SLOVENSKI STANDARD
oSIST prEN ISO 81060-2:2017

01-oktober-2017

Neinvazivni sfigmomanometri - 2. del: Klinične raziskave avtomatiziranih vrst merjenja s prekinitvami (ISO/DIS 81060-2:2017)

Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type (ISO/DIS 81060-2:2017)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung der intermittierenden automatisierten Bauart (ISO/DIS 81060-2:2017)

Sphygmomanomètres non invasifs - Partie 2: Validation clinique pour type intermittent à mesurage automatique (ISO/DIS 81060-2:2017)

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

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11.040.55	Diagnostična oprema	Diagnostic equipment

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DRAFT INTERNATIONAL STANDARD

ISO/DIS 81060-2

ISO/TC **121**/SC **3**

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Non-invasive sphygmomanometers —

Part 2:
Clinical investigation of intermittent automated measurement type

Sphygmomanomètres non invasifs —

Partie 2: Validation clinique pour type intermittent à mesurage automatique

ICS: 11.040.10

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

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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.

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 ISO documents 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 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).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

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

The most significant changes are the following modifications:

a) Same arm simultaneous method has been deleted;

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

European Foreword

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
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 80601-2-30:2009+AMD1:2013	EN 80601-2-30:2010 +AMD1:2015	IEC 80601-2-30:2009 +AMD1:2013
ISO 81060-1:2007	EN ISO 81060-1:2012	ISO 81060-1:2007

Introduction

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

Frequently determining the 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.

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.

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

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 the committees that the content of this document 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.

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

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

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 80601-2-30:2009, *Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*
+Amendment 1:2013

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, IEC 80601-2-30:2009+AMD1:2013, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-11:2015, IEC 60601-2-34:2011 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

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

3.1
INTERMITTENT
<adj> type of 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
<adj> 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 EVALUATION.

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 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.

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 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:

