Non-invasive sphygmomanometers - Part 3: Clinical investigation of continuous automated measurement type (ISO 81060-3:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 81060-3:2023 sisaldab Euroopa standardi EN ISO 81060-3:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 81060-3:2023 consists of the English text of the European standard EN ISO 81060-3:2023.
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 and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.01.2023.	Date of Availability of the European standard is 11.01.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

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

ICS 11.040.10

EUROPEAN STANDARD

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English Version

Non-invasive sphygmomanometers - Part 3: Clinical investigation of continuous automated measurement type (ISO 81060-3:2022)

Sphygmomanomètres non invasifs - Partie 3: Investigation clinique pour type à mesurage automatique continu (ISO 81060-3:2022)

Nicht-invasive Blutdruckmessgeräte - Teil 3: Klinische Prüfung der kontinuierlichen automatisierten Bauart (ISO 81060-3:2022)

This European Standard was approved by CEN on 20 October 2022.

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

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Ref. No. EN ISO 81060-3:2023 E

European foreword

This document (EN ISO 81060-3:2023) 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of an identical text or by endorsement, at the latest by July 2023, and conflicting national standards shall be withdrawn at the latest by July 2023.

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.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 81060-3:2022 has been approved by CEN as EN ISO 81060-3:2023 without any modification.

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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 or www.iec.ch/members_experts/refdocs).

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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. In the IEC, see www.iec.ch/understanding-standards.

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 62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 81060 series can be found on the ISO and IEC websites.

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 and www.iec.ch/national-committees.

Introduction

The number of continuously measuring non-invasive *automated sphygmomanometers* has increased significantly in the last 10 years. This document is intended to provide the necessary requirements for *clinical investigation* to ensure that the *essential performance* of these *sphygmomanometers* is at an adequate level, similar to those standards on *intermittent automated non-invasive sphygmomanometer*.

Non-invasive sphygmomanometers —

Part 3: Clinical investigation of continuous automated measurement type

1 Scope

This document specifies the requirements and methods for the *clinical investigation* of *continuous automated non-invasive sphygmomanometers* used for the measurement of the *blood pressure* of a patient.

This document does not cover usability aspects such as the form and manner of the data display or output. This document does not specify a numerical threshold on the *minimum output period*. A *continuous automated non-invasive sphygmomanometer* providing *blood pressure* parameters (e.g., *systolic blood pressure*, *diastolic blood pressure* or *mean arterial pressure*) with an *output period* considerably larger than 30 s is not typically considered a *continuous automated non-invasive sphygmomanometer*.

This document covers both trending *continuous automated non-invasive sphygmomanometers* and absolute accuracy *continuous automated non-invasive sphygmomanometers* and focuses solely on requirements for the *clinical investigation*. Representation of output is not covered by this document.

NOTE 1 IEC 62366-1 provides requirements on the application of usability engineering to medical devices. The usability engineering *process* can be used to clarify for the intended user whether the displayed data concerns absolute accurate values or trending values.

The requirements and methods for the *clinical investigation* of *continuous automated non-invasive sphygmomanometers* provided in this document are applicable to any subject population, and any condition of use of the *continuous automated non-invasive sphygmomanometers*.

NOTE 2 Subject populations can, for example, be represented by age or weight ranges.

NOTE 3 This document does not provide a method to assess the effect of artefacts during the *clinical investigation* (e.g. motion artefacts induced by the movement of the subject or the movement of the platform supporting the subject).

This document specifies additional disclosure requirements for the *accompanying documents* of *continuous automated non-invasive sphygmomanometers* that have undergone *clinical investigation* according to this document.

This document is not applicable to:

— the *clinical investigation* of a *non-automated sphygmomanometer* as given in ISO 81060-1,

— the *clinical investigation* of an *intermittent automated non-invasive sphygmomanometer* as given in ISO 81060-2,

— an *automated non-invasive sphygmomanometer* as given in IEC 80601-2-30, 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.

ISO 14155:2020, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

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

ISO 81060-2:2018+Amd 1:2020, *Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-34:2011, *Medical electrical equipment — Part 2-34: Particular requirements for the safety, including 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 14155:2020, ISO 14971:2019, ISO 81060-1:2007, ISO 81060-2:2018+Amd 1:2020, IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-2-34:2011, IEC 80601-2-30:2018, and the following apply.

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

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

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

3.1
change evaluation interval
time period for which a *continuous automated non-invasive sphygmomanometer* is demonstrated to track changes in *blood pressure*

3.2
continuous automated non-invasive sphygmomanometer
ME equipment estimating *blood pressure* from each cardiac cycle without arterial puncture and providing a continual series of *blood pressure* parameters

Note 1 to entry: While the *continuous automated non-invasive sphygmomanometer* analyses each heart cycle, this does not mean the *continuous automated non-invasive sphygmomanometer* always uses data from each heart cycle to estimate the *blood pressure*. Not using data from a specific heart cycle can be useful, for example, to omit data from premature ventricular contractions.

Note 2 to entry: The only *blood pressure* parameters considered in this document are *systolic blood pressure*, *diastolic blood pressure* and *mean arterial pressure*.

Note 3 to entry: This document does not cover usability aspects such as the form and manner of the data display or output. Hence, this document does not specify a numerical threshold on the *minimum output period*. However, a *continuous automated non-invasive sphygmomanometer* providing *blood pressure* parameters (e.g. *systolic blood pressure*, *diastolic blood pressure* or *mean arterial pressure*) with an *output period* considerably larger than 30 s are not typically considered a *continuous automated non-invasive sphygmomanometer*.

Note 4 to entry: There is guidance or rationale for this definition contained in Clause A.2.