INTERNATIONAL STANDARD

ISO 81060-2

Third edition
2018-11

Non-invasive sphygmomanometers —

Part 2: Clinical investigation of intermittent automated measurement type

Sphygmomanomètres non invasifs —

Partie 2: Investigation clinique pour type ponctuel à mesurage automatique

Reference number
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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 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:

1) gender (see 5.1.2);

2) age (see 5.1.3);

3) limb size (see 5.1.4); and

4) BLOOD PRESSURE (see 5.1.5).

e) A summary of the definition of the special PATIENT population 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 CLINICAL INVESTIGATION method with a REFERENCE SPHYGMOMANOMETER

5.2.1 * Subject preparation

a) Unless otherwise indicated by the instructions for use of the SPHYGMOMANOMETER-UNDER-TEST, position the subject such that the subject:

1) is comfortable;

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

2) has the back, elbow and forearm supported;

3) has the measurement site at the level of the left ventricle of the heart.

b) It is recommended that:

1) the subject be as relaxed as possible; and

2) the subject avoids talking during the entire PROCEDURE.

c) The CUFF shall be applied on the bare arm and there shall be no arm compression proximal to the CUFF.

d) Before the first REFERENCE reading is taken, 5 min should elapse.

NOTE Additional details can be found in Reference [16].

Check compliance by inspection of the instructions for use and the CLINICAL INVESTIGATION REPORT.

5.2.2 * Observer preparation

a) Observers shall be trained in using a proper methodology for performing a resting BLOOD PRESSURE reading by utilizing an accepted clinical protocol for BLOOD PRESSURE measurement. References [15], [16], and [25] contain additional information.

b) Observers shall have sufficient practice in performing BLOOD PRESSURE readings.

c) Each observer's recording of observations of the REFERENCE SPHYGMOMANOMETER shall not be visible to the other observer.

d) The DETERMINATIONS of the SPHYGMOMANOMETER-UNDER-TEST shall not be visible to either of these observers.

EXAMPLE 1 Utilizing a third observer for recording the DETERMINATIONS of the SPHYGMOMANOMETER-UNDER-TEST.

EXAMPLE 2 Utilizing an electronic means for recording the DETERMINATIONS of the SPHYGMOMANOMETER-UNDER-TEST.

e) The Korotkoff sound [fifth phase (K5)] shall be used by the observers for determining the REFERENCE DIASTOLIC BLOOD PRESSURE.

f) If the Korotkoff sound [fifth phase (K5)] for determining REFERENCE DIASTOLIC BLOOD PRESSURE is not audible, the subject shall be excluded.

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

5.2.3 * REFERENCE readings

a) Two observers shall simultaneously determine the SYSTOLIC BLOOD PRESSURE and DIASTOLIC BLOOD PRESSURE on each subject using a double stethoscope.

b) Unless the SPHYGMOMANOMETER-UNDER-TEST is intended for use during significantly irregular heart rhythm, if either observer detects significantly irregular heart rhythm, that reading shall be excluded.

EXAMPLE Bigeminy, trigeminy, isolated ventricular premature beat (VPB), atrial fibrillation.

NOTE 1 Although CLINICAL INVESTIGATION 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.

c) Any pair of observers' SYSTOLIC BLOOD PRESSURE VALUE or DIASTOLIC BLOOD PRESSURE VALUE with a difference greater than 4 mmHg (0,53 kPa) shall be excluded.

d) The observers' individual values of each reading shall be averaged according to Formula (1) to create the REFERENCE BLOOD PRESSURE value.

$$p_{\mathrm{REF}_i} = \frac{p_{\mathrm{REF}_{i,1}} + p_{\mathrm{REF}_{i,2}}}{2} \quad (1)$$

where

$p_{\mathrm{REF}_{i,1}}$ is the BLOOD PRESSURE determined by observer 1 for the i^{th} reading;

$p_{\mathrm{REF}_{i,2}}$ is the BLOOD PRESSURE determined by observer 2 for the i^{th} reading;

p_{REF_i} is the REFERENCE BLOOD PRESSURE value for the i^{th} reading.

e) The observer-to-observer differences shall be reviewed after completing a set of pairs of test-REFERENCE values.

1) If any readings are excluded, additional pair(s) of readings shall be taken to ensure that the required number of valid test-REFERENCE pairs are available.

2) A maximum of eight pairs of readings per subject shall be taken.

f) Use a REFERENCE SPHYGMOMANOMETER that complies with the requirements of ISO 81060-1, except that the maximum permissible error shall be ±1 mmHg (0,13 kPa).

1) Reading of the values on the REFERENCE SPHYGMOMANOMETER should be as accurate as possible.

2) When reading the value on the REFERENCE SPHYGMOMANOMETER, the observers should avoid parallax errors and rounding.

NOTE 2 Rounding has a negative effect on the results of the CLINICAL INVESTIGATION.

g) Measurement of the upper arm circumference:

1) The upper arm midpoint is first determined by marking the arm posteriorly at a point halfway between the acromion and olecranon, measured while the arm is flexed 90 degrees at the elbow with the palm facing up.

2) The subject's upper arm circumference shall be determined by measuring at the midpoint of the upper arm while the elbow is relaxed and the arm is dangling freely to the side.

h) *CUFFS for the reference SPHYGMOMANOMETER shall have:

1) a bladder length of 75 % to 100 % of the upper arm circumference; and

2) a bladder width of 37 % to 50 % of the upper arm circumference.

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

5.2.4 CLINICAL INVESTIGATION methods

5.2.4.1 Same arm sequential method

5.2.4.1.1 * PROCEDURE

a) Either arm may be utilized.