

American National Standard



ANSI/AAMI/ ISO 81060- 2:2019

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

Objectives and uses of AAMI standards and recommended practices

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

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

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

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

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

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

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

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

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

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

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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 Online monthly newsletter. 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 Standards Monitor Online.

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

Approved 22 March 2019 by
AAMI

Approved 10 May 2019 by
American National Standards Institute, Inc.

Abstract: Specifies the requirements and methods for the clinical investigation of medical electrical equipment used for the intermittent non-invasive automated estimation of the arterial blood pressure by utilizing cuff. This document 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 document 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 and blood pressure monitors for the home healthcare environment for self-measurement as well as use in a professional healthcare facility).

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

AAMI Standard

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Contents

Page

Committee representation.....	iv
Background of ANSI/AAMI adoption of ISO 81060-2:2018	vi
Foreword.....	vii
Introduction	viii
1 Scope.....	1
2 Normative references	1
3 Terms and definitions.....	2
4 General requirements for CLINICAL INVESTIGATIONS	2
5 CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER.....	3
6 CLINICAL INVESTIGATION with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT	18
7 * Pregnant PATIENT populations.....	25
Annex A (informative) Rationale and guidance	26
Annex B (informative) Reference to the ESSENTIAL PRINCIPLES	34
Annex C (informative) Terminology—alphabetized index of defined terms	35
Bibliography	36

Committee representation

Association for the Advancement of Medical Instrumentation Sphygmomanometers Device Committee

The adoption of IEC 80601-2-30 as a revision to an existing national standard, ANSI/AAM/IEC 80601-2-30:2009 +A1:2013, was initiated by the AAMI Sphygmomanometer Committee. U.S. representatives played an active role in developing the IEC standard.

Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

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

Cochairs: *Tammy Brady, MD, PhD*
David Quinn

Members: *Bruce Alpert, MD*
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Jim Brown, Colder Products Company
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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 ANSI/AAMI adoption of ISO 81060-2:2018

As indicated in the foreword to the main body of this document (page vii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO Member bodies that took an active role in the development of this document, which was developed by a Joint Working Group between IEC Technical Subcommittee 62D, Electromedical equipment, and ISO Technical Subcommittee 121/SC 3, Lung ventilators and related equipment.

U.S. participation in ISO/TC 121/SC 3 and IEC/SC 62D is organized through the U.S. Technical Advisory Group (TAG) for both of these international groups, administered by AAMI on behalf of the American National Standards Institute. The U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the final draft of ISO 81060-2, the AAMI SP, Sphygmomanometer Committee decided to adopt it verbatim.

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

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

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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 advances are made in technology and as new data come to light.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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

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

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see <http://patents.iec.ch>).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*.

This third edition cancels and replaces the second edition (ISO 81060-2:2013), which has been technically revised.

The main changes compared to the previous edition are as follows:

- same arm simultaneous method has been deleted;
- numerous clarifications have been added and kPa equivalent values for the mmHg values have been included.

A list of all parts in the ISO/IEC 81060 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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

BLOOD PRESSURE serves as aid to control the drug titration and fluid management and to provide warning about the changes in PATIENT'S state of health.

Frequently determining BLOOD PRESSURE is routine during anaesthesia. BLOOD PRESSURE serves to aid to control drug titration and fluid management and to provide warning about the changes in the PATIENT'S state of health.

In this document, the following print types are used:

- requirements, compliance with which can be verified, and definitions: roman type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller roman type. Normative text of tables is also in a smaller roman type;
- *test methods: italic type*; and
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS TYPE.

In this document, 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 document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- “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 A.

Annex B maps the clauses and subclauses of this document with the ESSENTIAL PRINCIPLES of ISO 16142-1:2016.

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

1 Scope

This document specifies the requirements and methods for the CLINICAL INVESTIGATION of ME EQUIPMENT used for the INTERMITTENT non-invasive automated estimation of the arterial BLOOD PRESSURE by utilizing a CUFF.

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

EXAMPLE AUTOMATED SPHYGMOMANOMETER as given in IEC 80601-2-30 undergoing CLINICAL INVESTIGATION according to this document.

This document specifies additional disclosure requirements for the ACCOMPANYING DOCUMENTS of SPHYGMOMANOMETERS that have passed a CLINICAL INVESTIGATION according to this document.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

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

ISO 14971:2007, *Medical devices—Application of risk management to medical devices*

ISO 16142-1:2016, *Medical devices—Recognized essential principles of safety and performance of medical devices—Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

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

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

IEC 60601-1-11:2015, *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*

IEC 60601-2-34:2011, *Medical electrical equipment—Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment*

IEC 80601-2-30:2018, *Medical electrical equipment—Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14155:2011, ISO 14971:2007, ISO 16142-1:2016, ISO 81060-1:2007, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-11:2015, IEC 60601-2-34:2011 and IEC 80601-2-30:2018, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

NOTE For convenience, an alphabetized index of defined terms is found in Annex C.

3.1

intermittent

<non-invasive SPHYGMOMANOMETER> utilizing a PROCESS of estimating BLOOD PRESSURE that provides a single set of pressure values from a number of heart beats

3.2

reference

ref

established accuracy used for the CLINICAL INVESTIGATION of other instruments

3.3

sphygmomanometer

ME EQUIPMENT for non-invasive estimation of systemic arterial BLOOD PRESSURE

3.4

sphygmomanometer-under-test

sut

AUTOMATED SPHYGMOMANOMETER undergoing CLINICAL INVESTIGATION

4 General requirements for CLINICAL INVESTIGATIONS

4.1 CLINICAL INVESTIGATION methods

- a) AUTOMATED SPHYGMOMANOMETERS shall undergo CLINICAL INVESTIGATION according to this document in each mode of operation by either using:

- 1) a non-invasive auscultatory REFERENCE SPHYGMOMANOMETER at the upper arm; or
- 2) a REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT.

EXAMPLE 1 Adult and neonatal modes.

EXAMPLE 2 Slow and fast CUFF deflation rate modes.

- b) A clinical investigation shall be considered a type test.
- c) An automated sphygmomanometer intending to display central or aortic blood pressure shall utilize a central or aortic invasive reference site for clinical investigation (see 6.2.2).

NOTE Such an automated SPHYGMOMANOMETER is investigated according to Clause 6.

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

4.2 Good clinical practice

- a) All CLINICAL INVESTIGATIONS shall comply with the requirements of ISO 14155:2011.
- b) CLINICAL INVESTIGATION with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT should not be used for PATIENTS or subjects solely for the purpose of investigating SPHYGMOMANOMETER performance.

NOTE Some authorities having jurisdiction have additional requirements.

- c) The requirements of this document, which are more specific than the corresponding requirements of ISO 14155:2011, shall prevail.

Check compliance by application of the requirements of ISO 14155:2011.

4.3 Status of previous CLINICAL INVESTIGATIONS

The CLINICAL INVESTIGATION results for SPHYGMOMANOMETERS that have been successfully clinically investigated according to previous versions of ISO 81060-2 remain valid and a CLINICAL INVESTIGATION need not be repeated to comply with this document.

4.4 Disclosure of summary of CLINICAL INVESTIGATION

The technical description of a SPHYGMOMANOMETER shall contain contact information permitting the RESPONSIBLE ORGANIZATION to acquire a copy of the summary of the CLINICAL INVESTIGATION.

5 CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER

5.1 Subject requirements

5.1.1 * Number

- a) An auscultatory REFERENCE SPHYGMOMANOMETER CLINICAL INVESTIGATION shall consist of a minimum of 85 subjects.
- b) If not otherwise specified, at least three valid paired BLOOD PRESSURE values shall be taken for each subject [see 5.2.4.1.1 o)].

- c) There shall be a minimum of 255 valid paired BLOOD PRESSURE values.

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

5.1.2 * Gender distribution

- a) At least 30 % of the subjects shall be male.
- b) At least 30 % of the subjects shall be female.

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

5.1.3 * Age distribution

- a) For a SPHYGMOMANOMETER intended for use on adults or adolescent PATIENTS, the age of every subject included in the CLINICAL INVESTIGATION shall be greater than 12 years.

NOTE 1 Minimum total of 85 subjects.

- b) For a SPHYGMOMANOMETER additionally intended for use in children, 35 child subjects aged between 3 years and 12 years shall be included in the CLINICAL INVESTIGATION.

NOTE 2 Minimum total of 85 subjects (35 children aged 3-12 years and 50 subjects older than 12 years).

- c) 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 such a study, children are exempt from the BLOOD PRESSURE distribution requirements of 5.1.5.
- d) Children aged less than 3 years shall not be included in a CLINICAL INVESTIGATION utilizing auscultatory REFERENCE readings by observers with a REFERENCE SPHYGMOMANOMETER.

Check compliance by inspection of the ACCOMPANYING DOCUMENT and the CLINICAL INVESTIGATION REPORT.

5.1.4 * Limb size distribution

- a) For a SPHYGMOMANOMETER intended for use with a single CUFF size:
 - 1) 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;
 - 2) at least 40 % of the subjects shall have a limb circumference within the lower half of the specified range of use of the CUFF;
 - 3) at least 20 % of the subjects shall have a limb circumference which lies within the upper quarter of the specified range of use of the CUFF;
 - 4) at least 20 % of the subjects shall have a limb circumference within the lower quarter of the specified range of use of the CUFF; and
 - 5) at least 10 % of the subjects shall have a limb circumference which lies within the upper octal of the specified range of use of the CUFF; and
 - 6) at least 10 % of the subjects shall have a limb circumference within the lower octal of the specified range of use of the CUFF.

b) For a SPHYGMOMANOMETER intended for use with multiple CUFF sizes:

- 1) each CUFF size shall be tested on at least $\frac{1}{2 \times n}$ of the total number of subjects, where n is the number of CUFF sizes; and
- 2) 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
- 3) at least 40 % of the subjects shall have a limb circumference within the lower half of the specified range of use of the CUFF.

Check compliance by inspection of the ACCOMPANYING DOCUMENT and the CLINICAL INVESTIGATION REPORT.

5.1.5 Blood pressure distribution

- a) At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≤ 100 mmHg (13,33 kPa).
- b) At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≥ 160 mmHg (21,33 kPa).
- c) At least 20 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≥ 140 mmHg (18,66 kPa).
- d) At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≤ 60 mmHg (8,0 kPa).
- e) At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≥ 100 mmHg (13,33 kPa).
- f) At least 20 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≥ 85 mmHg (11,33 kPa).

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

5.1.6 * Special PATIENT populations

- a) 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 undergo CLINICAL INVESTIGATION in those PATIENT populations.

NOTE Clause 7 has a specific example of a special PATIENT population with specific requirements.

- b) If the SPHYGMOMANOMETER has passed CLINICAL INVESTIGATION according to the requirements of 5.1.1 and 5.2, it shall then undergo CLINICAL INVESTIGATION in at least an additional 35 special population subjects.
- c) If the SPHYGMOMANOMETER has not successfully undergone CLINICAL INVESTIGATION according to the requirements of 5.1.1 and 5.2, the CLINICAL INVESTIGATION in accordance with the requirements of 5.1.1 and 5.2 shall consist only of subjects from the special PATIENT population.
- d) The special PATIENT population shall be defined in clear terms and address the following attributes: