SLOVENSKI STANDARD
SIST EN ISO 80601-2-61:2026

01-junij-2026

Nadomešča:
SIST EN ISO 80601-2-61:2019

Medicinska električna oprema - 2-61. del: Posebne zahteve za osnovno varnost in bistvene lastnosti pulznega oksimetra (ISO 80601-2-61:2026)

Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2026)

Medizinische elektrische Geräte - Teil 2-61: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Pulsoximetriegeräten (ISO 80601-2-61:2026)

Appareils électromédicaux - Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls (ISO 80601-2-61:2026)

Ta slovenski standard je istoveten z: **EN ISO 80601-2-61:2026**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN ISO 80601-2-61:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-61

April 2026

ICS 11.040.55

Supersedes EN ISO 80601-2-61:2019

English Version

Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2026)

Appareils électromédicaux - Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls (ISO 80601-2-61:2026)

Medizinische elektrische Geräte - Teil 2-61: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Pulsoximetriegeräten (ISO 80601-2-61:2026)

This European Standard was approved by CEN on 17 March 2026.

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.

CEN members are the national standards bodies of 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 United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 80601-2-61:2026 E

Contents

Page

European foreword **3**

European foreword

This document (EN ISO 80601-2-61:2026) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

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 2026, and conflicting national standards shall be withdrawn at the latest by October 2026.

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 80601-2-61:2019.

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 80601-2-61:2026 has been approved by CEN as EN ISO 80601-2-61:2026 without any modification.

International Standard

ISO 80601-2-61

Medical electrical equipment —

Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Appareils électromédicaux —

Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls

Third edition
2026-04

Reference number
ISO 80601-2-61:2026(en)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword v
Introduction vii
201.1 Scope, object, and related standards 1
201.2 Normative references 3
201.3 Terms and definitions 3
201.4 General requirements 17
201.5 General requirements for testing of *ME equipment* 19
201.6 Classification of *ME equipment* and *ME systems* 19
201.7 *ME equipment* identification, *marking* and documents 19
201.8 Protection against electrical *hazards* from *ME equipment* 24
201.9 Protection against mechanical *hazards* of *ME equipment* and *ME systems* 24
201.10 Protection against unwanted and excessive radiation *hazards* 24
201.11 Protection against excessive temperatures and other *hazards* 24
201.12 *Accuracy* of controls and instruments and protection against hazardous outputs 26
201.13 *Hazardous situations* and fault conditions for *ME equipment* 41
201.14 *Programmable electrical medical systems* (*PEMS*) 42
201.15 Construction of *ME equipment* 43
201.16 *ME systems* 44
201.17 Electromagnetic compatibility of *ME equipment* and *ME systems* 44
201.101 *Pulse oximeter probes* and *probe cable extenders* 44
201.102 Saturation pulse *information signal* 45
201.103 *Functional connection* 45
202 Electromagnetic disturbances – Requirements and tests 46
206 Usability 47
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems 48
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment 48
212 Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment 49
Annex C (informative) Guide to *marking* and labelling requirements for *ME equipment* and *ME systems* 50
Annex D (informative) *Symbols* on *marking* 54
Annex AA (informative) Particular guidance and rationale 55
Annex BB (informative) Skin temperature at the *pulse oximeter probe* 76

Annex CC (informative) Determination of *accuracy,* pigmentation *differential bias,* sample size, and study design considerations **80**

Annex DD (normative) Method for invasive studies for evaluating and documenting SpO_2 *accuracy* in human participants **100**

Annex EE (informative) Simulators, calibrators, and *functional testers* for *pulse oximeter equipment* **106**

Annex FF (informative) Concepts of *ME equipment* response time **115**

Annex GG (normative) Data interface requirements **119**

Annex HH (informative) Clinical context and rationales of data interface requirements **125**

Annex II (informative) Using a *functional tester* to assess *pulse oximeter equipment* conditions of signal inadequacy over a range of transmitted light and optical modulation **126**

Annex JJ (informative) Using a *transfer standard* in *pulse oximeter equipment* development **130**

Annex KK (informative) Reference to the IMDRF *essential principles* and labelling guidances **135**

Bibliography **138**

Terminology — Alphabetized index of defined terms **147**

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).

ISO and IEC draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO and IEC take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO and IEC had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents and https://patents.iec.ch. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

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

This document was prepared 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, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 80601-2-61:2017), which has been technically revised.

The main changes are as follows:

— alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012 +AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013 +AMD2:2020.

— increased disclosure requirements;

— increased the required number of participants in the clinical study and their diversity (a means to assure equal contributions across the range of skin pigmentation);

— reduced the maximum permissible A_{rms} to enhance measurement accuracy;

— required *differential bias* determination to enhance measurement accuracy;

— clarified that *accessories* need to be included in the clinical performance *verification* and conformity to the requirements of the document

— updated the reporting requirements for the clinical performance *verification*;

— added an Annex describing the use of *transfer standard* for product development purposes;

— added an Annex mapping the requirements of this document to the IMDRF *essential principles*[25] and labelling[26] guidances; and

— harmonization with ISO 20417, where appropriate.

A list of all parts in the ISO 80601 series and the IEC 80601 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 approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This document covers *basic safety* and *essential performance* requirements achievable within the limits of existing technology.

The committees recognized the need to revise the first edition of this document because of the publication of IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-12:2014+AMD1:2020, as well as IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-11:2015+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and IEC 60601-1-8:2006+AMD1:2012+AMD2:2020.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the reasoning of the committees that led to a requirement and identifying the *hazards* that the requirement addresses.

Annex BB is a literature survey relevant to the determination of the maximum safe temperature of the interface between a *pulse oximeter probe* and a *patient's* tissue.

Annex CC discusses the formulae used to evaluate the SpO_2 *accuracy* of *pulse oximeter equipment* measurements, *differential bias* and the names that are assigned to those formulae.

Annex DD presents a guideline for a *controlled desaturation study* for the calibration of *pulse oximeter equipment*.

Annex EE is a tutorial introduction to several kinds of testers used in pulse oximetry.

Annex FF describes concepts of *pulse oximeter equipment* response time.

Annex GG describes data interface requirements.

Annex HH describing the clinical context of this document and its rationale;

Annex II describing the use of a *functional tester*;

Annex JJ describing the use of *transfer standard*;

Annex KK maps the requirements of this document to the IMDRF *essential principles*[25] and labelling[26] guidances

In referring to the structure of this document, the term

– "clause" means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7.1, 201.7.2) and

– "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

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" indicates a requirement;

– “should” indicates a recommendation;

– “may” indicates a permission;

– “can” indicates a possibility or capability; and

– “must” is used to express an external constraint.