BS EN ISO 81060-2:2019+A2:2024

BSI Standards Publication

Non-invasive sphygmomanometers

Part 2: Clinical investigation of intermittent automated measurement type

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Full document details: BS EN ISO 81060-2:2019+A2:2024

National foreword

This British Standard is the UK implementation of EN ISO 81060-2:2019+A2:2024. It is identical to ISO 81060-2:2018, incorporating amendments 1:2020 and 2:2024. It supersedes BS EN ISO 81060-2:2019+A1:2020, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. Therefore Annex ZA/ZZ in the European text, and references to EU legislation, are still valid for this market.

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Date	Text affected
30 September 2020	Implementation of ISO amendment 1:2020 with CEN endorsement A1:2020
30 April 2024	Implementation of ISO amendment 2:2024 with CEN endorsement A2:2024

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 81060-2:2019+A2

April 2024

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English Version

Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type (ISO 81060-2:2018)

Sphygmomanomètres non invasifs - Partie 2: Investigation clinique pour type ponctuel à mesurage automatique (ISO 81060-2:2018)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung der intermittierenden automatisierten Bauart (ISO 81060-2:2018)

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European foreword

This document (EN ISO 81060-2:2019) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by November 2022.

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

This document supersedes EN ISO 81060-2:2014.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard “within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes ZZ.

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

Table — Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 14155:2011	EN ISO 14155:2011	ISO 14155:2011
ISO 14971:2007	EN ISO 14971:2012	ISO 14971:2007
ISO 16142-1:2016	–	ISO 16142-1:2016
IEC 60601-1:2005+AMD1:2012	EN 60601-1:2006 +AMD1:2013 + AMD12:2014	IEC 60601-1:2005 +AMD1:2012
IEC 60601-1-11:2015	EN 60601-1-11:2015	IEC 60601-1-11:2015
IEC 60601-2-34:2011	EN 60601-2-34:2014	IEC 60601-2-34:2011
IEC 80601-2-30:2018	EN 80601-2-30:2019	IEC 80601-2-30:2018
ISO 81060-1:2007	EN ISO 81060-1:2012	ISO 81060-1:2007

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Endorsement notice

The text of ISO 81060-2:2018 has been approved by CEN as EN ISO 81060-2:2019 without any modification.

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Foreword to amendment A1

The text of ISO 81060-2:2018/Amd 1:2020 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 81060-2:2019/A1:2020 by Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 81060-2:2019 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2021, and conflicting national standards shall be withdrawn at the latest by March 2021.

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Endorsement notice

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European foreword to amendment A2

This document (EN ISO 81060-2:2019/A2:2024) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 81060-2:2019 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.

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Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's joint standardization request M/295 concerning the development of European standards relating to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
10.1	4, 5 and 6	Only the characteristics of the measurement performance (accuracy), as well as the corresponding tests methods, are addressed.

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Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
13.6 a) j)	5.1.6 e), 6.2.1 d) 2), 6.2.2 a), 6.2.7, 7 h) and 7 i)	Covered only in respect of certain additional warnings contained in the indicated subclauses related to the following: – definition of special patient population; – that effectiveness has not been established in the presence of any dysrhythmias included in the exclusion criteria, where applicable; – specifying the arterial reference site; – disclosure of the method used to determine and verify the mean arterial pressure; – suitability for use with pregnant (including pre-eclamptic) patients, where applicable; – that effectiveness has not been established in pregnant (including pre-eclamptic) patients, where applicable.
Annex X, 2.3.1 to 2.3.3	5, 6 and 7	Covered only in respect of carrying our clinical investigations with – reference auscultatory sphygmomanometers; – reference invasive blood pressure monitoring equipment; and – pregnant patient populations, where applicable.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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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.

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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.

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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.

〈A2〉 This document is not applicable to clinical investigations 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. 〈A2〉

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*

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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

3.5 A1
TOTAL LIMB CIRCUMFERENCE RANGE
range, from the smallest limb circumference to the largest limb circumference, intended by the MANUFACTURER for use with the AUTOMATED SPHYGMOMANOMETER A1

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.

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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.

A2 d) All subjects shall be unique.

e) A subject shall only be used once in a clinical investigation. A2

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.

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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.

A2 5.1.4 * Limb size distribution

a) For a CLINICAL INVESTIGATION with only one CUFF, the requirements in 5.1.4 d) to i) apply based on the limb circumference range (r_{cuff}) of that CUFF.

b) For a CLINICAL INVESTIGATION with more than one CUFF to limit the overlap of all CUFFS intended for use with a SPHYGMOMANOMETER, Formula (17) shall apply.

c) If the distribution of CUFFS is not in accordance with Formula (17), multiple CLINICAL INVESTIGATIONS with subsets of these CUFFS shall be performed separately.

$$\frac{\sum r_{cuff}}{r_{total}} \leq 1{,}35 \qquad (17)$$

where

r_{cuff} is the limb circumference range for the individual CUFF in cm; and

r_{total} is the TOTAL LIMB CIRCUMFERENCE RANGE in cm.

d) For CUFFS having a size of the limb circumference range (r_{cuff}) of 12 cm or less:

1) at least 40 % of the subjects allocated to this CUFF 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 allocated to this CUFF shall have a limb circumference within the lower half of the specified range of use of the CUFF;

3) for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF having a size of the limb circumference range of 12 cm or less shall be tested on at least N_{cuff} subjects as calculated according to Formula (18); and

4) if N_{cuff}, according to Formula (18) is less than 12 subjects, N_{cuff} shall be a minimum of 12 subjects.

$$N_{cuff} = \frac{r_{cuff}}{2 \cdot r_{total}} \cdot N_{total} \qquad (18)$$

where

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