SLOVENSKI STANDARD
oSIST prEN ISO 81060-2:2026

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Neinvazivni sfigmomanometri - 2. del: Klinično preverjanje delovanja avtomatiziranih vrst merjenja s prekinitvami (ISO/DIS 81060-2:2026)

Non-invasive sphygmomanometers - Part 2: Clinical performance verification of intermittent automated measurement type (ISO/DIS 81060-2:2026)

Nichtinvasive Blutdruckmessgeräte ¿ Teil 2: Klinische Leistungsbewertungsprüfung der intermittierenden automatisierten Bauart (ISO/DIS 81060-2:2026)

Sphygmomanomètres non invasifs - Partie 2: Vérification des performances cliniques pour type ponctuel à mesurage automatique (ISO/DIS 81060-2:2026)

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Non-invasive sphygmomanometers —

Part 2: Clinical performance verification of intermittent automated measurement type

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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 [1]), which has been technically revised.

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

— same arm simultaneous method has been reinstated;

— numerous clarifications have been added and kPa equivalent values for the mmHg values have been included.

A list of all parts in the ISO 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 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” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

Annex A contains rationale and guidance.

Annex B maps the clauses and subclauses of this document with the relevant International Medical Device Regulators Forum (IMDRF) essential principles.

Annex C contains an alphabetized index of defined terms.

Non-invasive sphygmomanometers —

Part 2:
Clinical performance verification of intermittent automated measurement type

1 Scope (see Clause A.2)

This document specifies the requirement and methods for the clinical performance verification 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 environment and emergency medical services environment).

EXAMPLE Automated sphygmomanometer as given in IEC 80601-2-30 [2] undergoing clinical performance verification according to this document.

This document specifies additional disclosure requirements for the accompanying information of sphygmomanometers that conform with this document.

This document is not applicable to the clinical performance verification of a non-automated sphygmomanometer as given in ISO 81060-1:2007 or invasive blood pressure monitoring equipment as given in IEC 60601-2-34.

This document is not applicable to clinical performance verification of a set of cuffs that are not of same materials and construction. Each type of cuff set is required to be evaluated separately according to this document.

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.

ISO 14155:2026, *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 60601-2-34, *Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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 Table C.1.

3.1
accompanying information
DEPRECATED: accompanying documents
DEPRECATED: accompanying documention
information supplied by the *manufacturer* (3.15) with or marked on a medical device or accessory for the user or the *responsible organisation* (3.23), particularly regarding safe use

[SOURCE: ISO 20417:2026 [3], 3.2, modified – deleted notes.]

3.2
automated sphygmomanometer
ME equipment (3.17) used for the non-invasive estimation of the *blood pressure* (3.4) by utilizing an inflatable *cuff* (3.7), a pressure transducer, a valve for deflation and displays used in conjunction with automatic methods for determining *blood pressure* (3.4)

Note 1 to entry: Components of an *automated sphygmomanometer* (3.2) include manometer, *cuff* (3.7), valve for deflation (often in combination with the valve for rapidly exhausting the pneumatic system), pump for inflation of the *bladder* (3.3) and connection tubing.

[SOURCE: IEC 80601-2-30 [2]:—, 201.3.201]

3.3
bladder
that part of the *cuff* (3.7) that is inflatable

[SOURCE: ISO 81060-1:2007, 3.2]

3.4
blood pressure
pressure in the systemic arterial system of the body

[SOURCE: ISO 81060-1:2007, 3.3]

3.5
clinical investigation
systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness or safety of a medical device

[SOURCE: ISO 14155:2026, 3.9]

3.6
clinical investigation report
document describing the design, conduct, statistical analysis and results of a *clinical investigation* (3.5)

[SOURCE: ISO 14155:2026, 3.11]

3.7
cuff
part of the *sphygmomanometer* (3.24) that is wrapped around the limb of the *patient* (3.20)

Note 1 to entry: A *cuff* (3.7) usually comprises a *bladder* (3.3) and an inelastic part that encloses the *bladder* (3.3), or has an integral *bladder* (3.3) (i.e. the *cuff* (3.7), including the *bladder* (3.3), is one piece).

[SOURCE: IEC 80601-2-30 [2]:—, 201.3.202]

3.8
determination
determination value
result of the process of estimating *blood pressure* (3.4) by a *sphygmomanometer* (3.24)

[SOURCE: IEC 80601-2-30 [2]:—, 201.3.203]

3.9
diastolic blood pressure
diastolic blood pressure value
minimum value of the *blood pressure* (3.4) resulting from a relaxation of the systemic ventricle

Note 1 to entry: Because of hydrostatic effects, this value should be determined with the *cuff* (3.7) at the same elevation as the heart (phlebostatic axis).

[SOURCE: IEC 80601-2-30 [2]:—, 201.3.204]

3.10
essential principles
essential principles of safety and performance
fundamental high-level requirements that, when conformed with, ensure a medical device or accessory is safe and performs as intended

[SOURCE: ISO 20417:2026 [3], 3.10]

3.11
intended use
intended purpose
use for which a product or process is intended according to the specifications, *instructions for use* (3.13) and other information supplied by the *manufacturer* (3.15)

[SOURCE: ISO/IEC Guide 63:2019 [4], 3.4, modified — deleted “or service” and replaced “instructions” with “instructions for use”, “provided” with “supplied”, added “other” and deleted note.]

3.12
intermittent
⟨non-invasive sphygmomanometer⟩ utilizing a process of estimating *blood pressure* (3.4) that provides a single set of pressure values from a number of heart beats

3.13
IFU
instructions for use
package insert
portion of the *accompanying information* (3.1) that is:

— directed to the primary user; and

— essential for the safe and effective use of a medical device or accessory

[SOURCE: ISO 20417:2026 [3], 3.16, modified —deleted notes.]

3.14
invasive blood pressure monitoring equipment
ME equipment (3.17) including associated pressure transducers, that is used for internal measurement or monitoring of circulatory system pressures

[SOURCE: IEC 60601-2-34, 201.3.63]

3.15
manufacturer
organization with responsibility for design or manufacture of a medical device or accessory with the intention of making the medical device or accessory available for use, under its name; whether such a medical device or accessory is designed or manufactured by that organization itself or on its behalf by another organization

[SOURCE: IEC 60050-880 [5]:—, 880-12-14, modified — deleted notes.]

3.16
mean arterial pressure
MAP
value of the integral of one heartbeat cycle of the *blood pressure* (3.4) curve divided by the time of that cycle

Note 1 to entry: Because of hydrostatic effects, this value should be determined with the *cuff* (3.7) at the same elevation as the heart (phlebostatic axis).

[SOURCE: IEC 80601-2-30 [2]:—, 201.3.206]

3.17
ME equipment
medical electrical equipment
electrical medical device having an applied part or transferring energy or substances to or from the *patient* (3.20) or detecting such energy or substance transfer to or from the *patient* (3.20)

[SOURCE: IEC 60050-880 [5]:—, 880-08-26, modified — deleted notes.]

3.18
non-automated sphygmomanometer
ME equipment (3.17) used for the non-invasive estimation of *blood pressure* (3.4) by utilizing an inflatable *cuff* (3.7) 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* (3.4)

Note 1 to entry: Components of these instruments include a manometer, *cuff* (3.7), 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* (3.3), and connection tubing. A *non-automated sphygmomanometer* (3.18) can also contain electro-mechanical components for *cuff* (3.7) pressure control.

[SOURCE: IEC 80601-2-30 [2]:—, 201.3.208]

3.19
objective evidence
data supporting the existence or verity of something

Note 1 to entry: *Objective evidence* (3.19) can be obtained through observation, measurement, test or by other means.

[SOURCE: ISO 14971:2019 [6], 3.11]

3.20
patient
living being receiving healthcare services

Note 1 to entry: Living being means person or animal.

Note 2 to entry: Healthcare services include diagnostic, therapeutic, monitoring, surgical or dental procedures and can be delivered in the home healthcare environment, professional healthcare environment, EMS environment or a special environment.

Note 3 to entry: A *patient* (3.20) can be a user.

Note 4 to entry: Safety limit values can be different for different *patients* (3.20), especially for animal *patients* (3.20).

[SOURCE: IEC 60050-880 [5]:—, 880-12-16]

3.21
procedure
specified way to carry out an activity or a process

Note 1 to entry: *Procedures* (3.21) can be documented or not.

[SOURCE: ISO 9000:2015 [7], 3.4.5]

3.22
reference
measurement that has a known accuracy

3.23
responsible organisation
organization accountable for the installation, use, processing, maintenance, decommissioning or disposal of a medical device or accessory and their detachable parts

Note 1 to entry: The responsible organization includes those individuals performing the activities for the responsible organization including the preparation of the infrastructure needed to support the installation.

Note 2 to entry: The responsible organization can be, for example, a hospital, an individual healthcare professional provider or a lay person. In home use applications, the *patient* (3.20), user and responsible organization can be one and the same person.

Note 3 to entry: Education and training are included in "use".

[SOURCE: IEC 60050-880 [5]:—, 880-12-18]

3.24
sphygmomanometer
medical device for non-invasive estimation of systemic arterial *blood pressure* (3.4)

3.25
sphygmomanometer-under-test
automated sphygmomanometer (3.2) undergoing clinical performance *verification* (3.30)

3.26
systolic blood pressure
systolic blood pressure value
maximum value of the *blood pressure* (3.4) resulting from a contraction of the systemic ventricle

Note 1 to entry: Because of hydrostatic effects, this value should be determined with the *cuff* (3.7) at the same elevation as the heart (phlebostatic axis).

[SOURCE: IEC 80601-2-30 [2]:—, 201.3.216]

3.27
technical description
portion of the *accompanying information* (3.1) that is:

— directed to the *responsible organisation* (3.23) and service personnel; and

— essential for installation, preparation for the first use and safe use, maintenance or repair as well as processing, transport or storage for the expected lifetime including decommissioning or disposal of a medical device or accessory

[SOURCE: ISO 20417:2026 [3], 3.43, modified —deleted note 2.]

3.28
total limb circumference range
range, from the smallest limb circumference to the largest limb circumference, intended by the *manufacturer* (3.15) for use with the *sphygmomanometer* (3.24)

3.29
type test
test on one or more representative samples of a product, as designed and manufactured, with the objective of determining conformity

Note 1 to entry: A representative sample means taken from production or being a production equivalent.

[SOURCE: IEC 60050-880 [5]:—, 880-09-16]

3.30
verification
verified
confirmation, through the provision of *objective evidence* (3.19), that specified requirements have been fulfilled

Note 1 to entry: The *objective evidence* (3.19) needed for a *verification* (3.30) can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for *verification* (3.30) are sometimes called a qualification process. In short, *verification* (3.30) gives the confidence that the system was built correctly to meet identified requirements and specifications.

Note 3 to entry: In the case of software specifically, *verification* (3.30) is conducted at various stages of development, examining the software and its constituents to determine conformity.

Note 4 to entry: The word "*verified* (3.30)" is used to designate the corresponding status.

Note 5 to entry: In design and development, *verification* (3.30) concerns the inspection of the result of an activity to determine conformity with the stated requirements.

[SOURCE: IEC 60050-880 [5]:—, 880-14-24]

4 General requirements for clinical investigations

4.1 Clinical investigation methods

a) An automated sphygmomanometer shall undergo a clinical performance verification according to this document in each mode of operation by either using:

   EXAMPLE 1 Adult and neonatal modes.

   EXAMPLE 2 Slow and fast cuff deflation rate modes.

   1) a reference non-invasive auscultatory sphygmomanometer at the upper arm; or

   2) a reference invasive blood pressure monitoring equipment.

b) The clinical investigation shall be considered a type test.

c) An automated sphygmomanometer intending to display central or aortic blood pressure shall utilize a reference central or aortic invasive site for the clinical performance verification (see 6.2.2).

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

d) Consider conformity 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 performance verifications shall be clinical investigations in accordance with the requirements of ISO 14155:2026.

   1) The requirements of this document, which are more specific than the corresponding requirements of ISO 14155:2026, shall prevail.

b) Clinical performance verification 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) All subjects shall be unique.

d) A subject shall only be used once in a clinical performance verification.

e) Check conformity by application of the requirements of ISO 14155:2026 and by inspection of the clinical investigation report.

4.3 Status of previous clinical performance verifications

The clinical performance verification results for sphygmomanometers that have been successfully investigated according to previous versions of ISO 81060-2:2018 [8] remain valid and a clinical performance verification need not be repeated to conform with this document.

4.4 Disclosure of summary of clinical performance verification

The technical description of a sphygmomanometer shall contain contact information permitting the responsible organization to acquire a copy of the summary of the clinical performance verification.

5 Clinical performance verification with a reference auscultatory sphygmomanometer

5.1 Subject requirements

5.1.1 Number (see Clause A.3)

a) A reference auscultatory sphygmomanometer clinical performance verification shall consist of a minimum of 85 subjects.

b) If not otherwise specified, at least three valid paired blood pressures shall be taken for each subject.

c) There shall be a minimum of 255 valid paired blood pressures.

Check conformity by inspection of the clinical investigation report.

5.1.2 Sex distribution (see Clause A.4)

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

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

Check conformity by inspection of the clinical investigation report.