEC 80601-2-30:2009	Identical (with inclusion)
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical

International designation	U.S. designation	Equivalency
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
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ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
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ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
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ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
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ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Sphygmomanometer Committee

This standard was adopted by the AAMI Sphygmomanometer Committee. Committee approval of this document 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.

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Bruce A. Friedman

Members: Bruce Stephen Alpert, MD, University of Tennessee at Memphis College of Graduate Health Sciences
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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 AAMI adoption of ISO 81060-2:2009

This standard was developed by the International Organization for Standardization (ISO)/TC 121/SC3 and International Electrotechnical Commission (IEC)/SC 62D Joint Working Group 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 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.

This is a revision of the American National Standard SP10:2002 (and Amendment 1:2003 as well as Amendment 2:2006), *Manual, electronic, or automated sphygmomanometers*. During the course of this international standard undergoing U.S. review, the U.S. Technical Advisory sub-Group (sub-TAG) for the ISO and IEC Joint Working Group (JWG) 7 (AAMI Sphygmonomameter Committee) decided to adopt this then proposed international standard as an American National Standard. Serving as the U.S. sub-TAG for the ISO/IEC JWG, the AAMI Sphygmomanometer Committee was responsible for developing U.S. consensus on the international standard and otherwise participated in the drafting of that 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.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “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. “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 comes 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 Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page “viii”, this American National Standard is identical to ISO 81060-2:2009.

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 81060-2:2009), 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.

ISO 81060-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical Equipment in Medical Practice*, Subcommittee 62D, *Electromedical Equipment*.

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 validation of automated measurement type*

Introduction

Determination of **blood pressure** is an important procedure that is clinically used to assess the health of the **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.

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;

— terms defined in this document: **bold type**.

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

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

1 Scope

This part of ISO 81060 specifies the requirements and methods for the clinical validation of **me equipment** used for the intermittent non-invasive automatic 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** or self-measurement).

EXAMPLE **Automated sphygmomanometer** as given in IEC 80601-2-30 validated by this part of ISO 81060.

This part of ISO 81060 specifies additional disclosure requirements for the **accompanying documents** of **sphygmomanometers** validated according to this part of ISO 81060.

This part of ISO 81060 is not applicable to the validation 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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14155:—[1)], *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 81060-1:2007, *Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type*

IEC 80601-2-30:2009, *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*

IEC 60601-1-11, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in home care applications*

1) To be published.

IEC 60601-2-34:2000, *Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14155, IEC 80601-2-30, IEC 60601-1, IEC 60601-1-11, IEC 60601-2-34 and the following apply. For convenience, an alphabetized list of the sources of all defined terms used in this document is given in Annex D.

3.1
reference
established accuracy used for clinical evaluation of other instruments

3.2
sphygmomanometer
me equipment for non-invasive estimation of systemic arterial **blood pressure**

3.3
sphygmomanometer-under-test
sphygmomanometer being clinically evaluated

4 General requirements for validation studies

4.1 Validation methods

Sphygmomanometers other than **non-automated sphygmomanometers** shall be clinically validated either by using a non-invasive (auscultatory) **reference sphygmomanometer** or by using **reference invasive blood pressure monitoring equipment** according to this part of ISO 81060 in each mode of operation.

EXAMPLE 1 Adult and neonatal mode.

EXAMPLE 2 Slow and fast **cuff** deflation rate mode.

A clinical validation study shall be considered a **type test**.

Consider compliance with the requirements of this subclause to exist when the criteria of the relevant inspections and tests in this part of ISO 81060 are met.

4.2 Ethical requirements

All clinical validation studies shall comply with the requirements of ISO 14155. Validation with **reference invasive blood pressure monitoring equipment** should not be used for **patients** or subjects solely for the purpose of validating **sphygmomanometer** performance.

NOTE Some authorities with jurisdiction have additional requirements.

Check compliance by application of the requirements of ISO 14155.

5 Validation with auscultatory reference sphygmomanometer

5.1 Subject requirements

5.1.1 * Number

An auscultatory **reference sphygmomanometer** validation study shall consist of a minimum of 85 subjects. If not otherwise specified, at least three valid **blood pressure** determinations shall be taken for each subject. There shall be a minimum of 255 valid paired **blood pressure** determinations.

Check compliance by inspection of the **clinical investigation** report.

5.1.2 * Gender distribution

At least 30 % of the subjects shall be male and at least 30 % of the subjects shall be female.

Check compliance by inspection of the **clinical investigation report**.

5.1.3 * Age distribution

For a **sphygmomanometer** intended for use on adults and/or adolescent **patients**, the ages of the subjects included in the validation study shall be $>$ 12 y.

NOTE 1 Minimum total of 85 subjects.

For a **sphygmomanometer** additionally intended for use in children, 35 child subjects aged between 3 y and 12 y shall be included in the validation study.

NOTE 2 Minimum total of 85 subjects.

If the **sphygmomanometer** has a special mode for children, in that mode, children shall be considered a special **patient** population (see 5.1.6). In that mode, children are exempt from the **blood pressure** distribution requirements of 5.1.5.

Children $<$ 3 y shall not be included in an auscultatory **reference sphygmomanometer** validation study.

Check compliance by inspection of the **accompanying document** and the **clinical investigation report**.

5.1.4 * Limb size distribution

For a **sphygmomanometer** intended for use with a single **cuff** size, at least 40 % of the subjects shall have a limb circumference which lies within the upper half of the specified range of use of the **cuff** and at least 40 % shall have a limb circumference within the lower half. At least 20 % of the subjects should have a limb circumference which lies within the upper quarter of the specified range of use of the **cuff** and at least 20 % should have a limb circumference within the lower quarter.

For a **sphygmomanometer** intended for use with multiple **cuff** sizes, each **cuff** size shall be tested on at least $1/(2 \times n)$ of the subjects, where n is the number of **cuff** sizes.

Check compliance by inspection of the **accompanying document** and the **clinical investigation report**.

5.1.5 * Blood pressure distribution

At least 5 % of the readings shall have a **systolic blood pressure** ≤ 100 mmHg.

At least 5 % of the readings shall have a **systolic blood pressure** ≥ 160 mmHg.

At least 20 % of the readings shall have a **systolic blood pressure** ≥ 140 mmHg.

At least 5 % of the readings shall have a **diastolic blood pressure** ≤ 60 mmHg.

At least 5 % of the readings shall have a **diastolic blood pressure** ≥ 100 mmHg.

At least 20 % of the readings shall have a **diastolic blood pressure** ≥ 85 mmHg.

Check compliance by inspection of the **clinical investigation report**.

5.1.6 * Special patient populations

A **sphygmomanometer** that is intended for use in special **patient** populations where there is **objective evidence** that the accuracy of the **sphygmomanometer** might be problematic in those **patient** populations, shall be clinically evaluated in those **patient** populations. See also Clause 7.

EXAMPLES Use with **patients** who have atrial fibrillation (AF), premature ventricular beats and peripheral arterial disease (PAD).

If the **sphygmomanometer** has been evaluated according to the requirements of 5.1.1, it shall then be validated in at least an additional 35 special population subjects. Otherwise, the evaluation in accordance with the requirements of 5.1.1 shall only consist of subjects from the special population.

The special population shall be defined in clear terms and address the following attributes: gender (see 5.1.2), age (see 5.1.3), limb size (see 5.1.4) and **blood pressure** (see 5.1.5). A summary of this information shall be disclosed in the instructions for use.

Check compliance by inspection of the instructions for use and the **clinical investigation report**.

5.2 Validation method with reference sphygmomanometer

5.2.1 * Subject preparation

See Reference [32].

Unless otherwise indicated by the instructions for use of the **sphygmomanometer-under-test**, position the subject such that the subject:

— is comfortable;

EXAMPLE Comfortably seated with legs uncrossed and feet flat on the floor.

— has the back, elbow and forearm supported;

— has the middle of **cuff** at the level of the right atrium of the heart.

Recommend that the subject be as relaxed as possible and that they avoid talking during the entire procedure. Before the first reading is taken, 5 min should elapse.

5.2.2 * Observer preparation

Observers should be trained in using a proper methodology for performing a resting **blood pressure** determination by utilizing an accepted clinical protocol for **blood pressure** measurement. See References [8], [28], [29], [32] and [45]. They should have sufficient practice in performing **blood pressure** determinations.

Each observer's recording of observations of the **reference sphygmomanometer** shall not be visible to the other observer. The readings of the **sphygmomanometer-under-test** shall not be visible to either of these observers.

EXAMPLE 1 Utilizing a third observer for recording the readings of the **sphygmomanometer-under-test**.

EXAMPLE 2 Utilizing an electronic means for recording the readings of the **sphygmomanometer-under-test**.

Instruct the observers to determine **diastolic blood pressure** as the last audible Korotkoff sound (fifth phase or K5), except in children between 3 y and 12 y, pregnant subjects, and subjects during exercise, where the fourth phase (K4) is used.

Instruct the observers to use K4 for the determination of **diastolic blood pressure** when sounds are audible with the **cuff** deflated.

Instruct the observers to record which Korotkoff sound has been used for the determination of **diastolic blood pressure**.

The Korotkoff sound used for determination of **diastolic blood pressure** in the clinical validation study shall be disclosed in the instructions for use of a **sphygmomanometer**.

EXAMPLE K5 was used on 65 subjects and K4 was used on 20 subjects.

5.2.3 * Reference determination

Two observers shall make simultaneous **blood pressure** determinations on each subject using a double stethoscope.

Unless the **sphygmomanometer-under-test** is intended for use during significantly irregular heart rhythm and if either observer detects significantly irregular heart rhythm, that determination shall be excluded.

EXAMPLES Bigeminy, trigeminy, isolated VPB, atrial fibrillation.

NOTE 1 Although evaluation of **blood pressure** in **patients** with atrial fibrillation is clinically important, there are currently no generally-accepted guidelines for determining the **blood pressure** in such individuals.

Any pair of observers' determinations with a difference greater than 4 mmHg shall be excluded. The observers' individual values of each determination shall be averaged to create the **reference blood pressure** determination.

The observer-to-observer differences shall be reviewed after completing a set of pairs of test-**reference** determinations. If any determinations are excluded, additional pair(s) of determinations shall be taken to

ensure that the needed number of valid test-**reference** pairs are available. A maximum of eight pairs of determinations should be taken.

Use a **reference sphygmomanometer** that complies with the requirements of ISO 81060-1, except that the maximum permissible error shall be ± 1 mmHg. Reading of the values on the **reference sphygmomanometer** should be as accurate as possible. When reading the value on the **reference sphygmomanometer**, the observers should avoid parallax errors. Rounding has a negative effect on the results of the clinical validation.

NOTE 2 The **cuff** is considered part of the **reference sphygmomanometer**. A **cuff** that does not comply with ISO 81060-1 cannot be used.

5.2.4 Validation methods

5.2.4.1 Same arm simultaneous method

5.2.4.1.1 * Procedure

This method shall only be used with a **sphygmomanometer-under-test**:

— that is designed for use on the upper arm;

— where:

  — the continuous linear deflation rate is 2 mmHg/s to 3 mmHg/s or

  — for a **sphygmomanometer-under-test** that controls the deflation as a function of the pulse rate, the deflation rate is between 2 mmHg/pulse and 3 mmHg/pulse.

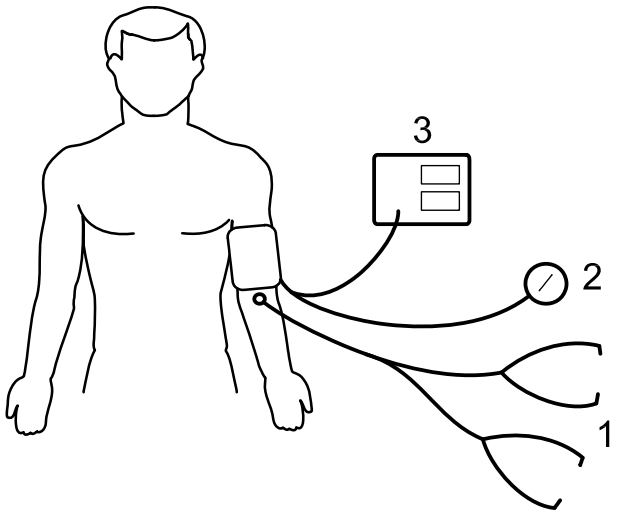
This method shall only be used when the **sphygmomanometer-under-test cuff** meets the requirements of ISO 81060-1.

The **sphygmomanometer-under-test** shall not deflate prior to the detection of the **reference diastolic blood pressure**. The **sphygmomanometer-under-test** may be modified to meet this criterion.

NOTE Valid same arm simultaneous determinations require the **sphygmomanometer-under-test** to inflate the **cuff** to at least 20 mmHg higher than the actual **systolic blood pressure**, as determined by the **reference sphygmomanometer**, and to at least 20 mmHg below the actual **diastolic blood pressure**, as determined by the **reference sphygmomanometer**.

Perform the following:

a) Have the observers using the **reference sphygmomanometer** and the **sphygmomanometer-under-test** simultaneously determine the subject's **blood pressure** utilizing the same **cuff** and inflation/deflation cycle (see Figure 1).



Key

1 double stethoscope

2 **reference sphygmomanometer** display

3 **sphygmomanometer-under-test**

Figure 1 — Illustration of same arm simultaneous method

b) Clear the **sphygmomanometer-under-test** memory of the previous determination and then wait at least 60 s.

EXAMPLE Switching the power off and on, removing the **blood pressure** module or issuing a reset command as methods to clear any memory of the previous determination.

c) These data points are not used in the determination of accuracy.

d) Have the observers using the **reference sphygmomanometer** and the **sphygmomanometer-under-test** simultaneously determine the subject's **blood pressure** utilizing the same **cuff** and inflation/deflation cycle.

e) Wait at least 60 s between determinations.

f) Repeat d) and e) until the needed number of determinations have been performed.

If an individual subject is unstable during the period of the test, two valid determination pairs may be used. In this case, additional subjects may be used to complete the method. No more than 10 % of the subjects shall have fewer than three valid determination pairs.

All data from a subject shall be excluded if any two **reference systolic blood pressure** determinations differ by more than 12 mmHg or if any two **reference diastolic blood pressure** determinations differ by more than 8 mmHg.

5.2.4.1.2 * Data analysis

The **sphygmomanometer-under-test** shall meet the following two criteria.

a) Criterion 1

For **systolic** and **diastolic blood pressures**, the mean error of determination, $\overline{x}_n$, of the n individual paired determinations of the **sphygmomanometer-under-test** and the **reference sphygmomanometer** for all subjects shall not be greater than 5.0 mmHg, with a standard deviation, s_n, no greater than 8.0 mmHg when calculated according to Equation (1) and Equation (2):

$$\overline{x}_n = \frac{1}{n} \times \sum_{i=1}^{n} \left(p_{\mathrm{sut}_i} - p_{\mathrm{ref}_i} \right) \tag{1}$$

$$s_n = \sqrt{\frac{1}{n-1} \times \sum_{i=1}^{n} \left(x_i - \overline{x}_n \right)^2} \tag{2}$$

where

$\overline{x}_n$ is the mean error;

x_i = $p_{\mathrm{sut}_i} - p_{\mathrm{ref}_i}$ of a paired **blood pressure** determination (**sphygmomanometer-under-test** – **reference sphygmomanometer**);

i is the index for the individual element;

n is the number of determinations.

$\overline{x}_n$ and s_n shall be calculated and expressed to 0.1 mmHg.

EXAMPLE 1 n = 255 for a **sphygmomanometer** intended for use in adults and/or adolescent **patients** (an 85 subject study).

EXAMPLE 2 n = 255 for a **sphygmomanometer** intended for use in adults and/or adolescents and children aged between 3 y and12 y (an 85 subject study).

EXAMPLE 3 n = 105 for a **sphygmomanometer** intended for a special intended use (a 35 subject study). The **sphygmomanometer** that has a separate 85 subject study.

b) Criterion 2

For the **systolic** and **diastolic blood pressures** for each of the m subjects, the standard deviation, s_m, of the averaged paired determinations per subject of the **sphygmomanometer-under-test** and of the **reference sphygmomanometer** shall meet the criteria listed in Table 1 when calculated according to Equation (3):

$$s_m = \sqrt{\frac{1}{m-1} \times \sum_{j=1}^{m} \left(x_j - \bar{x}_n \right)^2} \tag{3}$$

where

$\bar{x}_n$ is the mean error over all subjects (see Equation 1);

m is the number of subjects;

j is the index for the individual element;

x_j is calculated from Equation (4).

$$x_j = \frac{1}{d} \times \sum_{k=1}^{d} (p_{\text{sut}_k} - p_{\text{ref}_k}) \tag{4}$$

where

d is the number of determinations per subject;

k is the index for the individual element.

Table 1 — Averaged subject data acceptance (criterion 2)

$\bar{x}_n$	**Maximum permissible standard deviation**, s_m, **as function of mean error**, $\bar{x}_n$ mmHg									
	0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
± 0.	6.95	6.95	6.95	6.95	6.93	6.92	6.91	6.90	6.89	6.88
± 1.	6.87	6.86	6.84	6.82	6.80	6.78	6.76	6.73	6.71	6.68
± 2.	6.65	6.62	6.58	6.55	6.51	6.47	6.43	6.39	6.34	6.30
± 3.	6.25	6.20	6.14	6.09	6.03	5.97	5.89	5.83	5.77	5.70
± 4.	5.64	5.56	5.49	5.41	5.33	5.25	5.16	5.08	5.01	4.90
± 5.	4.79	—	—	—	—	—	—	—	—	—
EXAMPLE For mean error of ± 4.2, the maximum permissible standard deviation is 5.49.										

EXAMPLE 4 m = 85 for a **sphygmomanometer** intended for use in adults and/or adolescent **patients** (an 85 subject study).

EXAMPLE 5 m = 85 for a **sphygmomanometer** intended for use in adults and/or adolescents and children aged between 3 y and 12 y (an 85 subject study).

EXAMPLE 6 m = 35 for a **sphygmomanometer** intended for (an additional) special intended use (a 35 subject study). The **sphygmomanometer** that has a separate 85 subject study.

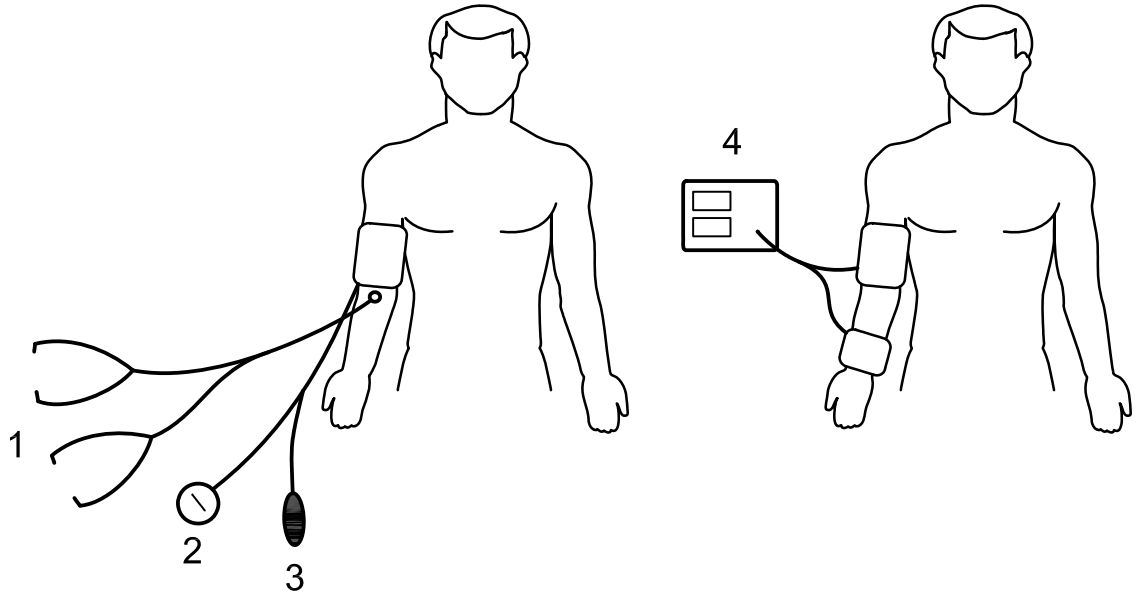
EXAMPLE 7 m = 85 for a **sphygmomanometer** intended only for a special intended use (an 85 subject study).

5.2.4.2 * Same arm sequential method

5.2.4.2.1 Procedure

Perform the following method:

a) Have the observers using the **reference sphygmomanometer** determine the subject's **blood pressure** (see Figure 2).



Key

1 double stethoscope

2 **reference sphygmomanometer** display

3 **reference sphygmomanometer** hand pump

4 **sphygmomanometer-under-test**

Figure 2 — Illustration of same arm sequential method

b) Wait at least 60 s.

c) Have the observers using the **sphygmomanometer-under-test** determine the subject's **blood pressure**.

d) Clear the **sphygmomanometer-under-test** memory of the previous determination and then wait at least 60 s.

EXAMPLE Switching the power off and on, removing the **blood pressure** module or issuing a reset command as methods to clear any memory of the previous determination.

e) These data points shall not be used in the determination of accuracy.

f) The starting order [see g)] of **sphygmomanometer-under-test** and **reference sphygmomanometer** determinations shall be alternated between subjects, or a randomizations procedure may be used to determine the starting order.

g) Have the observers using the **reference sphygmomanometer** and the **sphygmomanometer-under-test** determine the subject's **blood pressure** sequentially.

h) Wait at least 60 s between each determination.

i) Repeat g) and h) until the needed number of determinations has been performed.

All data from a subject shall be excluded if any two **reference systolic blood pressure** determinations differ by more than 12 mmHg or if any two **reference diastolic blood pressure** determinations differ by more than 8 mmHg.

5.2.4.2.2 Data analysis

The **sphygmomanometer-under-test** shall meet the following two criteria.

a) Criterion 1

For **systolic** and **diastolic blood pressures**, the mean error of determination, $\bar{x}_n$, of the n individual paired determinations of the **sphygmomanometer-under-test** and the **reference sphygmomanometer** for all subjects shall not be greater than 5.0 mmHg, with a standard deviation, s_n, no greater than 8.0 mmHg when calculated according to Equation (5) and Equation (6):

$$\bar{x}_n = \frac{1}{n} \times \sum_{i=1}^{n} \left(p_{\text{sut}\,i} - p_{\text{ref}\,i} \right) \tag{5}$$

$$s_n = \sqrt{\frac{1}{n-1} \times \sum_{i=1}^{n} \left(x_i - \bar{x}_n \right)^2} \tag{6}$$

where

$\bar{x}_n$ is the mean error;

$x_i = p_{\text{sut}} - p_{\text{ref}}$ of a paired **blood pressure** determination (**sphygmomanometer-under-test** – **reference sphygmomanometer**);

n is the number of determinations.

The p_{ref} or **reference sphygmomanometer** determinations shall not be the average of the preceding and following **reference blood pressures**. $\bar{x}_n$ and s_n shall be calculated and expressed to 0.1 mmHg.

EXAMPLE 1 n = 255 for a **sphygmomanometer** intended for use in adults and/or adolescent **patients** (an 85 subject study).

EXAMPLE 2 n = 255 for a **sphygmomanometer** intended for use in adults and/or adolescents and children aged between 3 y and 12 y (an 85 subject study).

EXAMPLE 3 n = 105 for a **sphygmomanometer** intended for a special intended use (a 35 subject study).

b) Criterion 2

For the **systolic** and **diastolic blood pressures** for each of the m subjects, the standard deviation, s_m, of the averaged paired determinations per subject of the **sphygmomanometer-under-test** and of the **reference sphygmomanometer**, shall meet the criteria listed in Table 1 when calculated according to Equation (7).

$$s_m = \sqrt{\frac{1}{m-1} \times \sum_{j=1}^{m} \left(x_j - \bar{x}_n \right)^2} \tag{7}$$

where

$\bar{x}_n$ is the mean error over all subjects (see Equation 5);

m is the number of subjects;

x_j is calculated from Equation (8).

$$x_j = \frac{1}{d} \times \sum_{k=1}^{d} (p_{\text{sut}_k} - p_{\text{ref}_k}) \tag{8}$$

where d is the number of determinations per subject.

EXAMPLE 4 m = 85 for a **sphygmomanometer** intended for use in adults and/or adolescent **patients** (an 85 subject study).

EXAMPLE 5 m = 85 for a **sphygmomanometer** intended for use in adults and/or adolescents and children aged between 3 y and 12 y (an 85 subject study).

EXAMPLE 6 m = 35 for a **sphygmomanometer** intended for (an additional) special intended use (a 35 subject study).

EXAMPLE 7 m = 85 for a **sphygmomanometer** intended only for a special intended use (an 85 subject study).

5.2.4.3 Opposite arm simultaneous method

5.2.4.3.1 * Procedure

The starting limb side of the **sphygmomanometer-under-test** and the **reference sphygmomanometer** determinations shall be alternated between subjects.

Perform the following:

a) Have the observers using the **reference sphygmomanometer** and the **sphygmomanometer-under-test** simultaneously determine the subject's **blood pressure** in opposite arms (see Figure 3).

b) These data points are not used in the determination of accuracy.

c) Clear the **sphygmomanometer-under-test** memory of the previous determination and wait at least 60 s.

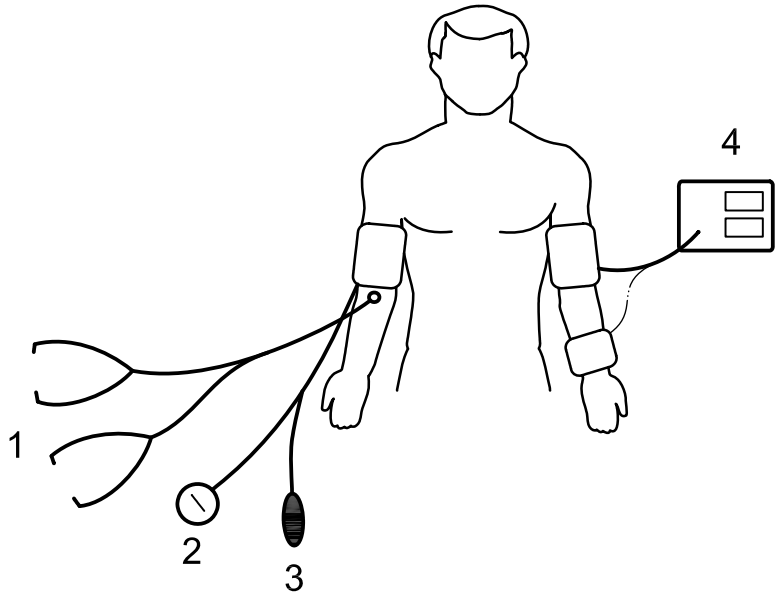
EXAMPLE Switching the power off and on, removing the **blood pressure** module or issuing a reset command as methods to clear any memory of the previous determination.

d) Interchange arm sides of the **reference sphygmomanometer** and the **sphygmomanometer-under-test**.

e) Wait at least 60 s from the completion of the previous determination.

f) Repeat c) to e) until six paired determinations have been performed.

g) If the determination by the **reference sphygmomanometer** or the **sphygmomanometer-under-test** is not successfully completed, repeat the determination on the same arm sides, i.e., without interchanging limb sides.



Key

1 double stethoscope
2 **reference sphygmomanometer** display
3 **reference sphygmomanometer** hand pump
4 **sphygmomanometer-under-test**

Figure 3 — Illustration of opposite arm simultaneous method

All data from a subject shall be excluded if the lateral difference of the **reference systolic blood pressure** determinations is more than 15 mmHg or the lateral difference of the **reference diastolic blood pressure** determinations is more than 10 mmHg.

The lateral difference, LD, is calculated separately for **systolic** and **diastolic blood pressures**, according to Equation (9).

$$LD = \frac{1}{3} \times \left(\sum_{i=1}^{3} P_{\text{ref\_R}i} - \sum_{j=1}^{3} P_{\text{ref\_L}j} \right) \tag{9}$$

where

$P_{\text{ref\_R}i}$ and $P_{\text{ref\_L}j}$ are **reference blood pressure** in right (R) limb and left (L) limb, respectively.

5.2.4.3.2 * Data analysis

The **sphygmomanometer-under-test** error, x, is computed by taking the difference between the **sphygmomanometer-under-test blood pressur**e and **reference sphygmomanometer blood pressure** and by adding the lateral difference, LD, according to Equation (10) if the **sphygmomanometer-under-test blood pressure** was taken in the left arm or by subtracting the lateral difference, LD, according to Equation (11) if the **sphygmomanometer-under-test blood pressure** was taken in the right arm.

$$x = P_{\text{sut\_L}} - P_{\text{ref\_R}} + LD \tag{10}$$

$$x = P_{\text{sut\_R}} - P_{\text{ref\_L}} - LD \tag{11}$$

where $P_{\text{sut\_R}}$ and $P_{\text{sut\_L}}$ are **sphygmomanometer-under-test blood pressures** in right (R) arm and left (L) arm, respectively.

The **sphygmomanometer-under-test** shall meet the following two criteria.

a) Criterion 1

For **systolic** and **diastolic blood pressures**, the mean error of determination, $\bar{x}_n$, of the n individual paired determinations of the **sphygmomanometer-under-test** and the **reference sphygmomanometer** for all subjects shall not be greater than 5.0 mmHg, with a standard deviation, s_n, not greater than 8.0 mmHg when calculated according to Equation (12) and Equation (13).

$$\bar{x}_n = \frac{1}{n} \times \sum_{i=1}^{n} x_i \tag{12}$$

$$s_n = \sqrt{\frac{1}{n-1} \times \sum_{i=1}^{n} \left(x_i - \bar{x}_n \right)^2} \tag{13}$$

Where n is the number of determinations.

EXAMPLE 1 n = 510 for a **sphygmomanometer** intended for use in adults and/or adolescent **patients** (an 85 subject study).

EXAMPLE 2 n = 510 for a **sphygmomanometer** intended for use in adults and/or adolescents and children aged between 3 y and 12 y (an 85 subject study).

EXAMPLE 3 n = 210 for a **sphygmomanometer** intended for (an additional) special intended use (a 35 subject study).

Criterion 2

For the average of the **systolic** and **diastolic blood pressures** for each subject, the standard deviation, s_m, of the m averaged paired determinations of the **sphygmomanometer-under-test** and the **reference sphygmomanometer**, per subject, shall meet the criteria listed in Table 1 when calculated according to Equation (14).

$$s_m = \sqrt{\frac{1}{m-1} \times \sum_{j=1}^{m} \left(x_j - \bar{x}_n \right)^2} \tag{14}$$

where

m is the number of subjects;

x_j is the mean error per subject calculated from Equation (15).

$$x_j = \frac{1}{6} \times \sum_{k=1}^{6} x_k \tag{15}$$

EXAMPLE 4 m = 85 for a **sphygmomanometer** intended for use in adults and/or adolescent **patients** (an 85 subject study).

EXAMPLE 5 m = 85 for a **sphygmomanometer** intended for use in adults and/or adolescents and children aged between 3 y and 12 y (an 85 subject study).

EXAMPLE 6 m = 35 for a **sphygmomanometer** intended for (an additional) special intended use (a 35 subject study).

EXAMPLE 7 m = 85 for a **sphygmomanometer** intended only for a special intended use (an 85 subject study).

5.2.5 * Additional requirements for a sphygmomanometer intended for use in exercise stress testing environments

For a **sphygmomanometer** intended for use in exercise stress testing, an additional clinical validation shall be performed. During this evaluation, the subjects shall be stressed by dynamic (aerobic) exercise on a bicycle ergometer so as to increase their heart rate from their resting heart rate to a target heart rate of 50 % to 70 % of their average maximum heart rate (see Annex B). The physical load setting of the ergometer and target heart rate shall be recorded. The arm used for a determination shall be supported at heart level during the determination of **blood pressure**.

The same arm sequential method of 5.2.4.2 shall not be used. The validation study shall consist of a minimum of 35 subjects. A stress testing study shall be exempt from the **blood pressure** distribution requirements of 5.1.5. At least 10 % of the subjects shall have a resting **systolic blood pressure** ≥ 160 mmHg. At least 10 % of the subjects shall have a resting **diastolic blood pressure** ≥ 100 mmHg.

Check compliance by inspection of the **clinical investigation report**.

5.2.6 Additional requirements for a sphygmomanometer intended for use in ambulatory monitoring

For a **sphygmomanometer** intended for use in ambulatory monitoring, an additional clinical validation shall be performed. During this evaluation, the subjects shall be stressed by dynamic (aerobic) exercise on a bicycle ergometer or treadmill so as to increase their heart rate to 10 % to 20 % above their resting heart rate. The physical load setting of the ergometer and heart rate shall be recorded. The arm used for a determination shall be supported at heart level during the determination of **blood pressure**.

The same arm sequential method of 5.2.4.2 shall not be used. The validation study shall consist of a minimum of 35 subjects. An ambulatory monitoring study shall be exempt from the **blood pressure** distribution requirements of 5.1.5. At least 10 % of the subjects shall have a resting **systolic blood pressure** $>$ 160 mmHg. At least 10 % of the subjects shall have a resting **diastolic blood pressure** $>$ 100 mmHg.

Check compliance by inspection of the **clinical investigation report**.

6 Validation with reference invasive blood pressure monitoring equipment

6.1 Patient requirements

6.1.1 Number

A **reference invasive blood pressure monitoring** equipment validation study shall consist of a minimum of 15 **patients**. For each **patient**, no more than 10 valid **blood pressure** measurements shall be taken. There shall be a minimum of 150 valid **blood pressure** measurements in the validation study.

Check compliance by inspection of the **clinical investigation report**.

6.1.2 * Gender distribution

At least 30 % of the measurements shall be from male **patients** and at least 30 % of the measurements shall be from female **patients**.

Check compliance by inspection of the **clinical investigation report**.

6.1.3 * Age distribution

6.1.3.1 Sphygmomanometers intended for use in adults, adolescents or children

For a **sphygmomanometer** intended for use in adult and/or adolescent **patients**, the ages of the **patients** included in the validation study shall be $>$ 12 y.

NOTE 1 Minimum total of 15 subjects.

For a **sphygmomanometer** additionally intended for use in children, an additional 5 children aged between 3 y and 12 y shall be included in the validation study.

NOTE 2 Minimum total of 20 subjects.

For a **sphygmomanometer** additionally intended for use in children, the data analysis (see 6.1.1) of adults, adolescents and children shall be pooled. Children are exempt from the **blood pressure** distribution requirements of 6.1.5.

Check compliance by inspection of the **accompanying document** and the **clinical investigation report**.

6.1.3.2 Sphygmomanometer for neonatal or infant populations

A **sphygmomanometer** intended for use in neonates, infants and children of less than 3 years of age, shall be validated in those **patient** populations.

The following age or weight ranges are required for a neonatal mode validation study:

— At least 3 **patients** shall be $<$ 1,000 g in weight.

— At least 3 **patients** shall be 1,000 g to 2,000 g in weight.

— At least 3 **patients** shall be $>$ 2,000 g in weight.

— At least 3 **patients** shall be ≥ to 29 days and $<$ 1 year of age.

— At least 3 **patients** shall be ≥ 1 year and $<$ 3 years of age.

— The remaining **patients** may be from any of the above age or weight groups in order to complete the sample size of 18.

NOTE Minimum total of 18 **patients**. A **patient** can be in more than one category simultaneously.

Neonates, infants and children of less than 3 years of age are exempt from the **blood pressure** distribution requirements of 6.1.5, the gender distribution requirements of 6.1.2 and the limb size distribution requirements of 6.1.4.

Check compliance by inspection of the **accompanying document** and the **clinical investigation report**.

6.1.4 * Limb size distribution

For a **sphygmomanometer** intended for use with a single **cuff** size, at least 40 % of the subjects shall have a limb circumference that lies within the upper half of the specified range of use of the **cuff** and at least 40 % shall have a limb circumference within the lower half.

For a **sphygmomanometer** intended for use with multiple **cuff** sizes, at least $1/(2 \times n)$ of the subjects shall be tested with each **cuff** size, where n is the number of **cuff** sizes.

Check compliance by inspection of the **accompanying document** and the **clinical investigation report**.

6.1.5 * Blood pressure distribution

At least 10 % of the subjects shall have a **systolic blood pressure** ≤ 100 mmHg.

At least 10 % of the subjects shall have a **systolic blood pressure** ≥ 160 mmHg.

At least 10 % of the subjects shall have a **diastolic blood pressure** ≤ 70 mmHg.

At least 10 % of the subjects shall have a **diastolic blood pressure** ≥ 85 mmHg.

These requirements shall be met by calculating the mean of the **reference systolic** and **diastolic blood pressure** measurements taken during the study. Additional **reference** measurements may be taken prior to the study to aid in determining inclusion criteria.

Check compliance by inspection of the **clinical investigation report**.

6.1.6 Special patient populations

A **sphygmomanometer** that is intended for use in special **patient** populations where there is **objective evidence** that the accuracy of the **sphygmomanometer** might be problematic in those **patient** populations shall be clinically evaluated in those **patient** populations. See also Clause 7.

EXAMPLES Use with **patients** who have atrial fibrillation (AF), premature ventricular beats, arteriosclerosis obliterans (ASO), arterial calcification at the **cuff** site.

If the **sphygmomanometer** has been evaluated according to the requirements of 6.1.1, then only seven additional special population **patients** shall be included in the validation study. Otherwise, the evaluation in accordance with the requirements of 6.1.1 shall consist only of **patients** from the special population.

Check compliance by inspection of the **accompanying document** and the **clinical investigation report**.

6.2 Validation methods with reference invasive blood pressure monitoring equipment

6.2.1 * Reference measurement

Use **reference invasive blood pressure monitoring equipment** that complies with the requirements of IEC 60601-2-34, except that the maximum allowable error shall be $\pm$ 1 mmHg. The resonant frequency and damping coefficient of the **reference invasive blood pressure monitoring equipment** shall be characterized. See References [16] and [42]. The intra-arterial (IA) transducer and the **sphygmomanometer-under-test cuff** should both be kept at the level of the right atrium of the heart.

Unless the **sphygmomanometer-under-test** is intended for use during a clinically significantly irregular heart rhythm or if the **reference** intra-arterial recording indicates the presence of a significantly irregular heart rhythm, that intra-arterial **blood pressure** recording and its associated **sphygmomanometer-under-test blood pressure** determination shall be excluded. The records of the invasive pressure values shall be checked for the occurrence of dysrhythmias against the **manufacturer's** exclusion criteria. The instructions for use shall indicate that the effectiveness of this **sphygmomanometer** has not been established in the presence of any dysrhythmias included in the exclusion criteria. The effect of isolated premature ventricular beats (VPBs) may be addressed by removing the pressure pulse associated with the VPB and the following compensatory beat.

EXAMPLES Bigemeny, trigemeny, isolated VPB, atrial fibrillation.

NOTE Although evaluation of **blood pressure** in **patients** with atrial fibrillation is clinically important, there are currently no generally-accepted guidelines for determining the **blood pressure** in such individuals.

6.2.2 * Arterial reference site

No arterial site is excluded, but the instructions for use of the **sphygmomanometer** shall disclose the arterial site used as the **reference** site.

NOTE Different sites produce different results due to the pressure difference between the central aorta and other arteries.

Sites on the same limb, a central, subclavian or femoral **reference** may be used for simultaneous comparison of intra-arterial **blood pressure** recordings and **sphygmomanometer-under-test blood pressure** determination. The arterial transducer should be at the level of the heart. The **reference** site may be on the opposite limb. If the opposite limb is used, the results shall be corrected for the lateral difference [see Equation (A.1)]. Simultaneous non-invasive determinations may be used to determine the lateral difference. The lateral difference in pressure shall be calculated prior to validation. **Patients** with a **systolic** or **diastolic** lateral difference greater than 12 mmHg shall be excluded from the study.

Check compliance by inspection of the **accompanying document**.

6.2.3 Procedure

Appropriate measures should be taken to remove air bubbles and clots from the system prior to taking the **reference** measurements.

NOTE The ability to accurately measure arterial **blood pressure** can be degraded by the presence of air bubbles and/or blood clots in the catheter/transducer system.

Perform the following:

a) Have the observers using the **sphygmomanometer-under-test** determine the subject's **blood pressure**.

b) Remove the **cuff** from the subject.

c) Clear the **sphygmomanometer-under-test** memory of the previous determination and wait at least 3 min.

EXAMPLE Switching the power off and on, removing the **blood pressure** module or issuing a reset command as methods to clear any memory of the previous determination.

d) These data points shall not be used in the determination of accuracy.

e) Have the observers using the **reference invasive blood pressure monitoring equipment** and the **sphygmomanometer-under-test** simultaneously record and determine the subject's **blood pressure**.

f) Wait at least 60 s between determinations or, for neonatal **patients**, 3 min.

g) Repeat e) and f) until the needed number of recordings and determinations has been performed.

6.2.4 Determining the reference blood pressure

The invasive **systolic** and **diastolic blood pressure** values shall be determined from the recordings. Compute the mean and standard deviation of the **systolic** and **diastolic blood pressure** from the recordings. Isolated premature ventricular beats (VPBs) may be addressed by removing the pressure pulse associated with the VPB and the following compensatory beat. The mean **systolic blood pressure** values $\pm$ 1 standard deviation of the invasive **blood pressure** curve obtained during the determination performed by the **sphygmomanometer-under-test** shall be used to determine the range of the variation of **systolic blood pressure**. The range of the variation of **diastolic blood pressure** shall be determined in the same way.

NOTE These ranges of variation of **blood pressures** represent an experimental uncertainty. The **sphygmomanometer-under-test** has determined the **patient's blood pressure** when it was somewhere within these ranges.

Unless the **sphygmomanometer-under-test** is intended for use during significantly irregular heart rhythm, all data from a subject shall be excluded if the range of **systolic blood pressure** differs by more than 20 mmHg or if the range of **diastolic blood pressure** differs by more than 12 mmHg.

In those cases, where the arterial curve is interrupted due to the **cuff** inflation, the **reference blood pressure** ranges shall be determined from the curve of the invasive **blood pressure** 30 s before and 30 s after the interruption.

As the determination of the **mean blood pressure** (MAP) from the curve of the recording requires a special algorithm, the **reference mean blood pressure** range may be read from the values displayed on the **reference invasive blood pressure monitoring equipment** or manually determined for each individual beat.

Record the range of the variation of **blood pressure** for all three **blood pressure** values (**systolic blood pressure**, **diastolic blood pressure**, MAP) as determined by this subclause.

Check compliance by inspection of the **accompanying document** and the **clinical investigation report**.

6.2.5 Determining the blood pressure error

If the value obtained from the **sphygmomanometer-under-test** determination lies within the range of the variation of **blood pressure** (see 6.2.4), assign an error of 0 mmHg to this determination.

If the value obtained from the **sphygmomanometer-under-test** determination lies outside the range of the variation of **blood pressure**, subtract the value of the determination from the adjacent limit of the range of the variation of **blood pressure**. That difference represents the error for this determination.

EXAMPLE 1 The range of the variation of **diastolic blood pressure** is 73 mmHg to 82 mmHg. **Diastolic blood pressure** value determined by the **sphygmomanometer-under-test** is 76 mmHg. The error for this determination is 0 mmHg.

EXAMPLE 2 The range of the variation of **diastolic blood pressure** is 73 mmHg to 82 mmHg. **Diastolic blood pressure** value determined by the **sphygmomanometer-under-test** is 70 mmHg. The error for this determination is −3 mmHg.

From the errors of each determination of each **patient**, calculate the arithmetic mean of the error and its standard deviation.

6.2.6 Data analysis

For **systolic** and **diastolic blood pressures**, the mean error of determination, $\bar{x}_n$, of the n individual paired determinations of the **sphygmomanometer-under-test** and the **reference sphygmomanometer** for all subjects shall not be greater than 5.0 mmHg, with a standard deviation, s_n, no greater than 8.0 mmHg when calculated according to Equation (16) and Equation (17).

$$\bar{x}_n = \frac{1}{n} \times \sum_{i=1}^{n} x_i \tag{16}$$

$$s_n = \sqrt{\frac{1}{n-1} \times \sum_{i=1}^{n} \left(x_i - \bar{x}_n \right)^2} \tag{17}$$

where n is the number of determinations.

EXAMPLE 1 n = 150 for a **sphygmomanometer** intended for use in adults and/or adolescent **patients** (a 15 subject study).

EXAMPLE 2 n = 200 for a **sphygmomanometer** intended for use in adults and/or adolescents and children aged between 3 y and 12 y (a 20 subject study).

6.2.7 Mean blood pressure (MAP)

If a **sphygmomanometer** displays a value for **mean blood pressure** (MAP), the **accompanying document** shall disclose the method used to determine and verify the **mean blood pressure**.

Check compliance by inspection of the **accompanying document** and the **clinical investigation report**.

7 * Pregnant, including pre-eclamptic, patient populations

A **sphygmomanometer** that is intended for use in pregnant, including pre-eclamptic, **patients** shall be clinically evaluated in that **patient** population.

If the **sphygmomanometer** has been evaluated according to the requirements given in 5.1.1, then at least an additional 45 pregnant, including pre-eclamptic, **patients** or, if evaluating according to the requirements given in 6.1.1, then at least an additional 15 pregnant, including pre-eclamptic, **patients**, shall be separately validated. Otherwise, the evaluation according to the requirements given in 5.1.1 shall consist only of pregnant, including pre-eclamptic, **patients**.

For a validation study for pregnant, including pre-eclamptic, **patients**, the **patient** population shall be equally distributed, $\pm$ 1, into the following three subgroups:

a) normotensive pregnant **patients** with **systolic blood pressure** $<$ 140 mmHg and **diastolic blood pressure** $<$ 90 mmHg;

b) hypertensive pregnant **patients** without proteinuria $>$ 300 mg in 24 h and with **systolic blood pressure** ≥ 140 mmHg or **diastolic blood pressure** ≥ 90 mmHg;

c) pre-eclampsia, **patients** with proteinuria $>$ 300 mg in 24 h and **diastolic blood pressure** ≥ 90 mmHg.

The **patient's** responsible healthcare provider needs to determine whether or not it is safe for a particular **patient** to participate in a validation study.

NOTE Data analysis is performed with the three subgroups pooled.

The instructions for use of a **sphygmomanometer** that has been validated to operate with pregnant, including pre-eclamptic, **patients** shall indicate that the **sphygmomanometer** is suitable for use with pregnant, including pre-eclamptic, **patients**. The instructions for use of a **sphygmomanometer** that has not been validated for use on pregnant, including pre-eclamptic, **patients** shall indicate the effectiveness of this **sphygmomanometer** has not been established in pregnant, including pre-eclamptic, **patients**.

Check compliance by inspection of the **instructions for use** and the **clinical investigation report**.

Annex A
(informative)

Rationale

General

This annex provides a rationale for some requirements of this part of ISO 81060 and is intended for those who are familiar with the subject of this part of ISO 81060 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 81060. The numbering is, therefore, not consecutive.

5.1.1 Number

The sample size of 85 was determined from the statistics for a normal distribution. See Reference [6]. A 98 % confidence interval ($\alpha = 0.02$) and a statistical power of 95 % ($\beta = 0.05$) yield a sample size requirement of 85 subjects. This requirement originated from the early work of the AAMI blood pressure committee dating from 1987. See Reference [5].

Additionally, a sample size of 85 can be determined from the statistics for a t-distribution. A 95 % confidence interval ($\alpha = 0.05$) and a statistical power of 98 % ($\beta = 0.02$) yield a sample size of 85 subjects.

5.1.2 Gender distribution

While there is no definitive evidence that a **sphygmomanometer** performs differently on male and female **patients**, some studies indicate that there might be a bias. See References [42] and [43]. If bias exists, it is likely caused by differences in arm circumference and body fat distribution. This part of ISO 81060 already requires that the **sphygmomanometer-under-test** be tested over a range of arm circumferences. The requirement for gender distribution allows for investigation of gender differences without being difficult to implement.

5.1.3 Age distribution

The division between children and adults at the age of 12 y was based upon the only known publication that compares the utility of the use of either K4 or K5 as the auscultatory estimate of intra-arterial **diastolic blood pressure**. In 1963, Moss and Adams [26] studied whether K4 or K5 was a better estimate of aortic **blood pressure** measured during cardiac catheterization. The data demonstrated that, up to the age of 13 (u 12) y old, K4 was superior. In 1987, the Task Force on Blood Pressure Control in Children [11] changed its recommendation to state that K5 could be used in individuals older than 3 y of age. Unfortunately, this recommendation was made in the absence of supporting data. For that reason, this committee continues to utilize evidence-based findings, i.e., that in children from 3 y to 12 y old, auscultatory K4 may be utilized as the non-invasive **reference** standard estimate of **diastolic blood pressure** in validation studies.

During the growth period from age 3 y to age 12 y, the average child (50th percentile) increases in height from 93 cm to 96 cm (at age 3 y) to 150 cm to 152 cm (at age 12 y). Within the range from 3rd to 97th percentiles there can be as much as a 30 cm difference (age 12 y). Normal growth is remarkably linear

during this age range, although a child's body builds, and thus arm circumferences vary significantly. The committee was not aware of any longitudinal study of children's arm circumferences from age 3 y to age 12 y. Since non-invasive **blood pressure** accuracy is more strongly influenced by arm circumference than by subject height, the committee believed that the inclusion of each **cuff** size was more important than children of arbitrary ages. For example, a “large” 6 y old can have a significantly greater arm circumference than a “small” 9 y or 10 y old.

The upper normal **blood pressure** in children increases from about 114/66 mmHg at age 1 y to 135/91 mmHg at age 12 y for the tallest children analyzed. See Reference [7]. For this reason, it would not be practical to specify exact “hypertensive” **blood pressure** values, as can be done in adults for validation testing. In addition, the prevalence of essential hypertension in young children is very low, making validation studies requiring hypertensive children extremely difficult to perform. Further, the **systolic blood pressure** and **diastolic blood pressure** values in a hypertensive infant are at about the average for normotensive adults. Thus, the **sphygmomanometer-under-test** would not be significantly “challenged” with respect to accuracy in this **blood pressure** range. Thus, the committee believed there was no valid reason to require hypertensive children in any validation study of individuals ≤ 12 y of age and that children > 12 y of age should be pooled with adults.

5.1.4 Limb size distribution

This is a compromise between more detailed requirements for limb sizes and the difficulty of conducting the test. For a **sphygmomanometer** with a single **cuff** size, it is important to test the full range of limb circumferences intended for use.

5.1.5 Blood pressure distribution

These ranges were chosen to ensure that the performance of the **sphygmomanometer** is evaluated over the entire clinically relevant **blood pressure** range. Previous standards required a subject to remain in a single category for all measurements. This tended to bias the subject selection such that they were far away from the boundaries of the categories, even if the subject was very stable. This part of ISO 81060 retains the stability criteria for each subject, but categorizes each **reference blood pressure** independently.

5.1.6 Special patient populations

Although evaluation of **blood pressure** in **patients** with atrial fibrillation is clinically important, there are currently no generally-accepted guidelines to measure **blood pressure** in such **patients**. Since the accuracy of the auscultatory method for the determination of **blood pressure** in **patients** with atrial fibrillation is not known, it is desirable to establish another evaluation method for **sphygmomanometers** in **patients** with atrial fibrillation.

Although evaluation of **blood pressure** in **patients** during transport outside a healthcare facility is clinically important, there are currently no generally-accepted guidelines to measure **blood pressure** in such **patients**. Since existing clinical standards for **blood pressure** measurement can also be difficult to use during **patient** transport outside a healthcare facility, it is desirable to establish an evaluation method for a **sphygmomanometer** in **patients** during such transport.

5.2.1 Subject preparation

Since it is essential to reduce a subject's **blood pressure** variability during the study, factors that can cause changes in stability of **blood pressure** should be controlled.

EXAMPLES The **patients** should be asked to empty their bladders prior to validation and, particularly in older people, measurements should be done at least 2 h after a meal.

5.2.2 Observer preparation

There is now general consensus that the fifth phase should be used, except in situations in which the disappearance of sounds cannot be reliably determined because sounds are audible even after complete deflation of the **cuff**, for example, in pregnant women, **patients** with arteriovenous fistulas (e.g., for hemodialysis), aortic insufficiency and in children between 3 y and 12 y of age. See Reference [25] (see also rationale to 5.1.3) and Reference [32]. In the past, there had been some question as to whether the fourth (K4) or fifth (K5) Korotkoff sound should be used to determine the **diastolic blood pressure**. The International Society for the Study of Hypertension in Pregnancy currently recommends using K5 for the determination of **diastolic blood pressure** in pregnancy. See References [23] and [32].

There is considerable disagreement on how to determine **blood pressure** in pregnant women. Several national and international groups (e.g., WHO) recommend use of Korotkoff phase IV (K4) as the determinant of **diastolic blood pressure**. However, K4 can overestimate intra-arterial pressure by 7 mmHg to 15 mmHg and appears to be more difficult to determine accurately. Furthermore, most health personnel in the US are trained to recognize Korotkoff phase V (K5) as the sound by which they determine **diastolic blood** pressure in non-pregnant populations. These considerations led the NHBPEP Working Group to recommend use of K5 in pregnancy, reserving K4 for the 10 % or fewer gravidas in whom there is a large discrepancy between muffling and disappearance (with the latter at times approaching zero). See References [23] and [32].

5.2.3 Reference determination

It was felt that if more than eight determinations are required to get valid readings then either the observers or the subjects were presenting particular problems.

5.2.4.1.1 Procedure

Since WHO recommendations [46] advise performing auscultatory **blood pressure** determinations at **cuff** deflation rates of 2 mmHg/s to 3 mmHg/s or 2 mmHg/pulse to 3 mmHg/pulse, the same arm simultaneous method can only be utilized for a **sphygmomanometer-under-test** performing a determination at these deflation rates on the upper arm.

The determination of the **reference diastolic blood pressure** is impossible for the observers if the **sphygmomanometer-under-test**, which controls the **cuff** pressure, opens the rapid exhaust valve too early, i.e. at a time when the observers are still hearing Korotkoff sounds and have not yet determined the **diastolic blood pressure**. To prevent this, the **sphygmomanometer-under-test** might need to be modified accordingly, e.g. by disabling the rapid exhaust valve of the **sphygmomanometer-under-test**.

The initial measurement by the observers and the **sphygmomanometer-under-test** that is not included in the data validation is required for two reasons:

— it permits the subject to become familiar with the procedure, thereby minimizing any effect on their **blood pressure**;

— it permits this measurement to be used to modify the maximum **cuff** inflation, either manually or automatically, to be near the subject's **systolic blood pressure**.

5.2.4.1.2 Data analysis

Criterion 1 is derived from the requirement originating in the early work of the AAMI Sphygmomanometer committee dating from 1987 [5]. A T-test of the difference between the two means (test-**reference**) was chosen to determine the sample size. The mean error of determination, $\bar{x}_n$, of $\pm$ 5 mmHg and standard deviation, s_n, of 8 mmHg, was chosen based on the review of literature comparing auscultatory to intra-arterial values. The sample size of 85 was then determined from statistics for a normal distribution. See

Reference [6]. A 98 % confidence interval ($\alpha = 0.02$) and a statistical power of 95 % ($\beta = 0.05$) yield a sample size of 85 subjects. Additionally, a sample size of 85 can be determined from the statistics for a t-distribution. A 95 % confidence interval ($\alpha = 0.05$) and a statistical power of 98 % ($\beta = 0.02$) yield a sample size of 85 subjects.

Originally, the mean error of determination was calculated from the average of the three test determinations and three **reference** determinations from each of the 85 subjects. See Reference [5]. Later, the calculation was changed to the individual test-**reference** differences for the 255 individual determination pairs. See Reference [4]. In making this change, the AAMI blood pressure committee concluded that the change provided a slighter, more stringent acceptance criterion, since the standard deviation is larger when the values are not averaged by subject.

Criterion 2 is derived from the requirement that originated in more recent work of the AAMI blood pressure committee dating from 2002 [3]. In making this change, the AAMI blood pressure committee developed an alternate method to analyze the data in response to the request from clinicians for a more stringent acceptance criterion. This statistical analysis was developed with the goal of limiting the error to $\pm$ 10 mmHg for 95 % of **patients** when the mean of three repeated measurements is used clinically.

Criterion 2 uses the average of the error of the determinations (test-**reference** pairs, per subject) to help reduce the apparent error introduced by changes in the subject's **blood pressure** during the sequence of **blood pressure** determinations. The value of 10 mmHg was chosen as a tolerable error based on clinician input.

The sample mean error of the determination, $\bar{x}_m$, and sample standard deviation of errors, s_m, refer to the mean and standard deviation of 85 numbers, each being the average of three errors of the determination on the same subject. These sample statistics are only estimates of the true mean error (also called bias) and of the true standard deviation of errors (also called precision), which can only be determined by testing the **sphygmomanometer-under-test** on an unlimited number of subjects.

A **sphygmomanometer-under-test** is considered acceptable if its estimated probability of a tolerable error is at least 85 %. This condition requires that the upper limit for an acceptable sample standard deviation depend on the sample mean error.

The calculated probability that the tolerable error of the **sphygmomanometer-under-test** is within the limit (10 mmHg) is an estimate of the true probability in the population. As the sample size in the study increases, the estimated probability approaches the true probability. A sample size of $n = 85$ yields a 90 % chance that the estimated probability of a tolerable error does not differ by more than about 0.07 from the 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 lies between 78 % and 92 %.

In this part of ISO 81060, a **sphygmomanometer-under-test** is required to meet both Criterion 1 and Criterion 2.

Comparison of Criterion 1 and Criterion 2.

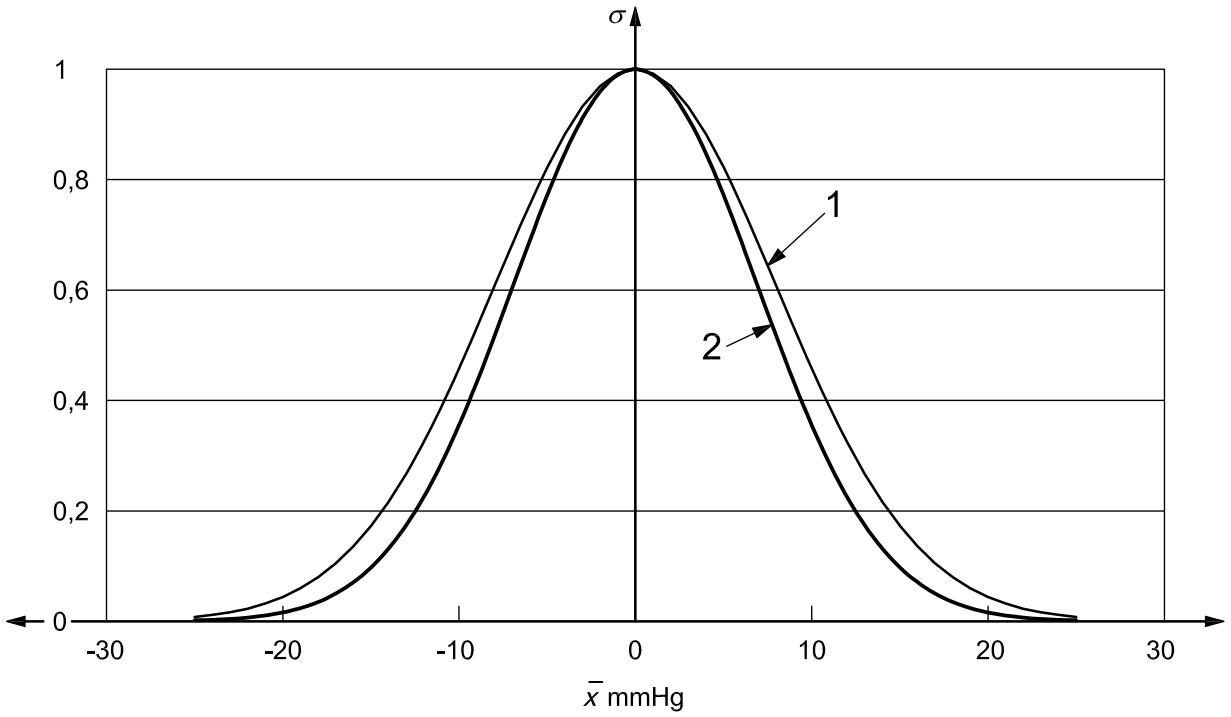
Criterion 1 uses the 255 individual test-**reference** differences to determine the performance of the **sphygmomanometer-under-test**. As a result, the calculated standard deviation, s_n, (or precision) will reflect both intra-subject and inter-subject variability. However, the allowable s_n is independent even when the mean error, $\bar{x}_n$, (or bias) is large.

Criterion 2 uses the average error from each subject, so the calculated s_m reflects only inter-subject variability, and a large intra-subject variability can still pass this method. Criterion 2 attempts to prevent that by reducing the allowable s_n as $\bar{x}_n$ increases, (s_n = 8.00 mmHg vs. s_m = 6.95 mmHg), thus addressing both bias and inter-subject precision.

Figure A.1 shows the allowable s for each criterion when $\bar{x}$ = 0.

The difference between the allowable standard deviations of the two methods is larger when $\bar{x}$ = 5 mmHg, as shown in Figure A.2. Criterion 1 requires an s_n ≤ 8.00 mmHg, while Criterion 2 requires an s_m ≤ 4.81 mmHg.

In summary, Criterion 1 evaluates the effect on both intra- and inter-subject variability, but allows for a relatively large error when the bias is large. Criterion 2 does not measure intra-subject variability, but reduces the allowable s_n over the range of allowable $\bar{x}_n$. The use of both criteria ensures that bias, intra- and inter-subject variability are evaluated when evaluating the **sphygmomanometer-under-test**.



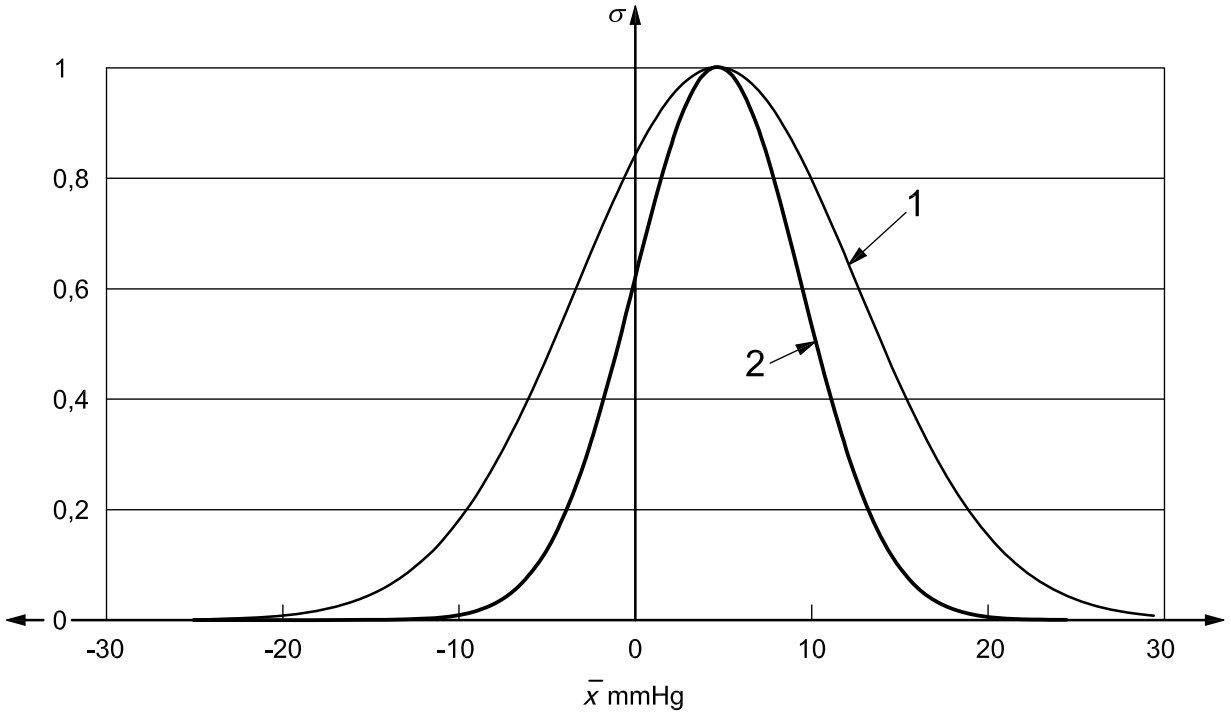
Key

1 criterion 1

2 criterion 2

NOTE The mean error of the determinations = 0.

Figure A.1 — Allowable standard deviation for each criterion when the mean error is zero



Key

1 criterion 1

2 criterion 2

NOTE The mean error of the determinations = 5 mmHg.

Figure A.2 — Allowable standard deviation for each criterion when the mean error is 5 mmHg

The statistical rationale for criterion 2 was developed based on the use of exactly three determinations per subject. While this ensures an equal contribution from each subject, it can create difficulties in completing the study, particularly in unstable hypertensive subjects.

One assumption of this method is that averaging the three values from each subject helps to reduce an apparent error caused by changes in the subject's **blood pressure** during the sequence of **blood pressure** determinations. This reduction in error is reduced if fewer determinations from each subject are used.

Relaxing the requirement for exactly three determinations per subject, but maintaining the requirement for 255 determinations, requires additional subjects to complete a study. The use of differing numbers of determinations per subject results in unequal contribution to the overall error. A compromise is to allow the use of fewer than three determinations per subject, but to require that at least 90 % of the subjects use exactly three determinations.

5.2.4.2 Same arm sequential method

Since the determinations are carried out in temporal succession, it is important that hemodynamically stable conditions exist during the testing period. The working group had some concern that this condition could be difficult to achieve in hypertensive **patients**. The use of smaller differences (4 mmHg and 6 mmHg) between consecutive determinations was also discussed, but there was concern that this would cause too many exclusions.

5.2.4.3.1 Procedure

The opposite arm simultaneous method is used when the **sphygmomanometer-under-test** operates in a manner that does not allow simultaneous determination of the auscultatory **reference** readings. This can be due to the use of a deflation rate by the **sphygmomanometer-under-test** that is outside the allowable range for a manual auscultatory determination, the use of a measurement method (e.g. determination on inflation) that does not support auscultation or the use of a measurement site that does not support auscultation (e.g. the wrist).

5.2.4.3.2 Data analysis

The advantage of the same arm sequential method (see 5.2.4.2) is that validation results are not as affected by lateral difference, LD, in **blood pressure**. However, in this method, **blood pressure** variability (BPV) is added to **sphygmomanometer-under-test** error and therefore the standard deviation of **sphygmomanometer-under-test** error could be overestimated. This hypothesis was experimentally supported by this committee's multiple-centre, independently-performed study based on 120 subjects, which showed significant positive correlation between **reference blood pressure** and intra-subject standard deviation of **sphygmomanometer-under-test** error.

Other standards, such as Reference [2], employ the opposite arm simultaneous method with lateral difference compensation based on three lateral difference measurements prior to, and another three lateral difference measurements after a series of **reference sphygmomanometer** to **sphygmomanometer-under-test** comparisons. However, via the same experiment by the committee, it was demonstrated that the lateral difference compensation in this method was not precise enough. The inaccuracy in the lateral difference compensation could at least be partially explained by long-time lags between lateral difference measurements and **reference sphygmomanometer** to **sphygmomanometer-under-test** comparisons.

The new opposite arm simultaneous method in this part of ISO 81060 was developed to overcome these shortcomings of the currently-used methods. Because it compares **reference sphygmomanometer** to **sphygmomanometer-under-test** determinations simultaneously, its results are largely immune to BPV. The accuracy of lateral difference compensation is improved by using **reference** determinations taken simultaneously with **sphygmomanometer-under-test** determinations, i.e., essentially no time lag between the lateral difference measurement and **reference sphygmomanometer** to **sphygmomanometer-under-test** comparison.

Additional advantages of this new method are:

— the experimental time needed per subject is considerably shorter in comparison with the conventional opposite arm simultaneous method (six vs. nine determinations except preparatory measurement);

— more paired comparison data are available (six vs. three points per subject).

Modification of the number of repetitions per subject could be attempted. However, the committee confirmed that the lateral difference compensation was not successful with only four repetitions. This might be because an insufficient number of **reference** determinations (only two per side) were used to estimate lateral difference. If the repetition was increased to eight, the accuracy of lateral difference might also be reduced because of prolonged time lag and resulting BPV between the first determination and the last determination. Thus, six repetitions seems to be more appropriate for this method.

5.2.5 Additional requirements for a sphygmomanometer intended for use in exercise stress testing environments

The additional clinical validation requirements for exercise stress testing were chosen to assess a **sphygmomanometer** during simulated activity and motion. Achieving a target heart rate of 50 % to 70 % of a subject's average maximum heart rate allows an exercise level that can be sustained for the duration of the assessment without subjecting the subject to undue medical risk. Furthermore, the exercise needed to cause such a heart rate should not result in a motion artifact so severe as to render the data unacceptable. See Reference [17].

6.1.2 Gender distribution

While there is no definitive evidence that a **sphygmomanometer** performs differently on male and female **patients**, some studies indicate that there might be a bias. See References [42] and [43]. If bias exists, it is likely caused by differences in arm circumference and body fat distribution. This part of ISO 81060 already requires that the **sphygmomanometer-under-test** be tested over a range of arm circumferences. The requirement for gender distribution allows for investigation of gender differences without being difficult to implement.

6.1.3 Age distribution

The age classifications of pediatric **patients** were chosen to be consistent with FDA guidance [6]. The FDA suggested transition from infant to child at 2 y of age has been adjusted to 3 y of age, consistent with Korotkoff sound physiology (see rationale to 5.1.3). Table A.1 shows the suggested FDA guidance pediatric subgroups.

Table A.1 — Suggested age ranges of pediatric subgroups from FDA guidance

Pediatric subgroup	Approximate age range
Newborn (neonate)	from birth to 1 month of age
Infant	> 1 month to 2 y of age
Child	> 2 y to 12 y of age
Adolescent	> 12 y to 21 y of age

6.1.4 Limb size distribution

This is a compromise between more detailed requirements for **cuff** sizes and the difficulty of conducting the test. For a **sphygmomanometer** with a single **cuff** size, it is important to test the full range of circumferences intended for use with the **cuff**.

6.1.5 Blood pressure distribution

These ranges were determined to ensure that the performance of the **sphygmomanometer** is evaluated over the entire clinically relevant **blood pressure** range.

6.2.1 Reference measurement

The intra-arterial pressure can be measured with a saline-filled catheter and external pressure transducer or with a catheter-tip transducer. A catheter-tip transducer is rarely used in clinical practice, but provides an improved dynamic response compared to catheter transducer systems.

The accurate determination of the intra-arterial **reference** requires the use a computerized data collection system or a multi-channel strip-chart recorder (DCS). The values displayed on the invasive **blood pressure** (IBP) channel of a **patient** monitoring system are subject to filtering and do not represent true beat-to-beat values. In addition, the recording of the intra-arterial waveform allows for the recognition of significant arrhythmias or artifacts, which distort the intra-arterial values.

The **sphygmomanometer-under-test** should be calibrated with the same manometer as the invasive transducer to avoid any error. All calibration records should be kept on a DCS. The static calibration of both the invasive and the **sphygmomanometer-under-test** should be within ± 2 mmHg of the **reference**.

The frequency response and damping coefficient pair should meet the dynamic requirements proposed by Gardner [18]. The use of short, stiff tubing and the removal of air bubbles from the catheter-transducer system will improve the frequency response characteristics. During the study, any deterioration in the waveform recorded by the intra-arterial catheter should be noted and appropriate corrective measures taken immediately (e.g., flushing or adjusting the position of the catheter).

The **blood pressure** transducer needs to be kept at the same level as the **blood pressure cuff** to avoid hydrostatic effects. A difference in vertical height of 1.3 cm between the pressure transducer and the **cuff** causes an offset error of 1 mmHg in measured pressure between the two readings. Both the **cuff** and transducer should be at the level of the heart (phlebostatic axis).

During each measurement by the **sphygmomanometer-under-test**, the DCS should be recording the intra-arterial pressures and the analogue signals from the **sphygmomanometer-under-test** (if these are available).

6.2.2 Arterial reference site

Some previous standards exclude the radial artery site due to concerns about differences between central and peripheral pressures because of pulse amplification and reflected wave effects. It is unlikely that radial **reference** data will have clinical validity for the diagnosis of hypertension, i.e., all morbidity/mortality data are based on brachial artery pressures, which are not equivalent to radial artery pressures. However, it is recognized that the more frequent use of radial artery catheters for invasive pressure measurement in the operating theatre and intensive care unit reduces the difficulty of obtaining **patients** for a study. See Reference [3].

The lateral difference, LD, measurement can be made using a previously validated **automated sphygmomanometer**. The LD should be determined by simultaneous determinations on both limbs (using two identical **automated sphygmomanometers**). However, LD can also be determined using a single **automated sphygmomanometer** and alternating the site of measurement between the two limbs.

The LD is calculated as the average difference between the determinations made on each limb using Equation (A.1).

$$LD = \frac{1}{3} \times \left(\sum_{i=1}^{3} P_i - \sum_{j=1}^{3} P_j \right) \quad \text{(A.1)}$$

where

i is the index for the determination on the limb used for the **sphygmomanometer-under-test** determination;

j is the index for the determination on the limb used for the **reference** determination.

The LD is determined for each subject and is used as indicated in Equations (10) and (11).

Clause 7 Pregnant, including pre-eclamptic, patient populations

Pregnancy is a fundamentally different hemodynamic state and therefore, there is the potential for **sphygmomanometers** to work differently. However, the clinical evidence is that most validation studies in non-pre-eclamptic pregnancies are equivalent to the adult validation (about 20 studies). Pre-eclampsia has altered hemodynamics (reduced intra-vascular volume, lowered cardiac output, increased interstitial oedema) and the evidence suggests a majority of **automated sphygmomanometers** underestimate the **blood pressure** in this **patient** population. See References [16], [19], [34], [35], [39] and [40]. Although pre-eclampsia only occurs in less than 5 % of an antenatal population, the onset of the hypertension associated with this condition is potentially dangerous. An emphasis on accuracy in this state is essential to ensure the safety of these **patients**.

To have sufficient statistical power to separate the two hypertensive subgroups within two standard deviations = 5 mmHg (the maximum permissible mean error) using Student's t distribution, a subgroup size of 15 is required.

Annex B
(normative)

Target heart rates for exercise stress testing

Table B.1 indicates the target heart rate range by age for exercise stress testing.

Table B.1 — Target heart rate table
See Reference [10]

Age y	**Target heart rate range for exercise validation** **50 % to 70 % of average maximum heart rate** beats/min	**Target heart rate range for exercise** **50 % to 85 % of average maximum heart rate** beats/min	**Average maximum heart rate** **100 %** beats/min
20	100 to 140	100 to 170	200
25	98 to 137	98 to 166	195
30	95 to 133	95 to 162	190
35	93 to 130	93 to 157	185
40	90 to 126	90 to 153	180
45	88 to 123	88 to 149	175
50	85 to 119	85 to 145	170
55	83 to 116	83 to 140	165
60	80 to 112	80 to 136	160
65	78 to 109	78 to 132	155
70	75 to 105	75 to 128	150

NOTE The target heart rate range for exercise validation shall be at least 110 % of the resting heart rate. Target heart rates may be lower for **patients** taking **blood pressure** medication that lowers the maximum heart rate.

The following is an example target heart rate determination and exercise heart rate determination (see 5.2.5).

The subject is 70 y of age. The subject's resting heart rate is 75 beats/min. The average maximum heart rate from Table B.1 is 150 beats/min. 110 % of 75 beats/min (the subject's resting heart rate) is 83 beats/min. During an exercise stress testing validation, maintain the subject's heart rate between 83 beats/min and 105 beats/min.

Annex C
(informative)

Reference to the essential principles

This part of ISO 81060 has been prepared to support the essential principles of safety and performance of electronically-controlled, intermittent, **non-invasive blood pressure measurement me equipment** as medical devices in accordance with ISO/TR 16142[1]. This part of ISO 81060 is intended to be acceptable for conformity assessment purposes.

Compliance with this part of ISO 81060 provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible.

Table C.1 — Correspondence between this document and the essential principles

Corresponding essential principle of ISO/TR 16142:2006, Table A.1, Clause A	Clause(s)/subclause(s) of this document	Qualifying remarks/Notes
1	All	
2	All	
3	All	
4	—	
5	—	
6	—	
7.1	—	
7.2	—	
7.3	—	
7.4	—	
7.5	—	
7.6	—	
8.1	—	
8.1.1	—	
8.1.2	—	
8.2	—	
8.3	—	
8.4	—	
8.5	—	
8.6	—	
9.1	5.1.4, 6.1.4	

Table C.1 (*continued*)

Corresponding essential principle of ISO/TR 16142:2006, Table A.1, Clause A	Clause(s)/subclause(s) of this document	Qualifying remarks/Notes
9.2	—	
9.3	—	
10.1	—	
10.2	—	
10.3	—	
11.1.1	—	
11.2.1	—	
11.2.2	—	
11.3	—	
11.4	—	
11.5.1	—	
11.5.2	—	
11.5.3	—	
12.1	—	
12.2	—	
12.3	—	
12.4	—	
12.5	—	
12.6	—	
12.7.1	—	
12.7.2	—	
12.7.3	—	
12.7.4	—	
12.7.5	—	
12.8.1	—	
12.8.2	—	
12.8.3	—	
13.1	5.1.6, 5.2.2, 6.2.1, 6.2.2, 6.2.7, 7	
14.1	All	

Annex D
(informative)

Terminology — Alphabetized index of defined terms

accessory ..... 3.3 of IEC 60601-1:2005
accompanying document ..... 3.4 of IEC 60601-1:2005
automated sphygmomanometer ..... 201.3.202 of IEC 80601-2-30:2009
blood pressure ..... 201.3.203 of IEC 80601-2-30:2009
clinical investigation report ..... 2.8 of ISO 14155:— [2)]
cuff ..... 201.3.204 of IEC 80601-2-30:2009
diastolic blood pressure .....201.3.205 of IEC 80601-2-30:2009
home healthcare environment .....3.2 of IEC 60601-1-11:— [2)]
intended use ..... 3.44 of IEC 60601-1:2005
invasive blood pressure monitoring equipment ..... 3.3 of IEC 60601-2-34:2000
manufacturer ..... 3.55 of IEC 60601-1:2005
mean blood pressure ..... 201.3.207 of IEC 80601-2-30:2009
medical electrical equipment (me equipment) ..... 3.63 of IEC 60601-1:2005
model or type reference ..... 3.66 of IEC 60601-1:2005
non-automated sphygmomanometer ..... 201.3.209 of IEC 80601-2-30:2009
non-invasive blood pressure measurement ..... 201.3.210 of IEC 80601-2-30:2009
objective evidence ..... 3.72 of IEC 60601-1:2005
reference 3.1
sphygmomanometer 3.2
sphygmomanometer-under-test 3.3
systolic blood pressure ..... 201.3.216 of IEC 80601-2-30:2009
type test ..... 3.135 of IEC 60601-1:2005

2) To be published.

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[4] ANSI/AAMI SP10:1992, *Electronic or Automated Sphygmomanometers*

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3) Available at: http://www.fda.gov/cdrh/mdufma/guidance/1220.pdf

4) Available at: http://www.paritaet.org/rr-liga/prufsige.htm

5) Available at: http://www.americanheart.org/presenter.jhtml?identifier=4736

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American National Standard

ANSI/AAMI/IEC 80601-2-30:2009
(Identical to the corrected version of
IEC 80601-2-30:2009)

Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

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of Medical Instrumentation

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*.

American National Standard

ANSI/AAMI/IEC 80601-2-30:2009
and ANSI/AAMI/IEC 80601-2-30:2009/C1:2009
(Consolidated Text)

Medical Electrical Equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Approved 18 June 2009 by
Association for the Advancement of Medical Instrumentation

Approved 24 July 2009
Amendment C1 approved 10 December 2009 by
American National Standards Institute, Inc.

Abstract: This standard applies to the basic safety and essential performance of automated sphygmomanometers, which by means of an inflatable cuff, are used for intermittent indirect measurement of the blood pressure without arterial pressure. .

Keywords: automated sphygmomanometer, blood pressure, non-automated sphygmomanometer, non-invasive blood pressure measurement

AAMI Standard

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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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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

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 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 and 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009	ANSI/AAMI/IEC 80601-2-30:2009	Identical (with inclusion)
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Sphygmomanometer Committee

This standard was adopted with minor U.S. inclusion by the Sphygmomanometer Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of this document does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **Sphygmomanometer Committee** had the following members.

Cochairs:
Bruce Stephen Alpert, MD
Bruce A. Friedman

Members:
Bruce Stephen Alpert, MD, University of Tennessee at Memphis College of Graduate Health Sciences
Jim Brown, Colder Products Company
Richard A. Dart, MD, Marshfield Clinic Department of Clinical Research
Donald J. Fournier, Draeger Medical
Gerhard Frick, Microlife Services AG
Bruce A. Friedman, GE Healthcare
David Gallick, Sun Tech Medical
Jeff Gilham, Spacelabs Medical Inc.
John W. Graves, MD, Mayo Medical School - Mayo Clinic Division of Nephrology & Hypertension
Clarence E. Grim, MS, MD, Medical College of Wisconsin
Charles S. Ho, Ph.D, FDA/CDRH
Jiri Jilek, Independent Expert
Charles C. Monroe, Philips Medical Systems
Bruce Z. Morgenstern, MD, Mayo Clinic
Ronald Portman, MD, University of Texas Health Science Center at Houston
L. Michael Prisant, MD, FACC, FACP, Medical College of Georgia
David Quinn, Welch Allyn Inc.
Osamu Shirasaki, Omron Healthcare Co Ltd
Robert Smith, MD, Clinical Dynamics Corporation
Leonard Steinfeld, MD, Mount Sinai Medical Center
William B. White, MD, University of Connecticut School of Medicine

Alternates:
Greg Downs, Spacelabs Medical Inc.
Iwao Kojima, Omron Healthcare Co Ltd
David Osborn, Philips Medical Systems
John Seller, Welch Allyn Inc.
Charles B. Setzer, Sun Tech Medical
Andrea D. Stebor, PhD, GE Healthcare

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 AAMI adoption of IEC 80601-2-30:2009

This standard was developed by the International Organization for Standardization (ISO)/TC 121/SC3 and International Electrotechnical Commission (IEC)/SC 62D Joint Working Group 7 on Non-Invasive Blood Pressure Monitoring Equipment and has been adopted by the AAMI Sphygmomanometer Committee, with one minor U.S. inclusion. The objective of this standard is to provide the basic safety and essential performance requirements of automated sphygmomanometers which are used for the non-invasive blood pressure measurement.

This is a new American National Standard. During the course of this international standard undergoing U.S. review, the U.S. Technical Advisory sub-Group (sub-TAG) for the ISO and IEC Joint Working Group (JWG) 7 (AAMI Sphygmonomameter Committee) decided to adopt this then proposed international standard as an American National Standard. During the national balloting process, the committee decided to include one minor U.S. inclusion in Annex A, subclause 201.15.3.102, which does not change any technical content of ISO/IEC 80601-2-30:2009, but provides clarification of the section. Serving as the U.S. sub-TAG for the ISO/IEC JWG, the AAMI Sphygmomanometer Committee was responsible for developing U.S. consensus on the international standard and otherwise participated in the drafting of that document.

This text incorporates technical changes issued by IEC in 2009 as a Technical Corrigendum. Approved in the US as an amendment, ANSI/AAMI/IEC 80601-2-30:2009/C1:2009. Changes appear on pages 15, 22, and 26.

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.

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 comes 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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This background does not contain provisions of the American National Standard, *Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers* (ANSI/AAMI 80601-2-30:200x), but it does provide important information about the development and intended use of the document.

NOTE—Beginning with the IEC foreword on page x, this American National Standard is identical to IEC 80601-2-30:2009, with the exception of the minor inclusion in section 201.15.3.102* and subclause 201.15.3.102 of Annex A.

AAMI inclusion to IEC 80601-2-30:2009

201.15.3.102* Shock and vibration for transport

Add the following:

Note: See last paragraph of the Annex AA, Subclause 201.15.3.102 for U.S. inclusion.

Annex AA

Subclause 201.15.3.102 Shock and vibration for transport

Add at the end of section, the following paragraph**:**

Note: Since clause 201.15.3.102 of this standard requires functional testing before and after vibrations, but not during vibrations, the U.S. believes that there is no proof that the device can indeed perform within specifications during vibrations, such as enabling the user to accurately measure the blood pressure of a patient who is being transported in a moving ambulance. Thus, this standard cannot be used in the U.S. to substantiate a claim of functionality within the manufacturer's specifications during transport.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
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6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 80601-2-30 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electrical equipment, of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anesthetic and respiratory equipment.

This first edition of IEC 80601-2-30 cancels and replaces the second edition of IEC 60601-2-30, published in 1999. This edition constitutes a major technical revision as well as an alignment with the third edition of IEC 60601-1. Specific technical changes include: expansion of the scope to include all AUTOMATED SPHYGMOMANOMETERS including those where the PATIENT is the OPERATOR, identification of ESSENTIAL PERFORMANCE, new clinical accuracy requirements, additional mechanical strength requirements and prohibition of OPERATOR accessible 'Luer' connectors in the PNEUMATIC SYSTEM.

This publication is published as a double logo standard.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/721/FDIS	62D/737/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 13 P-members out of 17 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this particular standard will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

NOTE The attention of 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 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 the committee that the content of this publication be adopted for implementation nationally not 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.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of an AUTOMATED SPHYGMOMANOMETER.

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of AUTOMATED SPHYGMOMANOMETERS, hereafter referred to as ME EQUIPMENT, which by means of an inflatable CUFF, are used for intermittent indirect measurement of the BLOOD PRESSURE without arterial puncture.

NOTE 1 Equipment that performs indirect measurement of the BLOOD PRESSURE without arterial puncture does not directly measure the BLOOD PRESSURE. It only estimates the BLOOD PRESSURE.

This standard specifies requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE for this ME EQUIPMENT and its ACCESSORIES, including the requirements for the accuracy of a DETERMINATION.

This standard covers electrically-powered intermittent, indirect measurement of the BLOOD PRESSURE without arterial puncture, ME EQUIPMENT with automatic methods for estimating BLOOD PRESSURE, including BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT.

Requirements for indirect measurement of the BLOOD PRESSURE without arterial puncture ME EQUIPMENT with an electrically-powered PRESSURE TRANSDUCER and/or displays used in conjunction with a stethoscope or other manual methods for determining BLOOD PRESSURE (NON-AUTOMATED SPHYGMOMANOMETERS) are specified in document ISO 81060-1.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 201.11 and 201.105.3.3, as well as 7.2.13 and 8.4.1 of IEC 60601-1.

NOTE 2 See also 4.2 of the general standard.

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1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for an AUTOMATED SPHYGMOMANOMETER as defined in 201.3.201.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1 and Clause 2 of this particular standard.

IEC 60601-1-2 is amended by this particular standard. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and its collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 47.

Clause 2 of the general standard applies, except as follows:

Amendment of the following reference:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broad-band random and guidance*

IEC 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*

ISO 594-2:1991, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

ISO 81060-2:2009[2)], *Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type*

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2) To be published.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-8:2006, and IEC 60601-2-2:2009 apply, except as follows:

NOTE An index of defined terms is found beginning on page 49.

Addition:

201.3.201
AUTOMATED SPHYGMOMANOMETER
ME EQUIPMENT used for the non-invasive estimation of the BLOOD PRESSURE by utilizing an inflatable CUFF, a PRESSURE TRANSDUCER, a valve for deflation, and/or displays used in conjunction with automatic methods for determining BLOOD PRESSURE

NOTE Components of an AUTOMATED SPHYGMOMANOMETER include manometer, CUFF, valve for deflation (often in combination with the valve for rapidly exhausting the PNEUMATIC SYSTEM), pump for inflation of the BLADDER, and connection tubing.

201.3.202
BLADDER
part of the CUFF that is inflatable

[ISO 81060-1:2007, definition 3.2]

201.3.203
BLOOD PRESSURE
pressure in the systemic arterial system of the body

[ISO 81060-1:2007, definition 3.3]

201.3.204
CUFF
part of the AUTOMATED SPHYGMOMANOMETER that is wrapped around the limb of the PATIENT

NOTE A CUFF usually comprises a BLADDER and an inelastic part that encloses the BLADDER, or has an integral BLADDER (i.e., the CUFF, including the BLADDER, is one piece).

[ISO 81060-1:2007, definition 3.5, modified]

201.3.205
DETERMINATION (value)
result of the process of estimating BLOOD PRESSURE by the AUTOMATED SPHYGMOMANOMETER

201.3.206
DIASTOLIC BLOOD PRESSURE (value)
minimum value of the BLOOD PRESSURE as a result of relaxation of the systemic ventricle

NOTE Because of hydrostatic effects, this value should be determined with the CUFF at the level of the heart.

201.3.207

HOME HEALTHCARE ENVIRONMENT

dwelling place in which a patient lives or other environments that patients can occupy, excluding professional healthcare facility environments where operators with medical training are continually available when patients are present

NOTE 1 Professional healthcare facilities include hospitals, physician offices, freestanding surgical centers, dental offices, freestanding birthing centers, limited care facilities, multiple treatment facilities and ambulance services.

NOTE 2 In some countries, nursing homes are considered professional healthcare facilities.

NOTE 3 The home healthcare environment includes use in the outdoor environment and in personal automobiles.

[IEC 60601-1-11___[3)], definition 3.2]

201.3.208

LONG-TERM AUTOMATIC MODE

mode in which a timer, set by the OPERATOR, initiates multiple DETERMINATIONS

201.3.209

MEAN ARTERIAL PRESSURE (value)

value of the integral of one heartbeat cycle of the BLOOD PRESSURE curve divided by the time of that cycle

NOTE Because of hydrostatic effects, this value should be determined with the CUFF at the level of the heart.

201.3.210

NEONATAL MODE

mode of AUTOMATED SPHYGMOMANOMETER for use with neonates or infants

NOTE 1 The approximate age range for a newborn (neonate) is from birth to 1 month. [10][4]

NOTE 2 The approximate age range for an infant is from 1 month to 2 years. [10] For the purposes of this standard, up to 3 years of age are considered infants (see ISO 81060-2, 6.1.3).

NOTE 3 The NEONATAL MODE is used to limit the maximum pressure to 150 mmHg and frequently has a different algorithm from other modes intended for older PATIENTS.

201.3.211

NON-AUTOMATED SPHYGMOMANOMETER

ME EQUIPMENT used for the non-invasive measurement of the BLOOD PRESSURE by utilizing an inflatable CUFF with a pressure-sensing element, a valve for deflation, and display used in conjunction with a stethoscope or other manual methods for estimating BLOOD PRESSURE

NOTE Components of these instruments include manometer, CUFF, valve for deflation (often in combination with the valve for rapidly exhausting the PNEUMATIC SYSTEM), hand pump or electro-mechanical pump for inflation of the BLADDER, and connection tubing. A NON-AUTOMATED SPHYGMOMANOMETER can also contain electro-mechanical components for pressure control.

[ISO 81060-1:2007, definition 3.11, modified]

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3 IEC 60601-1-11___, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* (in preparation).

4) Figures in square brackets refer to the Bibliography.

201.3.212
PATIENT SIMULATOR
equipment for simulating the oscillometric CUFF pulses and/or auscultatory signals during inflation and deflation

NOTE This equipment is not used for testing accuracy but is used in assessing stability of performance.

201.3.213
PNEUMATIC SYSTEM
part of the AUTOMATED SPHYGMOMANOMETER that includes all pressurized and pressure-controlling components

EXAMPLES CUFF, tubing, connectors, valves, PRESSURE TRANSDUCER and pump.

[ISO 81060-1:2007, definition 3.16, modified]

201.3.214
PRESSURE TRANSDUCER
component that transforms sensed pressure into an electrical signal

201.3.215
PROTECTION DEVICE
part of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

201.3.216
SELF-MEASUREMENT AUTOMATIC MODE
mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated by the OPERATOR and in which a limited number of DETERMINATIONS are made

201.3.217
*** SHORT-TERM AUTOMATIC MODE**
mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated by the OPERATOR and in which repetitive automatic DETERMINATIONS are made rapidly within a specified time period

201.3.218
SYSTOLIC BLOOD PRESSURE (value)
maximum value of the BLOOD PRESSURE as a result of the contraction of the systemic ventricle

NOTE Because of hydrostatic effects, this value should be determined with the CUFF at the level of the heart.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 Essential performance

Additional subclause:

201.4.3.101 Additional essential performance requirements

Additional ESSENTIAL PERFORMANCE requirements for an AUTOMATED SPHYGMOMANOMETER are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Electrosurgery interference recovery	202.6.2.101
Limits of the error of the manometer, or generation of a TECHNICAL ALARM CONDITION	201.12.1.102 201.11.8.102 201.12.1.101
Limits of the change in the error of the BLOOD PRESSURE DETERMINATION and low and high BLOOD PRESSURE PHYSIOLOGICAL ALARM CONDITIONS (if provided), or generation of a TECHNICAL ALARM CONDITION	201.12.1.107 201.12.3.101 201.11.8.102 201.12.1.101

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.4 * Accessories

Addition:

A CUFF shall be marked with an indication of the correct positioning for the CUFF on the designated limb over the artery.

Additional subclauses:

201.7.2.101 Display of automated sphygmomanometers

If abbreviations are used on the display they shall be as follows:

– “S“ or “SYS” for the value of SYSTOLIC BLOOD PRESSURE;
– “D“ or “DIA“ for the value of DIASTOLIC BLOOD PRESSURE;
– “M” or “MAP“ for the value of MEAN ARTERIAL PRESSURE.

Single letter abbreviations shall be positioned in such a way as to avoid confusion with SI-Units.

The numerical step of BLOOD PRESSURE readings shall be 1 mmHg or 0.1 kPa.

201.7.2.102 automated sphygmomanometers for home healthcare environment

If the AUTOMATED SPHYGMOMANOMETER is intended for use in the HOME HEALTHCARE ENVIRONMENT, the sales packaging shall display information needed by the end user including, as a minimum:

– identification of the appropriate arm circumference;

– the operating and storage temperature and humidity ranges;

– any special requirements for a battery-powered AUTOMATED SPHYGMOMANOMETER.

201.7.2.103 * automated sphygmomanometers with neonatal mode

If an AUTOMATED SPHYGMOMANOMETER is intended for use with neonatal PATIENTS and other PATIENTS, it should have means for detecting that a CUFF intended for use with a neonatal PATIENT is connected to the AUTOMATED SPHYGMOMANOMETER and means for automatically placing the AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE when such a CUFF is present. If these means are not present, the instructions for use shall describe the method for placing the AUTOMATED SPHYGMOMANOMETER into NEONATAL MODE and include a warning statement describing the RISKS associated with using other than the NEONATAL MODE on a neonatal PATIENT.

All ACCESSORIES intended for use only in the NEONATAL MODE and where the use in other modes results in an unacceptable RISK shall be marked for neonatal use only.

201.7.2.104 * automated sphygmomanometers for public use

If the AUTOMATED SPHYGMOMANOMETER is intended for self-use in public areas, it shall be marked with the following:

– precautions for use, including a statement concerning the need to consult a physician for interpretation of BLOOD PRESSURE measurements;

– adequate operating instructions;

– this sphygmomanometer complies with IEC 80601-2-30.

EXAMPLE Self-measurement station in a pharmacy, fitness centre, workplace.

201.7.2.105 * Component replacement

If a component can be replaced by the OPERATOR or SERVICE PERSONNEL, and if replacement could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the AUTOMATED SPHYGMOMANOMETER, the AUTOMATED SPHYGMOMANOMETER or the component shall be marked with either a caution to the effect that substitution of a component different from that supplied might result in measurement error or with a safety sign ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, safety sign 10).

EXAMPLES CUFF, microphone, connection tube, external power supply

201.7.2.106 Disposal

The AUTOMATED SPHYGMOMANOMETER and its parts shall be marked with regard to disposal, as appropriate, in accordance with national or regional regulations.

NOTE See also IEC 60601-1-9[5)].

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5) IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design*

201.7.9.2 Instructions for use

201.7.9.2.1 General

Replacement of the three dashed items:

– the use of the AUTOMATED SPHYGMOMANOMETER as intended by the MANUFACTURER; and in particular

1) intended medical indication;

EXAMPLE 1 Condition(s) or disease(s) to be screened for, monitored, treated, diagnosed, or prevented

2) any known restrictions on use or contraindication(s) to the use of the AUTOMATED SPHYGMOMANOMETER;

EXAMPLE 2 AUTOMATED SPHYGMOMANOMETER for use in an ambulance or helicopter, for use in the HOME HEALTHCARE ENVIRONMENT, for use with neonatal or pre-eclamptic PATIENTS.

3) intended PATIENT population, including whether or not the AUTOMATED SPHYGMOMANOMETER is intended:

– for use with neonatal PATIENTS,

– for use with pregnant, including pre-eclamptic, PATIENTS;

EXAMPLE 3 Age, weight, region of body, health, condition or diagnosis

4) intended placement of the CUFF;

5) intended conditions of use

EXAMPLE 4 Environment including hygienic requirements, frequency of use, location, mobility.

– the frequently used functions;

– the permissible environmental conditions of use, including at least a temperature range of 10 °C to 40 °C with a relative humidity range of 15 % to 85 % (non-condensing).

201.7.9.2.2 Warning and safety notices

Addition, following the note:

The instructions for use shall include a warning:

– regarding the effect of blood flow interference and resulting harmful injury to the PATIENT caused by continuous CUFF pressure due to connection tubing kinking;

– indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference;

– regarding the application of the CUFF over a wound, as this can cause further injury;

– regarding the application of the CUFF and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury to the PATIENT;

– regarding the application of the CUFF and its pressurization on the arm on the side of a mastectomy;

– regarding the information that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb;

– regarding the need to check (for example, by observation of the limb concerned) that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the PATIENT.

201.7.9.2.5 Me equipment description

Addition, after the third dashed item in the first paragraph:

– a description of the operating principles of the AUTOMATED SPHYGMOMANOMETER;

– RATED ranges of the DETERMINATION.

201.7.9.2.9 Operating instructions

Addition:

The instructions for use shall contain the following information:

a) an explanation of the selection of a suitably sized CUFF and the application of the CUFF to the PATIENT;

b) an explanation of the operating steps needed to obtain accurate routine resting BLOOD PRESSURE measurements for the condition hypertension [20] including;

   – adjustment of the pressure reduction rate, if applicable,

   – PATIENT position in NORMAL USE, including

      1) comfortably seated

      2) legs uncrossed

      3) feet flat on the floor

      4) back and arm supported

      5) middle of the CUFF at the level of the right atrium of the heart

   – a recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE,

   – a recommendation that 5 min should elapse before the first reading is taken;

   – OPERATOR position in NORMAL USE,

c) an explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT (standing, sitting, lying down), exercise, or the PATIENT'S physiologic condition;

d) details of what the OPERATOR should do if unexpected readings are obtained;

e) details of the environmental or operational factors which can affect the performance of the AUTOMATED SPHYGMOMANOMETER and/or its BLOOD PRESSURE reading (e.g. common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, PATIENT motion, trembling, shivering);

f) a statement, if applicable, that the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude;

g) if applicable, an explanation of the need to avoid compression or restriction of the connection tubing.

h) the RATED range of CUFF pressure.

201.7.9.2.13 Maintenance

Addition, after the second paragraph:

If the AUTOMATED SPHYGMOMANOMETER is intended to be dismantled by the OPERATOR, the instructions for use shall indicate the correct method of reassembly.

NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa).

If the BLADDER can be incorrectly inserted into the inelastic part of the CUFF (e.g. after cleaning), the CUFF or the instructions for use shall include a detailed description of the correct manner of insertion of the BLADDER into the inelastic part of the CUFF.

Additional subclauses:

201.7.9.2.101 Compatibility with hf surgical equipment

If the AUTOMATED SPHYGMOMANOMETER complies with the requirements of 202.6.2.101, the instructions for use shall include a statement to the effect that this ME EQUIPMENT is suitable for use in the presence of electrosurgery.

If parts of the PRESSURE TRANSDUCER or AUTOMATED SPHYGMOMANOMETER are provided with protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT, such means shall be drawn to the attention of the OPERATOR in the instructions for use. If such means are absent, such parts shall be identified in the instructions for use.

201.7.9.2.102 automated sphygmomanometers for use in neonatal mode

If the AUTOMATED SPHYGMOMANOMETER is equipped with a NEONATAL MODE, the instructions for use shall include:

– the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in NEONATAL MODE;
– the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER can accommodate when in the NEONATAL MODE;
– the ACCESSORIES that the MANUFACTURER recommends for use in NEONATAL MODE to avoid errors and excessive pressure.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.5.5 Defibrillation-proof applied parts

Additional subclause:

201.8.5.5.101 * Patient connections of automated sphygmomanometer

If the APPLIED PART of an AUTOMATED SPHYGMOMANOMETER has PATIENT CONNECTIONS, it shall be classified as a DEFIBRILLATION-PROOF APPLIED PART.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Replacement:

ENCLOSURES of an AUTOMATED SPHYGMOMANOMETER, intended for use during PATIENT transport outside a healthcare facility, shall be designed to give an IPX2 degree of protection against harmful ingress of water or particulate matter and shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE following the tests in IEC 60529:1989 for IPX2.

Compliance is checked by application of the tests of IEC 60529:1989 with the AUTOMATED SPHYGMOMANOMETER in the least favorable position of NORMAL USE and by inspection and functional testing.

After these PROCEDURES, ensure that the ME EQUIPMENT shows no signs of bridging of insulation (or electrical components) that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests. Ensure that ESSENTIAL PERFORMANCE is maintained.

201.11.8 Interruption of the power supply/supply mains to ME EQUIPMENT

Addition:

201.11.8.101 * Switching off

When the AUTOMATED SPHYGMOMANOMETER is switched off by the OPERATOR, with the CUFF inflated, the CUFF shall deflate within 30 s to the values indicated in Table 201.102.

Table 201.102 – CUFF deflation pressure

Mode	CUFF pressure
NEONATAL MODE	≤ 5 mmHg (0.7 kPa)
Any other mode	≤ 15 mmHg (2.0 kPa)

Compliance is checked by functional testing.

201.11.8.102 SUPPLY MAINS

When SUPPLY MAINS to the AUTOMATED SPHYGMOMANOMETER is interrupted, the CUFF shall deflate within 30 s to the values indicated in Table 201.102 and any indication of BLOOD PRESSURE shall be cancelled.

When SUPPLY MAINS is restored the AUTOMATED SPHYGMOMANOMETER shall:

a) continue in the same mode of operation and with all OPERATOR settings unchanged, or

b) remain inoperative and, if equipped with SHORT-TERM AUTOMATIC MODE or LONG-TERM AUTOMATIC MODE, be equipped with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION that indicates the AUTOMATED SPHYGMOMANOMETER is inoperative.

An AUTOMATED SPHYGMOMANOMETER that automatically switches over to operation from an INTERNAL ELECTRICAL POWER SOURCE and continues to operate normally shall be exempt from these requirements.

Compliance is checked with the following test.

Make a DETERMINATION utilizing a PATIENT SIMULATOR and observe the AUTOMATED SPHYGMOMANOMETER operating mode. Interrupt the SUPPLY MAINS for a period exceeding 30 s.

Determine whether the CUFF is sufficiently deflated and that the indicated BLOOD PRESSURE disappears within 30 s.

Restore the SUPPLY MAINS and determine either that the AUTOMATED SPHYGMOMANOMETER continues in the same mode of operation and with all OPERATOR settings unchanged, or that a TECHNICAL ALARM CONDITION is generated.

201.11.8.103 * Internal electrical power source

An AUTOMATED SPHYGMOMANOMETER powered from an INTERNAL ELECTRICAL POWER SOURCE shall incorporate means:

– in case of INTERNAL ELECTRICAL POWER SOURCE failure or depletion, which does not allow the AUTOMATED SPHYGMOMANOMETER to meet the BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of this standard
  1) for protective shutdown, and
  2) for canceling the indicated BLOOD PRESSURE;
– of determining the state of the power supply.

Compliance is checked by functional testing.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

Replacement:

201.12.1 Accuracy of controls and instruments

201.12.1.101 Measuring and display ranges

The measuring and display ranges of the CUFF pressure shall be equal to the RATED range for CUFF pressure.

Values of BLOOD PRESSURE outside the RATED range for BLOOD PRESSURE shall not be displayed and the AUTOMATED SPHYGMOMANOMETER shall be equipped with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION that indicates when the determined BLOOD PRESSURE is outside the RATED range.

Compliance is checked by functional testing.

201.12.1.102 Limits of the error of the manometer from environmental conditions

Over the temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing), the maximum error for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to ± 3 mmHg (± 0.4 kPa) or 2 % of the reading, whichever is greater.

Compliance is checked by functional testing.

201.12.1.103 * Nominal blood pressure indication range

The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating DIASTOLIC BLOOD PRESSURE over at least the range of 20 mmHg (2.7 kPa) to 60 mmHg (8.0 kPa) in NEONATAL MODE and 40 mmHg (5.3 kPa) to 130 mmHg (17.3 kPa) otherwise.

The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating SYSTOLIC BLOOD PRESSURE over at least the range of 40 mmHg (5.3 kPa) to 110 mmHg (14.7 kPa) in NEONATAL MODE and 60 mmHg (8.0 kPa) to 230 mmHg (30.7 kPa) otherwise.

Compliance is checked with the following test:

Connect the AUTOMATED SPHYGMOMANOMETER to a PATIENT SIMULATOR.

Adjust the PATIENT SIMULATOR to generate signals in such a way that the AUTOMATED SPHYGMOMANOMETER displays DIASTOLIC BLOOD PRESSURE values of 20 mmHg (2.7 kPa) or less and SYSTOLIC BLOOD PRESSURE values of 110 mmHg (14.7 kPa) or more in NEONATAL MODE and DIASTOLIC BLOOD PRESSURE values of 60 mmHg (8.0 kPa) or less and SYSTOLIC BLOOD PRESSURE values of 230 mmHg (30.7 kPa) or more otherwise.

201.12.1.104 Maximum pressure in normal condition

The maximum pressure obtainable in NORMAL CONDITION shall not exceed 150 mmHg (20 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE and not exceed 300 mmHg (40 kPa) otherwise. An AUTOMATED SPHYGMOMANOMETER may have one, or more than one, mode.

Compliance is checked by functional testing in NORMAL CONDITION.

201.12.1.105 * Maximum pressure in single fault condition

A PROTECTION DEVICE shall be provided, functioning independently of the normal PNEUMATIC SYSTEM control, which in any SINGLE FAULT CONDITION, shall:

- prevent the pressure in the PNEUMATIC SYSTEM from exceeding the maximum RATED value specified in 201.12.1.104 by more than + 10 % for more than 3 s (see Figure 201.101); and
- activate if the pressure in the PNEUMATIC SYSTEM exceeds the maximum RATED value specified in 201.12.1.104 for 15 s (see Figure 201.102).

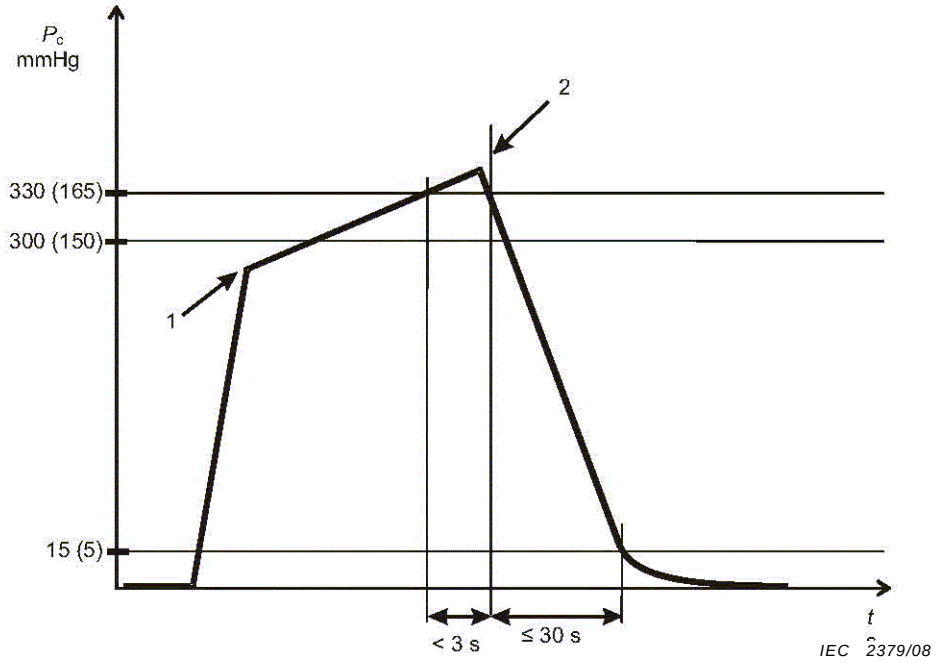
When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s to ≤ 15 mmHg (2.0 kPa) and to ≤ 5 mmHg (0.7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE.

An AUTOMATED SPHYGMOMANOMETER that only operates in the SELF-MEASUREMENT AUTOMATIC MODE, where the PATIENT is the OPERATOR or the OPERATOR is intended to be in continual attendance, and where the pressure can be released from the CUFF by the OPERATOR is exempt from this requirement.

EXAMPLE 1 Pressure released by disconnecting the CUFF from the AUTOMATED SPHYGMOMANOMETER.

EXAMPLE 2 Pressure released by removing the CUFF from the limb.

Compliance is checked by functional testing in SINGLE FAULT CONDITION.



Key

1 SINGLE FAULT CONDITION occurs

2 PROTECTION DEVICE activates due to overpressure

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.101 – CUFF pressure PROTECTION DEVICE, triggered by overpressure in SINGLE FAULT CONDITION

This figure was added as part of the Amendment and replaced the original figure.

201.12.1.106 * Manometer test mode

The AUTOMATED SPHYGMOMANOMETER shall have a manometer test mode that permits static pressure measurement over at least the NOMINAL BLOOD PRESSURE indication range (see

201.12.1.103). This mode shall not be available in NORMAL USE, but restricted to SERVICE PERSONNEL.

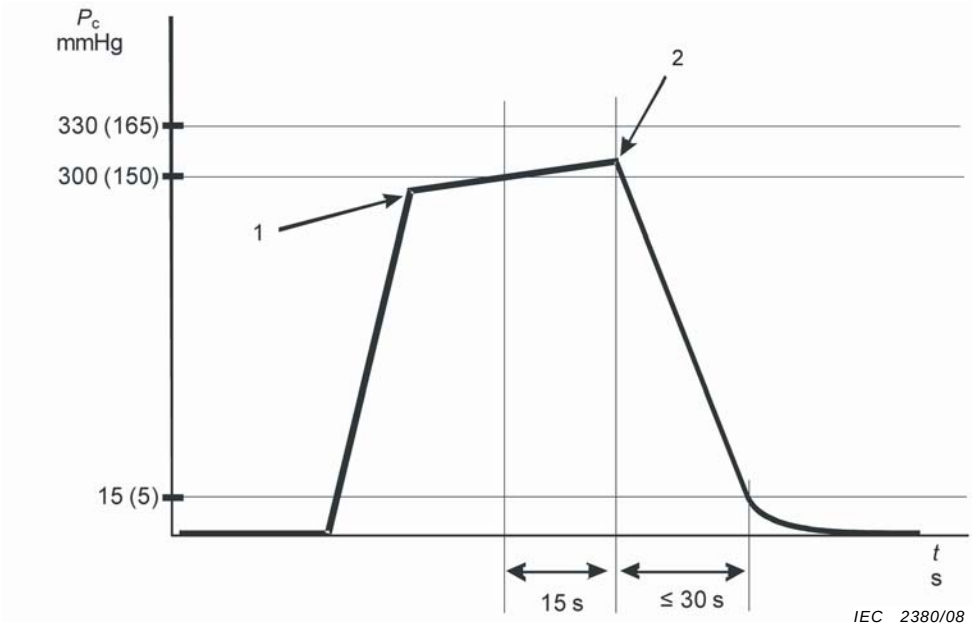
EXAMPLE 1 A port for connection to a pressure source so that the pressure can be measured by the AUTOMATED SPHYGMOMANOMETER in a test mode.

EXAMPLE 2 A port for connection to a reference manometer that can be pressurized by the AUTOMATED SPHYGMOMANOMETER in a test mode.

NOTE This mode can be used to verify manometer pressure accuracy.

The technical description shall include a test method that can be used to verify the calibration of the AUTOMATED SPHYGMOMANOMETER.

Compliance is checked by inspection and functional testing.



Key

1 SINGLE FAULT CONDITION occurs

2 PROTECTION DEVICE activates due to prolonged overpressure

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.102 – CUFF pressure PROTECTION DEVICE, triggered by prolonged overpressure in SINGLE FAULT CONDITION

201.12.1.107 Limits of the change in error of the blood pressure determination

The laboratory limits of the change in error of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER shall be less than 3 mmHg (0.4 kPa).

Compliance is checked with the following test:

a) Prior to performing the other tests of this standard, adjust the PATIENT SIMULATOR to generate signals in such a way that the AUTOMATED SPHYGMOMANOMETER displays approximately a

DIASTOLIC BLOOD PRESSURE value of 40 mmHg (2.7 kPa) and a SYSTOLIC BLOOD PRESSURE value of 70 mmHg (18.0 kPa) at a pulse rate of 140 beats/min in NEONATAL MODE and a DIASTOLIC BLOOD PRESSURE value of 80 mmHg (5.3 kPa) and a SYSTOLIC BLOOD PRESSURE value of 120 mmHg (30.7 kPa) at a pulse rate of 80 beats/min otherwise.

b) Perform 20 DETERMINATIONS and calculate the mean DIASTOLIC BLOOD PRESSURE and SYSTOLIC BLOOD PRESSURE.

c) Perform all the tests of this standard, except 201.106.

d) Using the same PATIENT SIMULATOR settings as in a), perform 20 DETERMINATIONS and calculate the mean DIASTOLIC BLOOD PRESSURE and SYSTOLIC BLOOD PRESSURE.

e) Calculate the difference of the means calculated in b) and d)

f) Ensure that the difference is below the limit.

201.12.3 Alarm systems

Addition:

201.12.3.101 Alarm systems

If an AUTOMATED SPHYGMOMANOMETER has an ALARM SYSTEM that includes PHYSIOLOGICAL ALARM CONDITIONS, it shall have both a PHYSIOLOGICAL ALARM CONDITION for low BLOOD PRESSURE and a PHYSIOLOGICAL ALARM CONDITION for high BLOOD PRESSURE of at least MEDIUM PRIORITY. These ALARM CONDITIONS may be for SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE, or MEAN ARTERIAL PRESSURE.

Compliance is checked by inspection and functional testing.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3.5 Rough handling test

Additional subclauses:

201.15. 3.5.101 * Shock and vibration for other than transport

An AUTOMATED SPHYGMOMANOMETER or its parts not intended for use during PATIENT transport outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping, and rough handling. A FIXED AUTOMATED SPHYGMOMANOMETER is exempt from the requirements of this subclause.

After the following tests, the AUTOMATED SPHYGMOMANOMETER shall not cause an unacceptable RISK and shall function normally.

Compliance is checked by the following tests:

a) Shock test in accordance with IEC 60068-2-27:2008 using the conditions of test type 1 or 2:

NOTE 1 This represents IEC 60721-4-7:1995, Class 7M2.

1) test type: Type 1:

- *peak acceleration: 100 m/s^2 (15 g);*
- *duration: 11 ms;*
- *pulse shape: half sine;*
- *number of shocks: 3 shocks per direction per axis (18 total).*

2) test type: Type 2:

- *peak acceleration: 300 m/s^2 (30 g);*
- *duration: 6 ms;*
- *pulse shape: half sine;*
- *number of shocks: 3 shocks per direction per axis (18 total).*

For a HAND-HELD AUTOMATED SPHYGMOMANOMETER, the requirements in 15.3.4.1 of the general standard may be substituted for this requirement.

b) Broad-band random vibration according to IEC 60068-2-64:2008 using the following conditions:

NOTE 2 This represents IEC 60721-4-7:1995, Classes 7M1 and 7M2

1) acceleration amplitude:

- *10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz;*
- *100 Hz to 200 Hz: −3 db/octave;*
- *200 Hz to 2,000 Hz: 0.5 (m/s^2)^2/Hz;*

2) duration: 30 min per each perpendicular axis (3 total).

The requirements in 201.15.3.5.102 in total or in part, may be substituted for the corresponding requirements of this subclause.

201.15.3.5.102 * Shock and vibration for transport

An AUTOMATED SPHYGMOMANOMETER or its parts, intended for use during PATIENT transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping, and rough handling.

After the following tests, an AUTOMATED SPHYGMOMANOMETER shall not cause an unacceptable RISK and shall function normally.

Compliance is checked by the following tests:

a) Shock test in accordance with IEC 60068-2-27:2008 using the conditions of test type 1 or 2:

NOTE 1 This represents IEC 60721-4-7:1995, Class 7M3.

1) *test type: Type 1:*
   - *peak acceleration: 300 m/s^2 (30 g);*
   - *duration: 11 ms;*
   - *pulse shape: half sine;*
   - *number of shocks: 3 shocks per direction per axis (18 total);*
2) *test type: Type 2:*
   - *peak acceleration: 1,000 m/s^2 (100 g);*
   - *duration: 6 ms;*
   - *pulse shape: half sine;*
   - *number of shocks: 3 shocks per direction per axis (18 total).*

b) *Broadband random vibration according to IEC 60068-2-64:2008 using the following conditions:*

NOTE 2 This represents IEC 60721-4-7:1995, Class 7M3.

1) *acceleration amplitude:*
   - *10 Hz to 100 Hz: 5.0 (m/s^2)^2/Hz;*
   - *100 Hz to 200 Hz: −7 db/octave;*
   - *200 Hz to 1,000 Hz: 1.0 (m/s^2)^2/Hz;*
2) *duration: 30 min per each perpendicular axis (3 total).*

c) *Free fall according to IEC 60068-2-31:2008, using Procedure 1:*

NOTE 3 This represents IEC 60721-4-7:1995, Class 7M2.

1) *fall height:*
   - *for mass < 1 kg, 0.25 m;*
   - *for mass between 1 kg and < 10 kg, 0.1 m;*
   - *for mass between 10 kg and < 50 kg, 0.05 m;*
   - *for mass ≥ 50 kg, 0.01 m;*
2) *number of falls: 2 in each specified attitude.*

For a PORTABLE AUTOMATED SPHYGMOMANOMETER that is intended to be used with a carrying case, that case may be applied to the AUTOMATED SPHYGMOMANOMETER during this test.

d) *Verify that BASIC SAFETY is maintained and that the AUTOMATED SPHYGMOMANOMETER functions normally.*

U.S. Inclusion

Note: See last paragraph of Annex AA, Subclause 201.15.3.102 for U.S. inclusion.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies, except as follows:

Addition:

NOTE An AUTOMATED SPHYGMOMANOMETER is not considered LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM as defined in IEC 60601-1-2.

New clauses:

201.101 Requirements for CUFFS

201.101.1 * Construction

The CUFF shall contain or incorporate a BLADDER.

The CUFF shall be constructed such that when the CUFF is applied to a limb, the construction ensures that the CUFF is the correct size or the CUFF shall be marked with an indication of the range of limb circumference for which the CUFF is appropriate.

Compliance is checked by inspection.

201.101.2 * Pressurization

The CUFF and BLADDER and connection tubing shall be capable of withstanding an internal pressure equal to 180 mmHg (24 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE and equal to 360 mmHg (48 kPa) otherwise. The BLADDER shall be completely retained in the CUFF during this pressurization.

Compliance is checked by functional testing. Utilize a mandrel for these tests.

201.102 Connection tubing and CUFF connectors

The connections between the AUTOMATED SPHYGMOMANOMETER, CUFF, and connection tubing shall not be equipped with a connector that couples with a connector complying with ISO 594-1 or ISO 594-2.

Compliance is checked by inspection.

201.103 Unauthorized access

To prevent tampering or unauthorized access, means shall be provided to restrict access to the RESPONSIBLE ORGANIZATION, for all controls, including those for PEMS, which can affect the accuracy of the AUTOMATED SPHYGMOMANOMETER.

EXAMPLE Requiring a TOOL for opening.

Compliance is checked by inspection.

201.104 * Maximum inflating time

In NORMAL CONDITION in any automatic cycling mode of operation, a pressure relief PROTECTION DEVICE shall ensure that the CUFF shall not inflate above the values in Table 201.103 for more than 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and for more than 180 s otherwise, see Figure 201.103.

In SINGLE FAULT CONDITION, a pressure relief PROTECTION DEVICE, functioning independently of the NORMAL CONDITION PROTECTION DEVICE, shall ensure that the CUFF shall not inflate above the values in Table 201.103 for more than 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and otherwise for more than 180 s, see Figure 201.103.

Table 201.103 – CUFF inflation pressure

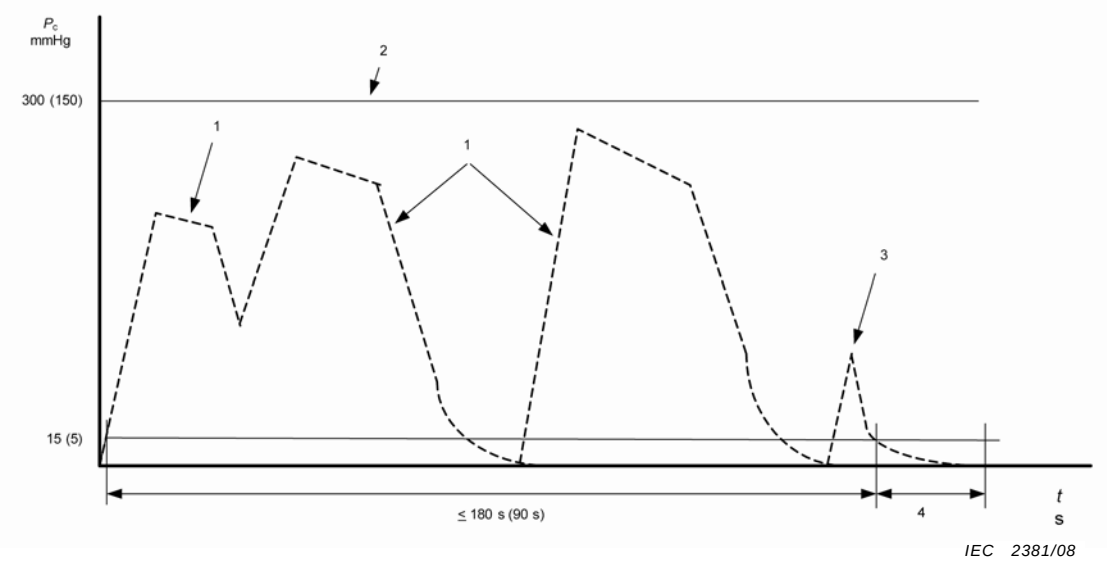
Mode	CUFF pressure
NEONATAL MODE	> 5 mmHg (0.7 kPa)
Any other mode	> 15 mmHg (2.0 kPa)

An AUTOMATED SPHYGMOMANOMETER that only operates in the SELF-MEASUREMENT AUTOMATIC MODE, where the PATIENT is the OPERATOR or the OPERATOR is intended to be in continual attendance, and where the pressure can be released from the CUFF or the limb by the OPERATOR is exempt from the SINGLE FAULT CONDITION requirement.

EXAMPLE 1 Pressure released by the OPERATOR by disconnecting the CUFF from the AUTOMATED SPHYGMOMANOMETER.

EXAMPLE 2 Pressure released by the OPERATOR by removing the CUFF from the limb.

Compliance is checked by introducing any SINGLE FAULT CONDITION and measuring the time that the CUFF remains inflated, beginning the timing measurement as soon as the CUFF pressure exceeds either 15 mmHg (2.0 kPa) or 5 mmHg (0.7 kPa), as appropriate.



Key

1 Unsuccessful DETERMINATION

2 Pressure limit, NEONATAL MODE values in parentheses

3 Aborted DETERMINATION

4 ≥ 30 s for LONG-TERM AUTOMATIC MODE and ≥ 5 s SELF-MEASUREMENT AUTOMATIC MODE

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.103 – CUFF pressure and maximum inflation time, NORMAL CONDITION and SINGLE FAULT CONDITION

201.105 * Automatic cycling modes

201.105.1 LONG-TERM AUTOMATIC MODE

If an AUTOMATED SPHYGMOMANOMETER is equipped with a LONG-TERM AUTOMATIC MODE, a PROTECTION DEVICE shall be provided to ensure that:

a) in NORMAL CONDITION ~~either~~:

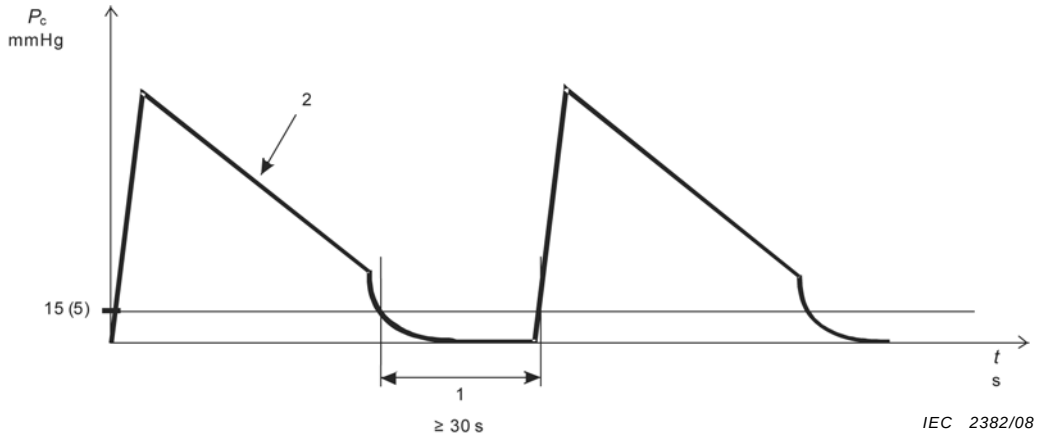
- the total duration of the alternating inflation/deflation periods in an unsuccessful DETERMINATION (see Figure 201.103) shall not exceed the maximum inflation time specified in 201.104; ~~or~~ and
- after each successful DETERMINATION;

  the CUFF pressure shall be released and shall remain below the values in Table 201.102 for at least 30 s (see Figure 201.104); and

b) in SINGLE FAULT CONDITION:

  if the duration of deflation below the values in Table 201.102 is less than 30 s (see Figure 201.105), then a pressure relief PROTECTION DEVICE functioning independently of the NORMAL CONDITION PROTECTION DEVICE, shall release the CUFF pressure to the values in Table 201.102.

Compliance is checked by functional testing.



Key

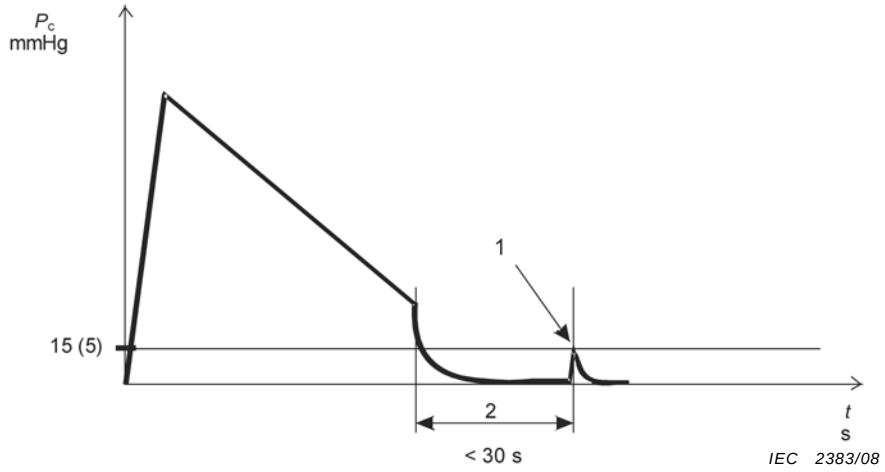
1 Deflated time

2 Linear CUFF deflation shown

NOTE Stepwise, exponential or other waveforms can be used for CUFF deflation.

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.104 – LONG-TERM AUTOMATIC MODE CUFF pressure in NORMAL CONDITION



Key

1 Pressure relief PROTECTION DEVICE activates

2 Deflated time

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.105 – LONG-TERM AUTOMATIC MODE CUFF pressure in SINGLE FAULT CONDITION

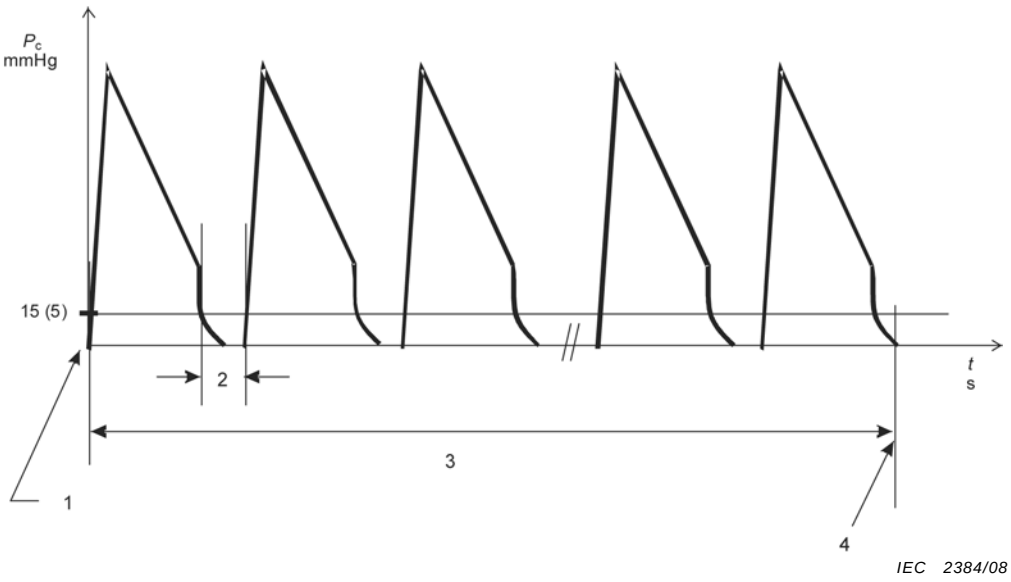
201.105.2 * SHORT-TERM AUTOMATIC MODE

If a SHORT-TERM AUTOMATIC MODE is available, a PROTECTION DEVICE shall be provided to:

– ensure that following each individual DETERMINATION, the pressure in the CUFF shall be reduced to the values indicated in Table 201.102 for at least 2 s, to allow venous return (see Figure 201.106), and

– restrict the duration of the SHORT-TERM AUTOMATIC MODE to a maximum of 15 min (see Figure 201.106). At the end of this time, the AUTOMATED SPHYGMOMANOMETER shall revert to the LONG-TERM AUTOMATIC MODE or a manual mode. A further period of the SHORT-TERM AUTOMATIC MODE may be selected by a deliberate action of the OPERATOR.

Compliance is checked by functional testing.



Key

1 OPERATOR starts SHORT TERM AUTOMATIC MODE

2 Deflated time ≥ 2 s after each DETERMINATION

3 SHORT TERM AUTOMATIC MODE limited to 15 min

4 SHORT TERM AUTOMATIC MODE ends

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.106 – SHORT-TERM AUTOMATIC MODE CUFF pressure

201.105.3 * SELF-MEASUREMENT AUTOMATIC MODE

201.105.3.1 General

If a SELF-MEASUREMENT AUTOMATIC MODE is available, the AUTOMATED SPHYGMOMANOMETER shall perform only a manually-initiated series of less than 7 DETERMINATIONS (see Figure 201.107). After the completion of this series of DETERMINATIONS, the AUTOMATED SPHYGMOMANOMETER shall revert to a manual mode. A subsequent SELF-MEASUREMENT AUTOMATIC MODE may be selected by a deliberate action of the OPERATOR.

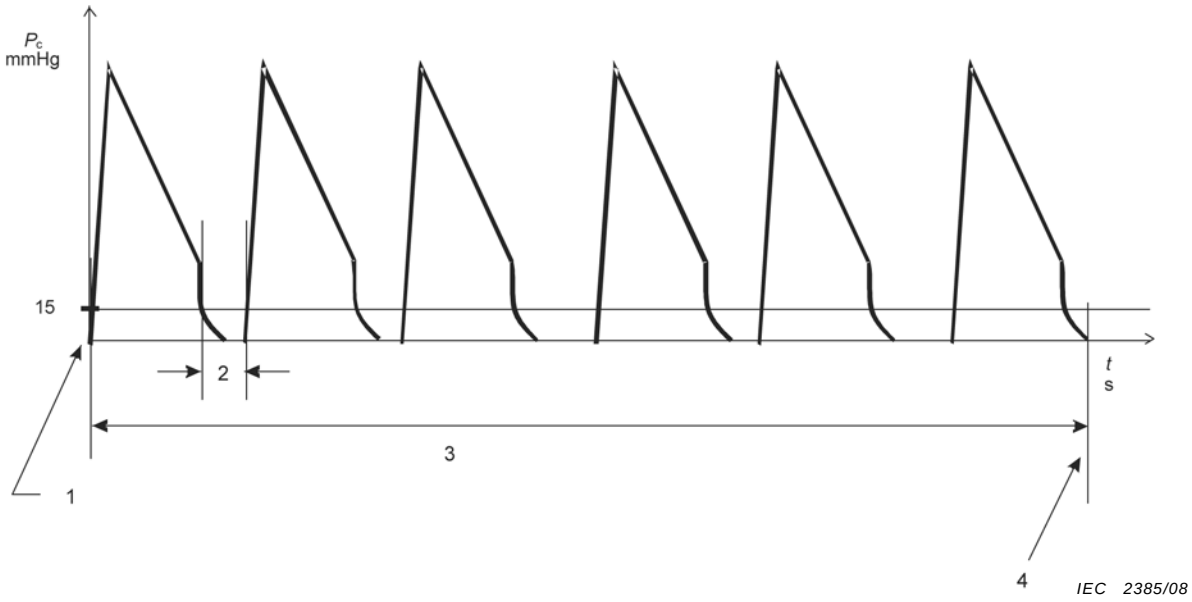
An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall not be intended for use with neonatal or infant PATIENTS. An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall be intended for use where:

– the PATIENT is the OPERATOR; or

– the OPERATOR is in continual attendance during the series of DETERMINATIONS.

An AUTOMATED SPHYGMOMANOMETER operating in the SELF-MEASUREMENT AUTOMATIC MODE may indicate only a single set of values derived from the series of DETERMINATIONS.

Compliance is checked by inspection and functional testing.



Key

1 OPERATOR starts SELF-MEASUREMENT MODE

2 Deflated time ≥ 5 s after each DETERMINATION

3 SELF-MEASUREMENT MODE limited to 6 DETERMINATIONS

4 SELF-MEASUREMENT MODE ends

CUFF pressure, P_c, as a function of time

Figure 201.107 – SELF-MEASUREMENT AUTOMATIC MODE CUFF pressure

201.105.3.2 NORMAL CONDITION

A PROTECTION DEVICE shall be provided to ensure that in NORMAL CONDITION ~~either~~:

– the total duration of the alternating inflation/deflation periods in an unsuccessful DETERMINATION (see Figure 201.103) shall not exceed the maximum inflation time specified in 201.104; ~~or~~ and

– after each successful DETERMINATION, the CUFF pressure shall be released and shall remain below the values in Table 201.102 for at least 5 s (see Figure 201.104).

Compliance is checked by functional testing.

201.105.3.3 * SINGLE FAULT CONDITION

A PROTECTION DEVICE shall be provided to ensure that in SINGLE FAULT CONDITION either:

– if the duration of deflation below the values in Table 201.102 is less than 30 s (see Figure 201.105), then a pressure relief PROTECTION DEVICE functioning independently of the NORMAL CONDITION PROTECTION DEVICE shall release the CUFF pressure to the values in Table 201.102; or

– where:

- the pressure can be released from the CUFF by the OPERATOR; or
- the CUFF can be removed from the limb by the intended OPERATOR when the CUFF is inflated to 360 mmHg (48 kPa).

Compliance is checked by functional testing and inspection of the USABILITY ENGINEERING FILE.

201.106 * Clinical accuracy

Except for the SHORT-TERM AUTOMATIC MODE, each clinical operating mode of an AUTOMATED SPHYGMOMANOMETER shall comply with ISO 81060-2, which contains the requirements for clinical accuracy and the protocols for validating the clinical accuracy.

NOTE Additional requirements for the ACCOMPANYING DOCUMENTS are found in ISO 81060-2.

Compliance is checked by application of the tests of ISO 81060-2.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.4 General requirements

Additional subclause:

202.4.101 Classification

An AUTOMATED SPHYGMOMANOMETER shall not be considered LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM.

202.6.2 Immunity

202.6.2.1.10 Compliance criteria

Replacement:

Under the test conditions specified in IEC 60601-1-2:2007, 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE. Under these conditions, the maximum change in the reading for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to 2 mmHg (0.3 kPa).

202.6.2.3.1 Requirements

a) General

Replacement:

An AUTOMATED SPHYGMOMANOMETER, except as specified in c) below or in the EXCLUSION BAND as specified in d) below, shall comply with the requirements of IEC 60601-1-2:2007, 6.2.1.10, at an IMMUNITY TEST LEVEL of 3 V/m over the frequency range 80 MHz to 2.5 GHz.

In addition, an AUTOMATED SPHYGMOMANOMETER intended for use during PATIENT transport outside the healthcare facility, except as specified in c) below or in the EXCLUSION BAND as specified in d) below, shall comply with the requirements of 6.2.1.10 at the IMMUNITY TEST LEVEL of 20 V/m (80 % amplitude modulated at 1,000 Hz) over the range of 80 MHz to 2 500 MHz.

Additional subclause:

202.6.2.101 * Electrosurgery interference recovery

If an AUTOMATED SPHYGMOMANOMETER is intended to be used together with HF SURGICAL EQUIPMENT, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT, without loss of any stored data.

Compliance is checked by functional testing using the test setup indicated in Figure 202.101 and Figure 202.102.

a) Use HF SURGICAL EQUIPMENT that complies with IEC 60601-2-2 and that:

- *has a cut mode with at least 300 W of power,*
- *has a coagulation mode with a least 100 W of power, and*
- *has a working frequency of 450 kHz ± 100 kHz.*

b) Test in cut mode:

Set up the ME EQUIPMENT to operate from a PATIENT SIMULATOR set to simulate a BLOOD PRESSURE of 100/70 mmHg ± 10 mmHg (13.3/9.3 kPa ± 1.3 kPa). On the HF SURGICAL EQUIPMENT select the cut mode at 300 W.

Touch the metal plate in the test setup (see Figure 202.101) with the active electrode and remove the electrode slowly to produce a spark (generate high-frequency interference).

Terminate the interference. Wait 10 s. Determine whether displayed parameters on the ME EQUIPMENT have returned to their pre-test readings.

Repeat this PROCEDURE as described, five times.

c) Test in coagulation mode:

Set up the ME EQUIPMENT to operate from a PATIENT SIMULATOR set to simulate a BLOOD PRESSURE of about 100/70 mmHg ± 10 mmHg (13.3/9.3 kPa ± 1.3 kPa). On the HF SURGICAL EQUIPMENT select the coagulation mode at 100 W.

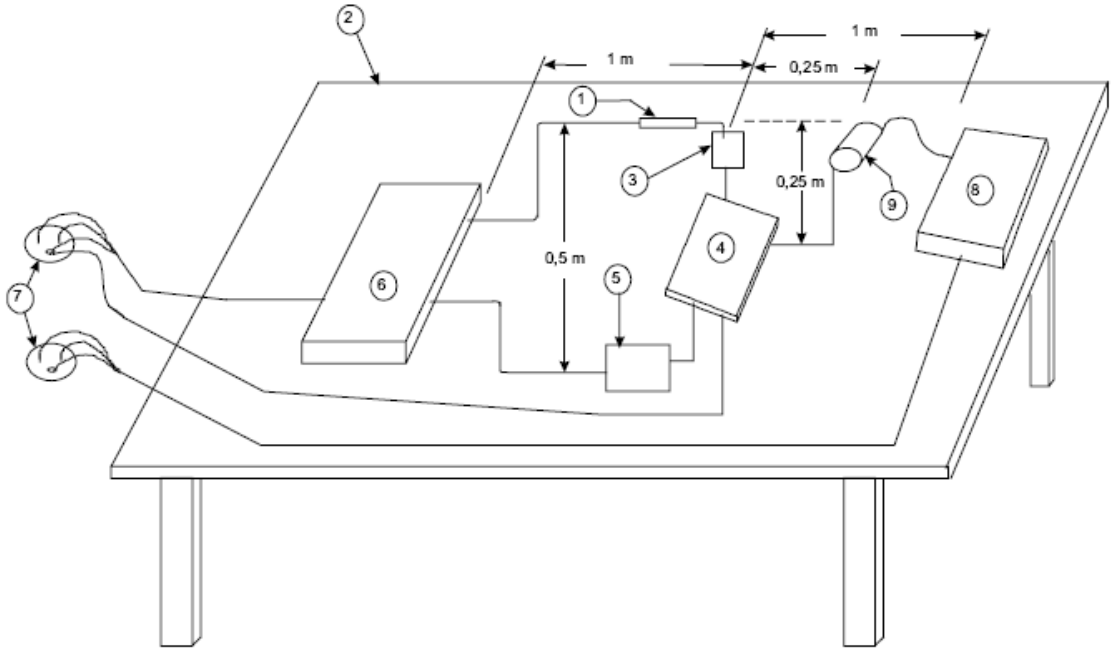
Touch the metal plate in the test setup (see Figure 202.101) with the active electrode and remove the electrode slowly to produce a spark (generate high-frequency interference).

Terminate the interference. Wait 10 s. Determine whether displayed parameters on the ME EQUIPMENT have returned to their pre-test readings.

Repeat this PROCEDURE as described, five times.

NOTE 1 Test of the spray coagulation is not required.

NOTE 2 If the HF SURGICAL EQUIPMENT interferes with the PATIENT SIMULATOR, shield the PATIENT SIMULATOR.



Key

1 Active electrode

2 Table made of insulating material

3 Metal plate

4 Simulated PATIENT for HF SURGICAL EQUIPMENT

5 Neutral electrode

6 HF SURGICAL EQUIPMENT

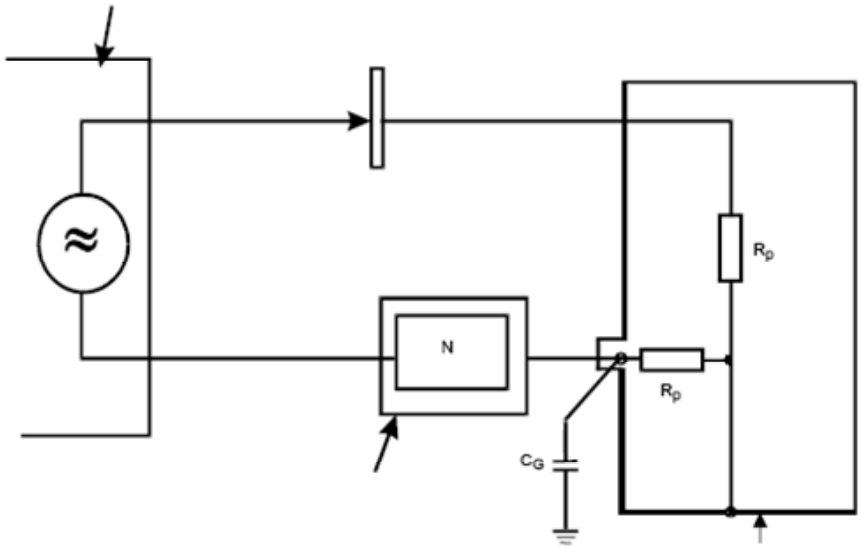
7 SUPPLY MAINS

8 AUTOMATED SPHYGMOMANOMETER under test

9 CUFF wrapped in foil that is wrapped around the mandrel of a PATIENT SIMULATOR

The PATIENT SIMULATOR is connected via a 'T' to the PNEUMATIC SYSTEM. Simulated PATIENT is connected to foil wrap of CUFF.

Figure 202.101 – HF SURGICAL EQUIPMENT test layout



Key

1 HF SURGICAL EQUIPMENT

2 Metal plate

3 Metal plate

Figure 202.102 – Simulated PATIENT test set-up for HF SURGICAL EQUIPMENT

Annexes

The annexes of the general standard apply, except as follows:

Annex C
(informative)

Guide to marking and labeling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of the general standard applies, except as follows.

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of the AUTOMATED SPHYGMOMANOMETER or its parts are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of AUTOMATED SPHYGMOMANOMETERS or their parts

Description of marking	Subclause
As appropriate, proper disposal methods	201.7.2.106
Correct positioning for the CUFF on the designated limb over the artery	201.7.2.4
For the HOME HEALTHCARE ENVIRONMENT, packaging marked with any special requirements for battery-powered equipment	201.7.2.102
For the HOME HEALTHCARE ENVIRONMENT, packaging marked with appropriate arm circumference	201.7.2.102
For the HOME HEALTHCARE ENVIRONMENT, packaging marked with operating and storage temperature and humidity ranges	201.7.2.102
For public use, adequate operating instructions	201.7.2.104
For public use, the measurement accuracy of the AUTOMATED SPHYGMOMANOMETER	201.7.2.104
For public use, the need to consult a physician for interpretation of BLOOD PRESSURE measurements	201.7.2.104
For public use, precautions for use	201.7.2.104
If applicable, ACCESSORIES intended for use only in the NEONATAL MODE	201.7.2.103
If applicable, caution to the effect that substitution of a component different from that supplied might result in measurement error, or with symbol ISO 7010-M002	201.7.2.105
If applicable, a detailed description of correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2.13
An indication of whether the CUFF is the correct size	201.101.1
The range of limb circumference for which the CUFF is appropriate	201.101.1

201.C.3 Marking of controls and instruments

Addition:

Additional requirements for marking of controls and instruments of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.102.

Table 201.C.102 – Marking of controls and instruments of AUTOMATED SPHYGMOMANOMETERS or their parts

Description of marking	Subclause
If applicable, display abbreviations for SYSTOLIC, DIASTOLIC and MEAN ARTERIAL PRESSURE	201.7.2.101

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

Additional requirements for general information to be included in the accompanying documents of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.103.

Table 201.C.103 – ACCOMPANYING DOCUMENTS, general information for AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
Additional requirements can be found in ISO 81060-2.	201.106

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Addition:

Additional requirements for ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.104.

Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
An explanation of the operating steps of the AUTOMATED SPHYGMOMANOMETER needed to obtain routine resting BLOOD PRESSURE measurements for the diagnosis of hypertension	201.7.9.2.9 b)
An explanation of the selection of a suitable size and application of the CUFF to the PATIENT	201.7.9.2.9 a)
An explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition	201.7.9.2.9 c)
Details of the environmental or operation factors which can affect the performance of the AUTOMATED SPHYGMOMANOMETER and/or its BLOOD PRESSURE reading	201.7.9.2.9 e)
Details of what the OPERATOR should do if unexpected readings are obtained	201.7.9.2.9 d)
Frequently used functions	201.7.9.2.1
Intended conditions of use	201.7.9.2.1 5)
Intended medical indication	201.7.9.2.1 1)
Intended PATIENT population, including whether or not intended for use with neonatal and infant PATIENTS and with pregnant, including pre-eclamptic, PATIENTS	201.7.9.2.1 3)
Intended placement of the CUFF	201.7.9.2.1 4)
Method for placing into the NEONATAL MODE	201.7.2.103
Permissible environmental conditions of use	201.7.9.2.1

Table 201.C.104 *(continued)*

Description of disclosure	Subclause
Restrictions or contraindications to use	201.7.9.2.1 2)
Use as intended by the MANUFACTURER	201.7.9.2.1
Warning indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference	201.7.9.2.2
Warning regarding application of the CUFF and its pressurization on a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because of temporary interference of blood flow and resulting injury to the PATIENT	201.7.9.2.2
Warning regarding applying the CUFF over a wound, as this can cause further injury	201.7.9.2.2
Warning regarding the need to check that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the PATIENT	201.7.9.2.2
Warning regarding the effect of continuous CUFF pressure due to connection tubing kinking on blood flow and possible injury to PATIENT	201.7.9.2.2
Warning that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb	201.7.9.2.2
Warning regarding the RISKS of not using the NEONATAL MODE on a neonatal PATIENT	201.7.2.103
If applicable, a statement that the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude	201.7.9.2.9 f)
An explanation of the need to avoid compression or restriction of the connection tubing	201.7.9.2.9 g)
RATED ranges of the DETERMINATION	201.7.9.2.5
RATED range of CUFF pressure	201.7.9.2.9 h)
If applicable, the correct method of reassembly	201.7.9.2.13
If applicable, a detailed description of the correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2.13
If applicable, that the ME EQUIPMENT is suitable for use in the presence of electrosurgery	201.7.9.2.101
If applicable, the protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2.101
If applicable, the absence of protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2.101
If applicable, the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in the NEONATAL MODE	201.7.9.2.102
If applicable, the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER can accommodate when in the NEONATAL MODE	201.7.9.2.102
If applicable, recommended ACCESSORIES to avoid errors and excessive pressure	201.7.9.2.102
Description of the operating principles	201.7.9.2.5

201.C.6 ACCOMPANYING DOCUMENTS, technical description

Addition:

Additional requirements for ACCOMPANYING DOCUMENTS, technical description of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.105.

Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description of AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
Test method that can be used to verify the calibration	201.12.1.106

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of IEC 80601-2-30, and is intended for those who are familiar with the subject of IEC 80601-2-30 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of IEC 80601-2-30 necessitated by those developments.

AUTOMATED SPHYGMOMANOMETERS are used in almost all clinical environments in healthcare. As such, BLOOD PRESSURE monitoring is used on almost all PATIENTS when they encounter the healthcare system. They are increasingly being used by PATIENTS in the HOME HEALTHCARE ENVIRONMENT.

Faults in the inflation and deflation cycles of AUTOMATED SPHYGMOMANOMETERS are the main non-electrical BASIC SAFETY issues. In the inflation cycle, the problems could be as follows:

– too high a target pressure for neonatal or young pediatric use, causing bruising and possibly bone deformation;
– too long an inflated period resulting in extended venous (and possibly arterial) occlusion; or
– a rapid repetition rate for an extended period, resulting in excessive venous occlusion, and hence venous blood pooling.

In the deflation cycle, there is only one non-electrical BASIC SAFETY issue that occurs, and that is the failure to deflate. In the short term, this can cause discomfort to a conscious PATIENT, but to an unconscious PATIENT the failure to deflate over an extended period of time can result in irreversible neuromuscular injury.

Various clauses in this Standard have as their express purpose the avoidance of these non-electrical BASIC SAFETY issues.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationale corresponds to the numbering of the clauses in IEC 80601-2-30. The numbering is, therefore, not consecutive.

Subclause 201.3.217 – SHORT-TERM AUTOMATIC MODE

The SHORT-TERM AUTOMATIC MODE of an AUTOMATED SPHYGMOMANOMETER is particularly relevant during the administration of anesthesia, but also finds application in accident and emergency departments, when a PATIENT is hemodynamically unstable. The ability to follow the trend of the BLOOD PRESSURE is more important to the OPERATOR than the absolute accuracy of individual DETERMINATIONS. As a result, the time between measurements is permitted to be very short even though that can negatively affect the clinical accuracy of DETERMINATIONS. Therefore an AUTOMATED SPHYGMOMANOMETER is not required to meet the clinical accuracy requirements when operating in this mode.

Subclause 201.7.2.4 – ACCESSORIES

The accuracy of a DETERMINATION requires the use of the correct size CUFF. If the CUFF used is too large or too small relative to the limb circumference of the PATIENT, or incorrectly positioned on the limb of the PATIENT, clinically significant errors in BLOOD PRESSURE estimation could result.

Subclause 201.7.2.103 – AUTOMATED SPHYGMOMANOMETERS with NEONATAL MODE

This standard specifies the use of lower maximum CUFF pressures and shorter measurement times with neonatal PATIENTS to reduce the RISK of injury. AUTOMATED SPHYGMOMANOMETERS need clear instructions for the OPERATOR to ensure that the proper mode is used with neonatal PATIENTS.

Subclause 201.7.2.104 – AUTOMATED SPHYGMOMANOMETERS for public use

AUTOMATED SPHYGMOMANOMETERS intended for use in public areas are typically used by OPERATORS measuring their own BLOOD PRESSURE. These OPERATORS do not have access to the instructions for use. The most important instructions need to be marked on the ME EQUIPMENT.

Subclause 201.7.2.105 – Component replacement

Replacement of components or parts that can impact BASIC SAFETY or ESSENTIAL PERFORMANCE should occur only with the appropriate awareness of the potential consequences of the replacement. Both clinical OPERATORS and SERVICE PERSONNEL need this awareness. Appropriate PROCEDURES, e.g. re-calibration, should occur following such replacements. The marking requirement is intended to give this awareness.

Subclause 201.8.5.5.101 – PATIENT CONNECTIONS of AUTOMATED SPHYGMOMANOMETER

AUTOMATED SPHYGMOMANOMETERS are frequently used in environments in which other pieces of ME EQUIPMENT are also connected to the same PATIENT. If the AUTOMATED SPHYGMOMANOMETER has PATIENT CONNECTIONS, it is important for the safety of the PATIENT and the OPERATOR that it be a DEFIBRILLATION-PROOF APPLIED PART.

Subclause 201.11.8.101 – Switching off

The intent of this requirement is to ensure reduced RISK of injury to a PATIENT due to excessive pressure applied to the limb when the AUTOMATED SPHYGMOMANOMETER is turned off or loses power unintentionally. The requirement is intended to ensure that the AUTOMATED SPHYGMOMANOMETER is in a safe state when power is removed. Examples include AUTOMATED SPHYGMOMANOMETERS for use on neonatal or infant PATIENTS and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple DETERMINATIONS without OPERATOR intervention over extended periods of time. See also the rationale for Subclause 201.12.1.105 for a discussion of pressure levels and deflation acceptance criterion.

Subclause 201.11.8.103 – INTERNAL ELECTRICAL POWER SOURCE

Failure to deflate the CUFF within 30 s to the values indicated in Table 201.102 is considered a failure to maintain BASIC SAFETY.

Subclause 201.12.1.103 – NOMINAL BLOOD PRESSURE indication range

This test is a compromise as it is not practicable to perform this test in human subjects since these BLOOD PRESSURE values are extremely rare in clinical care. It is important for AUTOMATED SPHYGMOMANOMETERS to be able to indicate BLOOD PRESSURES above the range over which they are clinically validated. An AUTOMATED SPHYGMOMANOMETER that either blanks or artificially limits the value of the display above that range would 'hide' the condition of the PATIENT from the OPERATOR.

Subclause 201.12.1.105 – Maximum pressure in SINGLE FAULT CONDITION

The intent of this requirement is to ensure reduced RISK of injury to a PATIENT due to excessive pressure applied to the limb when the primary pressure sensing and protection mechanism of the AUTOMATED SPHYGMOMANOMETER is not functioning due to a SINGLE FAULT CONDITION. The requirement is intended to reduce RISK in situations where the PATIENT is unable to remove the CUFF in the case of overpressure and there is no OPERATOR likely to be present. In these cases it is necessary to provide a PROTECTION DEVICE to release pressure from the CUFF without the intervention of the OPERATOR or the PATIENT. Examples include AUTOMATED SPHYGMOMANOMETERS for use on neonatal PATIENTS and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple DETERMINATIONS with no OPERATOR intervention over long periods of time.

Failure of the CUFF to deflate over an extended period of time can result in injury to the PATIENT. Reduction of the CUFF pressure to less than 15 mmHg is considered sufficient to reduce or eliminate the RISK of injury to adults. Since neonates are particularly sensitive to the effects of prolonged pressure on a limb, reduction of the CUFF pressure to 5 mmHg is required for these PATIENTS.

An alternative RISK CONTROL method is provided for AUTOMATED SPHYGMOMANOMETERS that operate in SELF-MEASUREMENT AUTOMATIC MODE. Since the total number of DETERMINATIONS is limited and the PATIENT is conscious and expected to be able to remove the CUFF or otherwise release the pressure, a PROTECTION DEVICE is not necessary. This alternative RISK CONTROL method is intended to provide a balance between the benefits of the availability of low-cost AUTOMATED SPHYGMOMANOMETERS intended for SELF-MEASUREMENT AUTOMATIC MODE and the added cost of the SINGLE FAULT CONDITION PROTECTION DEVICE.

The evaluation of the acceptance criterion for the performance of the PROTECTION DEVICE includes the time required to deflate the CUFF, which is affected by both the pressure in and the volume of the CUFF. The initial pressure chosen for the test should represent the highest pressure expected in NORMAL USE, which occurs at the end of the inflation cycle. In the NEONATAL MODE, the maximum pressure of 150 mmHg should be used; otherwise the allowable maximum pressure is 300 mmHg, but rarely exceeds 250 mmHg.

Since it can be difficult to establish consistent volumes with CUFFS, one method to standardize this test is to utilize fixed volumes to represent the CUFF (e.g. 100 ml ± 5 ml in NEONATAL MODE or for wrist AUTOMATED SPHYGMOMANOMETERS and 500 ml ± 25 ml otherwise). An alternative method is to utilize the largest CUFF specified in the instructions for use for each mode of operation. The CUFF should be wrapped around a rigid mandrel that represents the midpoint of the marked range for the CUFF.

The time of 3 s allows for momentary artifacts, common with this technology, which could cause the CUFF pressure to rise temporarily above the maximum permitted pressure without creating an ALARM CONDITION.

Subclause 201.12.1.106 – Manometer test mode

A manometer test mode of an AUTOMATED SPHYGMOMANOMETER is used to verify or calibrate the accuracy of the PRESSURE TRANSDUCER. Depending on its design and material, the accuracy of the PRESSURE TRANSDUCER can be affected by temperature, drift, aging processes etc. Therefore it is necessary for SERVICE PERSONNEL to have a means to check the accuracy of the PRESSURE TRANSDUCER for maintenance and calibration of an AUTOMATED SPHYGMOMANOMETER. Such checks are recommended by some MANUFACTURERS and are required by some authorities with jurisdiction. Since a manometer test mode is not used clinically, access is restricted to SERVICE PERSONNEL, which can include use of a TOOL to open the ENCLOSURE.

Subclause 201.15.3.5.101 – Shock and vibration for other than transport

AUTOMATED SPHYGMOMANOMETERS in NORMAL USE will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, an AUTOMATED SPHYGMOMANOMETER needs to be robust enough to withstand the vibration, shock, bumps and drops that it will encounter in NORMAL USE.

These tests were chosen by first reviewing the results of the work published in other PATIENT monitoring standards where those committees [1][3] qualitatively assessed the relative severity of the scenarios within various environments (i.e., HOME HEALTHCARE ENVIRONMENT, healthcare institution and professional transport (wings and wheels)), by various sizes and types of ME EQUIPMENT (i.e., HAND-HELD, PORTABLE and MOBILE ME EQUIPMENT).

After that qualitative assessment, those committees assessed the relevant particular standards for environmental testing in the IEC 60068 series and their respective rationales, as well as the IEC 60721 series of guidance documents. In selecting the requirements, those committees reviewed other sources for material related to these tests (e.g., FDA Reviewers Guidance for premarket notification submissions, Mil Std 810, etc) but found the best fit was with the standard IEC 60721-3-7:1995[6)]. There is also a guidance document, IEC TR 60721-4-7:2001[7)], that helps to correlate environmental condition classes of IEC 60721-3 to environmental tests according the IEC 60068 series. The aforementioned standards specify 3 classes of mechanical conditions, 7M1, 7M2 and 7M3. Those committees found that classes 7M1 and 7M3 best represent the conditions seen during PATIENT transport within healthcare facilities and PATIENT transport outside healthcare facilities, respectively. Those committees agreed that different tests and test levels should be applied to ME EQUIMENT intended for use in a healthcare facility versus ME EQUIMENT intended for use during PATIENT transport outside the healthcare facility.

Verifying that the instrument is functioning within the MANUFACTURER'S specifications while the vibration (random and sinusoidal) tests are being conducted was not believed necessary. This line of thought was considered and it was decided that a test done in this manner would be overly burdensome and would add only a minimum additional level of safety to the ME EQUIMENT that would not outweigh the costs. Verifying proper functioning after completion of the tests is believed adequate.

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6) IEC 60721-3-7:1995, *Classification of environmental conditions – Part 3: Classification of groups of environmental parameters and their severities – Section 7: Portable and non-stationary use*

7) IEC/TR 60721-4-7:2001, *Classification of environmental conditions – Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 – Portable and non-stationary use*

Subclause 201.15.3.5.102 – Shock and vibration for transport

The tests of this subclause are intended to demonstrate that an AUTOMATED SPHYGMOMANOMETER can survive the mechanical stresses associated with PATIENT transport outside a healthcare facility. These tests are not intended to evaluate the clinical efficacy of AUTOMATED SPHYGMOMANOMETER during PATIENT transport outside a healthcare facility.

AUTOMATED SPHYGMOMANOMETERS used for PATIENT transport outside a healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock, bump, and drop) and could randomly be subjected to additional stresses. Therefore, instruments intended to be used for PATIENT transport outside a healthcare facility need to be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7 level 7M3. IEC 60721-3-7 indicates that in addition to the conditions covered by class 7M2, the class 7M3 applies to use at, and direct transfer between, locations with significant vibrations, or with high level shocks. Rough handling and transfer of ME EQUIPMENT is expected in these environments.

An additional shock test for this class of ME EQUIPMENT is added even though there are no established generalized test programs that exactly reproduce the range of vibration and shock conditions that ME EQUIPMENT might meet when installed in a range of land vehicles and aircraft. Therefore the dynamic tests specified in this subclause have been chosen on the basis that ME EQUIPMENT tested to these levels are likely to withstand the normal dynamic disturbances that they will be subjected to when used in the vehicles and aircraft (including helicopters) likely to be used for transporting PATIENTS.

The use of ME EQUIPMENT in road ambulance, fixed-wing and rotary-wing aircraft, naval vessels, etc. can require additional tests and verification of safety when used in these different environments.

U.S. Inclusion

Note: Since clause 201.15.3.102 of this standard requires functional testing before and after vibrations, but not during vibrations, the U.S. believes that there is no proof that the device can indeed perform within specifications during vibrations, such as enabling the user to accurately measure the blood pressure of a patient who is being transported in a moving ambulance. Thus, this standard cannot be used in the U.S. to substantiate a claim of functionality within the manufacturer's specifications during transport.

Subclause 201.101.1 – Construction

This standard does not specify the details of the construction of CUFFS and BLADDERS. Studies [13] [17] [21] have suggested that the appropriate BLADDER size for the placement at the upper arm for auscultatory estimates of BLOOD PRESSURE is one with dimensions such that its width is 40 % of the limb circumference at the maximum range for each CUFF size and its length is 80 % to 100 % of the limb circumference at the centre of the range for each CUFF size. In auscultation, use of the wrong size CUFF can affect the accuracy of the estimates of BLOOD PRESSURE. These recommended dimensions are subject to ongoing consideration. AUTOMATED SPHYGMOMANOMETERS can be designed with different CUFF dimensions.

Use of an incorrect CUFF size (too small or too large) is a source of inaccurate DETERMINATION, e.g. CUFFS that are too small can result in erroneously high DETERMINATIONS. This RISK should be avoided by a design that does not allow a DETERMINATION to be initiated or displayed if the limb

circumference is outside the permissible range. Alternatively the RISK can be reduced by marking on the CUFF the permissible range of limb circumference.

The appropriate BLADDER size for placement at the wrist is dependent on the design of the AUTOMATED SPHYGMOMANOMETER. Commonly used wrist CUFFS have a width of approximately 6 cm and a length of 10 cm to 14 cm for a wrist circumference range of 13.5 cm to 19.5 cm.

Subclause 201.101.2 – Pressurization

While the maximum pressure allowed in the PNEUMATIC SYSTEM is 330 mmHg, prudent engineering design requires that the CUFF be tested at a higher pressure (+ 10 %). This is similar to the derating methods used to ensure that electronic components meet the requirements of a design.

Subclause 201.104 – Maximum inflating time

The pressures indicated in Table 201.102 were chosen, following clinical advice, as being CUFF pressures at which reasonable venous return can take place. They are also pressures that can be measured with reasonable reliability.

Two or more attempts at determining the BLOOD PRESSURE of restless or hypertensive PATIENTS can occur in 180 s. A large safety margin is still allowed before any neuromuscular injury is likely to take place.

The shortened maximum time in NEONATAL MODE is not only obviously desirable to reduce discomfort and trauma in these fragile PATIENTS, but also justified since the maximum pressure is 150 mmHg (20.0 kPa), which results in a shorter deflation time, and the typical heart rate of these PATIENTS is higher. An additional issue is that the longer the CUFF remains inflated, the more distressed an infant becomes, thus producing more artifacts that could cause more readings to be taken.

Since this requirement applies in SINGLE FAULT CONDITION, it is necessary to guard against the failure of a deflation valve by having two independent means of reducing the pressure.

An alternative RISK CONTROL method is provided for AUTOMATED SPHYGMOMANOMETERS that operate in SELF-MEASUREMENT AUTOMATIC MODE. See Subclause 201.12.1.105.

Subclause 201.105 – Automatic cycling modes

Table AA.1 provides a summary of the requirements and differences between the automatic cycling modes described in this standard.

Table AA.1 – Summary of requirements by mode

	LONG-TERM AUTOMATIC MODE 201.105.1	SHORT-TERM AUTOMATIC MODE 201.105.2	SELF-MEASUREMENT AUTOMATIC MODE 201.105.3
Number of DETERMINATIONS	Unlimited	Limited [a]	< 7
Duration of mode	Unlimited	≤15 min	Not Applicable [b]
Maximum inflating time (per DETERMINATION) (201.104)	180 s or 90 s in NEONATAL MODE	180 s or 90 s in NEONATAL MODE	180 s [c]
Deflated Period	≥ 30 s	≥ 2 s	≥ 5 s
Maximum pressure (201.12.1.104)	300 mmHg or 150 mmHg in NEONATAL MODE	300 mmHg or 150 mmHg in NEONATAL MODE	300 mmHg [c]
Pressure protection in SINGLE FAULT CONDITION	PROTECTION DEVICE	PROTECTION DEVICE	Manual means [d] or PROTECTION DEVICE
PATIENT population	All	All	Limited [e]
Clinical validation (201.106)	ISO 81060-2	Not required	ISO 81060-2

[a] The number of DETERMINATIONS is not specified, but is limited by the duration.

[b] The number of DETERMINATIONS is limited to 6, but there is no absolute time limit.

[c] NEONATAL MODE is not permitted in SELF-MEASUREMENT AUTOMATIC MODE.

[d] If an independent PROTECTION DEVICE is not provided, means are provided for the release of pressure by the OPERATOR or PATIENT.

[e] The PATIENT population is intended only for conscious adults and is required to be disclosed in the instructions for use.

The figures shown in this subclause are drawn to illustrate the DETERMINATION of BLOOD PRESSURE during the deflation cycle. Some AUTOMATED SPHYGMOMANOMETERS determine BLOOD PRESSURE during inflation. This results in a longer inflation cycle and a shorter deflation cycle when compared to the figures. This does not change the intent of the figures or any of the other requirements of this standard.

Subclause 201.105.2 – SHORT-TERM AUTOMATIC MODE

SHORT-TERM AUTOMATIC MODE is valuable for continuous surveillance of PATIENTS undergoing anesthetic PROCEDURES as well as emergency care where there can be a clinical need for frequent readings. However, a minimum period of deflation between inflations is necessary to allow some venous return. In addition, the total duration of the SHORT-TERM AUTOMATIC MODE should be limited to prevent venous pooling and reduce bruising.

Subclause 201.105.3 – SELF-MEASUREMENT AUTOMATIC MODE

SELF-MEASUREMENTAUTOMATIC MODE is useful for measurement of BLOOD PRESSURE both in physicians' offices and in the home. Current recommendations for measurement of BLOOD PRESSURE for use in the diagnosis of hypertension [20] recommend that at least 2 DETERMINATIONS should be taken at intervals of at least 1 min, and the average of those DETERMINATIONS should be taken as the PATIENT'S BLOOD PRESSURE.

The use of this mode in a physician's office provides the ability to obtain multiple measurements from a PATIENT without a clinician being present. This could reduce or eliminate the white coat hypertension effect.

The ability to access the individual DETERMINATIONS is useful to determine if there is significant variability in a PATIENT'S BLOOD PRESSURE.

While the use of the average of multiple DETERMINATIONS is widely used, other measures can be used to represent a PATIENT'S BLOOD PRESSURE (e.g. median or mode).

Subclause 201.105.3.3 – SINGLE FAULT CONDITION

The intent of this requirement is to provide a means of RISK CONTROL for potential injury to a PATIENT due to the HAZARDOUS SITUATION of excessive pressure applied to the limb when the primary pressure sensing or PROTECTION DEVICE of the AUTOMATED SPHYGMOMANOMETER is not functioning due to a SINGLE FAULT CONDITION. The requirement for a PROTECTION DEVICE is intended to reduce RISK to acceptable levels in situations where the PATIENT is commonly unable to remove the CUFF in the case of over pressure and there is no other OPERATOR likely to be present to physically remove the pressurized CUFF from the limb. In this case, it is necessary to provide an independent PROTECTION DEVICE to release pressure from the CUFF without the intervention of the OPERATOR or the PATIENT. Example cases include AUTOMATED SPHYGMOMANOMETERS for use on neonatal PATIENTS or PATIENTS in critical care units and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple determinations without OPERATOR intervention over an extended period.

An alternative means of RISK CONTROL is provided for AUTOMATED SPHYGMOMANOMETERS that only operate in the SELF-MEASUREMENT AUTOMATIC MODE. In this mode it is assumed that the period of operation will be relatively short while a single DETERMINATION is performed and that the OPERATOR is present during the entire operation and is available to release the pressure from the CUFF or remove the CUFF in the case of a SINGLE FAULT CONDITION. This also applies to the SELF-MEASUREMENT AUTOMATIC MODE when the PATIENT is the OPERATOR.

The alternative RISK CONTROL method is intended to provide an acceptable RESIDUAL RISK by trading off the cost of a PROTECTION DEVICE with OPERATOR action when OPERATOR/PATIENT action can be relied upon for RISK CONTROL. It is clearly an unacceptable RISK to PATIENTS if accurate, low cost AUTOMATED SPHYGMOMANOMETERS are not available for PATIENT self-measurement for use in the management of hypertension.

Subclause 201.106 – Clinical accuracy

The SHORT-TERM AUTOMATIC MODE is valuable for continuous surveillance of PATIENTS undergoing anesthetic PROCEDURES as well as emergency care where there can be a clinical need for very frequent readings to monitor critical, unstable PATIENTS. However, because of the minimal period of deflation permitted between inflations that enables the OPERATOR to obtain BLOOD PRESSURE readings in the shortest possible time, it is expected that accuracy is degraded to some extent.

In addition, the total duration of the SHORT-TERM AUTOMATIC MODE should be limited to prevent venous pooling and reduce bruising.

Subclause 202.6.2.101 – Electrosurgery interference recovery

If an AUTOMATED SPHYGMOMANOMETER is intended to be used together or in the presence with HF SURGICAL EQUIPMENT, OPERATORS should expect that the AUTOMATED SPHYGMOMANOMETER can

determine BLOOD PRESSURE following a recovery time. Since an AUTOMATED SPHYGMOMANOMETER determines BLOOD PRESSURE aperiodically and not continually, the committee judged that it was not a requirement for an AUTOMATED SPHYGMOMANOMETER to be able to make a DETERMINATION during the operation of HF SURGICAL EQUIPMENT, but that it would be an unacceptable RISK to a PATIENT if an AUTOMATED SPHYGMOMANOMETER were unable to make the expected DETERMINATION following operation of the HF SURGICAL EQUIPMENT.

Annex BB
(informative)

Environmental aspects

The environmental impact generated by an AUTOMATED SPHYGMOMANOMETER performing DETERMINATIONS is mainly isolated to the following occurrences:

– impact at local environment during operation, including routine inspection and adjustments by the OPERATOR, according to the instructions for use or routine procedures;

– use, cleaning and disposal of consumables during operation, including routine inspection and adjustments by the OPERATOR, according to the instructions for use or routine procedures;

– scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of an AUTOMATED SPHYGMOMANOMETER.

See Table BB.1 for a mapping of the life cycle of an AUTOMATED SPHYGMOMANOMETER to aspects of the environment.

Table BB.1 – Environmental aspects addressed by clauses of this standard

Environmental aspects (Inputs and Outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in subclause	Addressed in subclause	Addressed in subclause	Addressed in subclause
1	Resource use	IEC 60601-1-9 [a]	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
2	Energy consumption	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
3	Emission to air	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.106
4	Emission to water	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.106
5	Waste	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.106
6	Noise	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
7	Migration of hazardous substances	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.106
8	Impacts on soil	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.106
9	Risks to the environment from accidents or misuse	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
[a] See IEC 60601-1-9:2007.					

Annex CC
(informative)

Reference to the essential principles

This particular standard has been prepared to support the essential principles of safety and performance of AUTOMATED SPHYGMOMANOMETERS as medical devices according to ISO/TR 16142. This particular standard is intended to be acceptable for conformity assessment purposes.

Compliance with this particular standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible.

See Table CC.1 for a mapping of the clauses and subclauses of this standard to essential principles of ISO/TR 16142:2006.

Table CC.1 – Correspondence between this particular standard and the essential principles

Corresponding essential principle of ISO/TR 16142:2006	Clause(s)/sub-clause(s) of this International Standard	Qualifying remarks/Notes
A.1, A.2, A.3	All	
A.4	201.4, 201.7, 201.15	
A.5	201.4, 201.7, 201.15, 201.16	
A.6	201.4.3, 201.7.9.2.2	
A.7.1	201.9, 201.11, 201.15	
A.7.2	201.11, 201.15, 201.16	
A.7.3	201.4, 201.11	
A.7.4	-	
A.7.5	201.11, 201.13	
A.7.6	201.11, 201.13	
A.8.1	201.11, 201.16	
A.8.1.1	-	
A.8.1.2	-	
A.8.2	201.11	
A.8.3	201.11	
A.8.4	201.11	
A.8.5	201.11	
A.8.6	201.7	
A.9.1	201.4, 201.8, 201.9, 201.11, 201.14, 201.16, 201.101, 201.102	
A.9.2	201.4.3, 201.5, 201.8, 201.9, 201.12, 201.15, 201.103, 201.104, 201.105, 202	
A.9.3	201.4, 201.8, 201.11, 201.13, 201.15	
A.10.1	201.4, 201.12	

Table CC.1 *(continued)*

Corresponding essential principle of ISO/TR 16142:2006	Clause(s)/sub-clause(s) of this International Standard	Qualifying remarks/Notes
A.10.2	201.4, 201.12	
A.10.3	201.7	
A.11.1	201.4, 201.10, 201.12, 201.17, 202	
A.11.2.1	201.4, 201.10, 201.12	
A.11.2.2	201.4, 201.12	
A.11.3	201.4, 201.10, 201.12	
A.11.4	201.4, 201.7	
A.11.5.1	201.4, 201.10, 201.12	
A.11.5.2	201.4, 201.10, 201.12	
A.11.5.3	201.4, 201.10, 201.12	
A.12.1	201.4, 201.14	
A.12.2	201.11.8	
A.12.3	201.4, 201.7, 201.12, 201.11.8	
A.12.4	201.4, 201.7, 201.12	
A.12.5	201.4, 201.17, 202	
A.12.6	201.4, 201.8	
A.12.7.1	201.4, 201.9, 201.15	
A.12.7.2	201.4, 201.9	
A.12.7.3	201.4, 201.9	
A.12.7.4	201.4, 201.8	
A.12.7.5	201.4, 201.8, 201.11, 201.15, 201.16	
A.12.8.1	201.4, 201.12, 201.105	
A.12.8.2	201.4, 201.7, 201.12	
A.12.8.3	201.4, 201.7, 201.12	
A.13.1	201.7, 201.16	
A.14.1	201.4, 201.11, 19	

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