SLOVENSKI STANDARD
SIST EN ISO 81060-2:2014

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Nadomešča:
SIST EN 1060-4:2005

Neinvazivni sfigmomanometri - 2. del: Klinične raziskave avtomatiziranih vrst merjenja (ISO 81060-2:2013)

Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type (ISO 81060-2:2013)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung von Geräten der automatisierten Bauart (ISO 81060-2:2013)

Sphygmomanomètres non invasifs - Partie 2: Validation clinique pour type à mesurage automatique (ISO 81060-2:2013)

Ta slovenski standard je istoveten z: **EN ISO 81060-2:2014**

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11.040.55	Diagnostična oprema	Diagnostic equipment

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EUROPEAN STANDARD

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English Version

Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type (ISO 81060-2:2013)

Sphygmomanomètres non invasifs - Partie 2: Validation clinique pour type à mesurage automatique (ISO 81060-2:2013)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung von Geräten der automatisierten Bauart (ISO 81060-2:2013)

This European Standard was approved by CEN on 18 April 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 81060-2:2013 has been jointly prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and Sub-Committee IEC/SC 62D “Electromedical equipment” of the International Electrotechnical Commission (IEC) and has been taken over as EN ISO 81060-2:2014 by 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 October 2014, and conflicting national standards shall be withdrawn at the latest by April 2017.

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

This document supersedes EN 1060-4:2004.

EN ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

— *Part 1: Requirements and test methods for non-automated measurement type*

— *Part 2: Clinical validation of automated measurement type*

EN 80601-2-30, *Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*, is a related standard.

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

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 81060-2:2013 has been approved by CEN as EN ISO 81060-2:2014 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4 to 6	10.1	Only the characteristics of the measurement performance (accuracy), as well as the corresponding tests methods, are addressed.
5.1.6, 5.2.2, 6.2.1, 6.2.2, 6.2.7, 7	13.6	Only additional warnings and precautions specific to particular situations and subjects populations are addressed.
4.2	Annex X, 2.2	Normative reference to EN ISO 14155 in its entirety.
5 to 7	Annex X, 2.3.1 to 2.3.3	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 81060-2

Second edition
2013-05-01

Non-invasive sphygmomanometers —

Part 2: Clinical investigation of automated measurement type

Sphygmomanomètres non invasifs —

Partie 2: Validation clinique pour type à mesurage automatique

Reference number
ISO 81060-2:2013(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

This second edition cancels and replaces the first edition (ISO 81060-2:2009), subclauses 5.2.4.3.1 and 6.2.4 of which have been technically revised. Numerous clarifications have been added and kPa equivalent values for the mmHg values have been included in the standard, including the Criterion 2 requirements of 5.2.4.1.2. It also incorporates the Technical Corrigendum ISO 81060-2:2009/Cor 1:2011.

ISO 81060-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee 62D, *Electromedical equipment*, in accordance with ISO/IEC mode of cooperation 5.

ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

— *Part 1: Requirements and test methods for non-automated measurement type*

— *Part 2: Clinical investigation of automated measurement type*

In this document, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— test methods: *italic type*;

— terms defined in this document: SMALL CAPITALS TYPE.

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

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of ISO/TC 121 and IEC/TC 62 that the content of this part of ISO 81060 not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed, and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

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

Frequent determination of BLOOD PRESSURE is routine during anaesthesia. BLOOD PRESSURE serves to aid in drug titration and fluid management and to provide warning of conditions that could affect PATIENT morbidity and mortality.

Non-invasive sphygmomanometers —

Part 2:
Clinical investigation of the automated measurement type

1 Scope

This part of ISO 81060 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 part of ISO 81060 is applicable to all SPHYGMOMANOMETERS that sense or display pulsations, flow or sounds for the estimation, display or recording of BLOOD PRESSURE. These SPHYGMOMANOMETERS need not have automatic CUFF inflation.

This part of ISO 81060 covers SPHYGMOMANOMETERS intended for use in all PATIENT populations (e.g. all age and weight ranges), and all conditions of use (e.g. ambulatory BLOOD PRESSURE monitoring, stress testing BLOOD PRESSURE monitoring and BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT 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 part of ISO 81060.

This part of ISO 81060 specifies additional disclosure requirements for the ACCOMPANYING DOCUMENTS of SPHYGMOMANOMETERS that have undergone CLINICAL INVESTIGATION according to this part of ISO 81060.

This part of ISO 81060 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

IEC 80601-2-30:2009, *Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*

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

IEC 60601-1-11:2010, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14155, IEC 80601-2-30, IEC 60601-1, IEC 60601-1-11, IEC 60601-2-34 and the following apply.

NOTE For convenience, an alphabetized index of defined terms is found beginning on page 40.

3.1
REFERENCE, adj
established accuracy used for the CLINICAL INVESTIGATION of other instruments

3.2
SPHYGMOMANOMETER
ME EQUIPMENT for non-invasive estimation of systemic arterial BLOOD PRESSURE

3.3
SPHYGMOMANOMETER-UNDER-TEST
SPHYGMOMANOMETER undergoing CLINICAL INVESTIGATION

4 General requirements for CLINICAL INVESTIGATIONS

4.1 CLINICAL INVESTIGATION methods

SPHYGMOMANOMETERS other than NON-AUTOMATED SPHYGMOMANOMETERS shall undergo CLINICAL INVESTIGATION either by using a non-invasive (auscultatory) REFERENCE SPHYGMOMANOMETER or by using REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT according to this part of ISO 81060 in each mode of operation.

EXAMPLE 1 Adult and neonatal modes.

EXAMPLE 2 Slow and fast CUFF deflation rate modes.

A CLINICAL INVESTIGATION shall be considered a TYPE TEST.

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

4.2 Good clinical practice

All CLINICAL INVESTIGATIONS shall comply with the requirements of ISO 14155. 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.

The requirements of this International Standard, which are more specific than the corresponding requirements of ISO 14155, shall prevail.

Check compliance by application of the requirements of ISO 14155.

5 CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER

5.1 Subject requirements

5.1.1 * Number

An auscultatory REFERENCE SPHYGMOMANOMETER CLINICAL INVESTIGATION shall consist of a minimum of 85 subjects. If not otherwise specified, at least three valid BLOOD PRESSURE DETERMINATIONS shall be taken for each subject. There shall be a minimum of 255 valid paired BLOOD PRESSURE DETERMINATIONS.

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

5.1.2 * Gender distribution

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

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

5.1.3 * Age distribution

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

NOTE 1 Minimum total of 85 subjects.

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.

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.

Children aged less than 3 years shall not be included in a CLINICAL INVESTIGATION utilizing auscultatory DETERMINATIONS 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

For a SPHYGMOMANOMETER intended for use with a single CUFF size:

— at least 40 % of the subjects shall have a limb circumference which lies within the upper half of the specified range of use of the CUFF and at least 40 % shall have a limb circumference within the lower half; and

— 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 and at least 20 % shall have a limb circumference within the lower quarter.

For a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF size shall be tested on at least $\frac{1}{2 \times n}$ of the subjects, where n is the number of CUFF sizes.

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