Mitteinvasiivsed sfügmomanomeetrid. Osa 1: Mitteautomaatse mõõtmistüübi nõuded ja testmeetodid

Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)

EESTI STANDARDIKESKUS
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EESTI STANDARDI EESSÕNA	NATIONAL FOREWORD
See Eesti standard EVS-EN ISO 81060-1:2012 sisaldab Euroopa standardi EN ISO 81060-1:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 81060-1:2012 consists of the English text of the European standard EN ISO 81060-1:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 23.05.2012.	Date of Availability of the European standard is 23.05.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)

Sphygmomanomètres non invasifs - Partie 1: Exigences et méthodes d'essai pour type à mesurage non automatique (ISO 81060-1:2007)

Nicht invasive Blutdruckmessgeräte - Teil 1: Anforderungen und Prüfverfahren der nicht-automatisierten Bauart (ISO 81060-1:2007)

This European Standard was approved by CEN on 28 April 2012.

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
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 81060-1:2012: E

Foreword

The text of ISO 81060-1:2007 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 81060-1:2012 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 November 2012, and conflicting national standards shall be withdrawn at the latest by May 2015.

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 1060-1:1995+A2:2009, EN 1060-2:1995+A1:2009.

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.

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*

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, 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 81060-1:2007 has been approved by CEN as a EN ISO 81060-1:2012 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 *(1/3)*

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.4.3, 8.3, 8.4, 8.5	7.2	Prevention of risks related to mercury leakage and spillage only. Packaging is not addressed. Design and manufacture are addressed via tests on finished products.
8.3, 8.4, 8.5	7.5 (first sentence)	Only prevention of risks due to mercury leakage
10.1, 10.2	8.1	Only reduction of the risk of infection to a commonly accepted level is addressed (not “as far as possible”). Manufacturing processes are not addressed. Easy handling is not addressed.
10.3	8.4	
4.7 b)	8.7	ER 8.7 is partially addressed.
6.2, 7.1.2, 7.2.4, 7.2.5, 7.2.6, 12.2.1 c)	9.1	
6.3, 7.2.3	9.2 (1st indent)	Prevention of injury due to rough surfaces and prevention of injury due to excessive pressure are addressed.
6.2, 6.3, 6.4	9.2	ER 9.2 is partially addressed.
6.2	9.3	Only addressed for electrical devices via IEC 60601-1, Clauses 11 and 13.
4.4 e), 6.2, 7.1.1, 7.1.2, 7.2.1, 7.2.2, 7.4, 8.1, 9, 12.2.1 b), 12.2.1 l), 12.2.1 n), 12.2.1 q), 12.3.b), 12.3.c)	10.1	For electrical devices, see also IEC 60601-1 Clause 12, as required in Clause 6.2 of the present standard.

Table ZA.1 — *(2/3)*

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2, 4.3, 4.4 e), 4.5, 6.2,	10.2	For electrical devices, see also IEC 60601-1 Clauses 7 and 12, as required in Clause 6.2 of the present standard.
4.1, 6.2	10.3	For electrical devices, see also IEC 60601-1 subclause 7.4.3, as required in Clause 6.2 of the present standard.
6.2	12.1	Only addressed for electrical devices via IEC 60601-1, Clause 14.
6.2	12.1 a)	Only addressed for electrical devices via IEC 60601-1, Clause 14.
6.2	12.5	Only addressed for electrical devices via IEC 60601-1, Clause 17.
6.2	12.6	Only addressed for electrical devices via IEC 60601-1, Clause 8.
6.2, 6.3	12.7.1	For electrical devices, see also IEC 60601-1 Clauses 9 and 15, as required in Clause 6.2 of the present standard.
6.2	12.7.2	Only addressed for electrical devices via IEC 60601-1, Clause 9.
6.2	12.7.3	Only addressed for electrical devices via IEC 60601-1, Clause 9.
6.2	12.7.4	Only addressed for electrical devices via IEC 60601-1, Clauses 8 and 15.
6.2	12.7.5	Only addressed for electrical devices via IEC 60601-1, Clause 11.
12.2.1 f), 12.2.1 h)	12.9	
4, 6.2, 12	13.1	
4.4, 4.7, 12.2.1 h)	13.2	
4.4 a), 6.2, 12.1	13.3 a)	The part of ER 13.3.a) relating to the authorized representative is not addressed.
4.4 b), 4.7 a)	13.3 b)	
4.7 b)	13.3 c)	

Table ZA.1 — *(3/3)*

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.4 c)	13.3 d)	The presumption of conformity is only provided if the batch number is preceded by the word “LOT”.
4.7 c)	13.3 e)	
4.7 d)	13.3 f)	The presumption of conformity is only provided if the indication of single use is consistent across the Community.
4.7 e)	13.3 i)	
4.6 a), 4.6 b)	13.3 j)	
12.2.1 m), 12.2.1 n)	13.3 k)	
6.2	13.3 l)	
4.7 b)	13.3 m)	
4.6 b), 4.7 f), 12.2.1 a)	13.4	
4.4 b), 4.4 c), 6.2	13.5	
12.1, 12.2.1 g), 12.2.1 p), 12.2.1 r), 12.2.1 s)	13.6 a)	This Essential Requirement is partially addressed.
12.2.1.e), 12.2.1 k), 12.2.1 l), 12.2.4	13.6 c)	
12.2.1 e), 12.2.1 j), 12.2.1 k), 12.2.1 o), 12.2.1 s), 12.2.3	13.6 d)	
6.2	13.6 f)	ER 13.6 f) is addressed only for electrical devices via IEC 60601-1.
12.2.2	13.6 h)	The part of ER 13.6 h) relating to “single use” is not addressed.
12.2.1 c), k)	13.6 i)	For electrical devices, see also IEC 60601-1 Clause 7, as required in Clause 6.2 of the present standard.
4.4 d), 6.2, 12.2.1 t), 12.2.5	13.6 n)	

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

NOTE Table ZA.2 is only applicable to electrical devices.

Table ZA.2 – Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.5, 6.2	1.2.2	Only partly addressed
6.2	1.5.1	
7.2.6, 7.3	1.5.4	Errors of fitting are only reduced to a commonly accepted level, but are not made “impossible”
6.2	1.5.5	
6.2	1.5.6	
6.2	1.5.7	
6.2	1.6.3	Only partly addressed

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

Contents

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Introduction

The minimum safety requirements specified in this part of ISO 81060 are considered to provide a practical degree of safety in the operation of non-automated sphygmomanometers.

The requirements are followed by specifications for the relevant tests.

A “rationale and guidance” section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex A.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this part of ISO 81060 but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex A does not form part of the requirements of this part of ISO 81060.

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

Non-invasive sphygmomanometers —

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

1 * Scope

This part of ISO 81060 specifies requirements for non-automated sphygmomanometers, as defined in 3.11, and their accessories, which, by means of inflatable cuffs, are used for the non-invasive blood pressure measurement by operator observation.

This part of ISO 81060 specifies requirements for the safety and essential performance, including effectiveness and labelling, for non-automated sphygmomanometers and their accessories, including test methods to determine the accuracy of non-invasive blood pressure measurement.

The part of ISO 81060 covers non-invasive blood pressure measurement devices with a pressure-sensing element and display used in conjunction with means of detecting blood flow.

EXAMPLE 1 A stethoscope for detecting Korotkoff sounds, Doppler ultrasound or other manual methods.

Requirements for non-invasive blood pressure measurement equipment with electrically-powered pressure sensing elements and/or displays used in conjunction with other automatic methods determining blood pressure are specified in IEC 60601-2-30 [7].

Requirements for invasive blood pressure measurement equipment that directly measure blood pressure are specified in document IEC 60601-2-34 [8].

EXAMPLE 2 Measuring equipment, including associated transducers, that is used for the invasive measurement of circulatory system pressures.

2 Normative references

The following referenced documents are indispensable for the application 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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7010:2003, *Graphical symbols — Safety colours and safety signs — Safety signs used in workplaces and public areas*

ISO 10993-1[1)], *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. For convenience, an alphabetized list of the sources of all defined terms used in this document is given in Annex E.

3.1
accompanying document
document accompanying a **non-automated sphygmomanometer** or accessory and containing information for those accountable for the installation, use and maintenance of the **non-automated sphygmomanometer** or accessory, the **operator** or the **responsible organization**, particularly regarding safety

[Modified from ISO 14971:2007, definition 2.1]

3.2
bladder
that part of the **cuff** that is inflatable

3.3
blood pressure
pressure in the systemic arterial system of the body

3.4
clearly legible
capable of being read by a person with normal vision

[IEC 60601-1:2005, definition 3.15]

3.5
cuff
part of the **non-automated sphygmomanometer** that is wrapped around the limb of the **patient**

NOTE A cuff might comprise a bladder and an inelastic part that encloses the bladder, or have an integral bladder (i.e., the cuff including the bladder are fixed together or are one piece).

3.6
expected service life
maximum period of useful life as defined by the **manufacturer**

[IEC 60601-1:2005, definition 3.28]

1) To be published. (Revision of ISO 10993-1:2003)

