

ELEKTRILISED MEDITSIINISEADMED. OSA 2-61:  
ERINÕUDED MEDITSIINIOTSTARBELISE  
PULSSOKSÜMEETRI ESMASELE OHUTUSELE JA  
OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017, Corrected version 2018-02)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-61:2019 sisaldab Euroopa standardi EN ISO 80601-2-61:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-61:2019 consists of the English text of the European standard EN ISO 80601-2-61:2019.
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 30.01.2019.	Date of Availability of the European standard is 30.01.2019.
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](mailto:standardiosakond@evs.ee).

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English Version

Medical electrical equipment - Part 2-61: Particular  
requirements for basic safety and essential performance of  
pulse oximeter equipment (ISO 80601-2-61:2017,  
Corrected version 2018-02)

Appareils électromédicaux - Partie 2-61: Exigences  
particulières pour la sécurité de base et les  
performances essentielles pour les oxymètres de pouls  
(ISO 80601-2-61:2017, Version corrigée 2018-02)

Medizinische elektrische Geräte - Teil 2-61: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von  
Pulsoximetriegeräten (ISO 80601-2-61:2017)

This European Standard was approved by CEN on 13 December 2018.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 06 March 2019.

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.

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## European foreword

This document (EN ISO 80601-2-61:2019) 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 July 2019, and conflicting national standards shall be withdrawn at the latest by January 2022.

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 80601-2-61:2011.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 80601-2-61:2017, Corrected version 2018-02 has been approved by CEN as EN ISO 80601-2-61:2019 without any modification.

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## 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 the first edition of IEC 60601-1-12, as well as the fourth edition of IEC 60601-1-2, the second edition of IEC 60601-1-11 and the first Amendments to both the third edition of IEC 60601-1, the third edition of IEC 60601-1-6 and the second edition of IEC 60601-1-8.

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 both the formulae used to evaluate the  $SpO_2$  ACCURACY of PULSE OXIMETER EQUIPMENT measurements, and the names that are assigned to those formulae.

Annex DD presents guidance on when in vitro blood calibration of PULSE OXIMETER EQUIPMENT is needed.

Annex EE presents a guideline for a CONTROLLED DESATURATION STUDY for the calibration of PULSE OXIMETER EQUIPMENT.

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

Annex GG describes concepts of PULSE OXIMETER EQUIPMENT response time.

Annex HH describes data interface requirements.

Annex II contains Reference to the ESSENTIAL PRINCIPLES formerly found in Annex HH.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type; normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD<sup>1</sup> IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

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).

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<sup>1</sup> The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

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” 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; and
- “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 AA.



## Medical electrical equipment —

### Part 2-61:

## Particular requirements for basic safety and essential performance of pulse oximeter equipment

### 201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012, Clause 1 applies, except as follows:

#### 201.1.1 \* Scope

##### *Replacement:*

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of PULSE OXIMETER EQUIPMENT intended for use on humans, hereafter referred to as ME EQUIPMENT. This includes any part necessary for NORMAL USE, including the PULSE OXIMETER MONITOR, PULSE OXIMETER PROBE, and PROBE CABLE EXTENDER.

These requirements also apply to PULSE OXIMETER EQUIPMENT, including PULSE OXIMETER MONITORS, PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS, which have been REPROCESSED.

The intended use of PULSE OXIMETER EQUIPMENT includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate of PATIENTS in professional healthcare institutions as well as PATIENTS in the HOME HEALTHCARE ENVIRONMENT and the EMERGENCY MEDICAL SERVICES ENVIRONMENT.

This document is not applicable to PULSE OXIMETER EQUIPMENT intended for use in laboratory research applications nor to oximeters that require a blood sample from the PATIENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 201.11 and in 7.2.13 and 8.4.1 of the general standard.

NOTE 1 See also 4.2 of the general standard. "The general standard" is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

This document can also be applied to ME EQUIPMENT and their ACCESSORIES used for compensation or alleviation of disease, injury or disability.

This document is not applicable to PULSE OXIMETER EQUIPMENT intended solely for foetal use.

This document is not applicable to remote or slave (secondary) equipment that displays  $SpO_2$  values that are located outside of the PATIENT ENVIRONMENT.

NOTE 2 ME EQUIPMENT that provides selection between diagnostic and monitoring functions is expected to meet the requirements of the appropriate document when configured for that function.

This document is applicable to PULSE OXIMETER EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment or physician's office, such as in ambulances and air transport. Additional standards can apply PULSE OXIMETER EQUIPMENT for those environments of use.

This document is a particular standard in the IEC 60601-1 and ISO/IEC 80601 series of standards.

### **201.1.2 Object**

Subclause 1.2 of the general standard is replaced by:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PULSE OXIMETER EQUIPMENT [as defined in 201.3.217] and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the PULSE OXIMETER MONITOR and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of PULSE OXIMETER EQUIPMENT.

### **201.1.3 Collateral standards**

IEC 60601-1:2005+AMD1:2012, subclause 1.3 applies with the following addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and IEC 60601-1-12 apply as modified in Clauses 202, 206, 208, 211 and 212 respectively. IEC 60601-1-3<sup>[2]</sup> does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

### **201.1.4 Particular standards**

IEC 60601-1:2005+AMD1:2012, subclause 1.4 is replaced by:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 2xx, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.

## 201.2 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.

IEC 60601-1:2005+AMD1:2012, Clause 2 applies, except as follows:

*Replacement:*

IEC 60417, *Graphical symbols for use on equipment*

IEC 60529:2013, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*  
+ Amendment 1:2013

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*  
+ Amendment 1:2012

IEC 60825-1:2014, *Safety of laser products - Part 1: Equipment classification and requirements*

*Addition:*

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

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

ISO 14937:2009, *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 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock* + Amendment 1:2013

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

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 the home healthcare environment*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

IEC 60825-2:2004, *Safety of laser products — Part 2: Safety of optical fibre communication systems (OFCS)* + Amendment 1:2006+ Amendment 2:2012

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

### 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3744:2010, ISO 4135:2001, IEC 60601-1:2005+AMD 1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD 1:2013, IEC 60601-1-8:2006+AMD 1:2012, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 62366-1:2015 and the following apply.

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

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

NOTE An alphabetized index of defined terms is found in Annex JJ.

#### 201.3.201

##### **accuracy**

closeness of agreement between a test result and an accepted reference value

Note 1 to entry: Subclause 201.12.1.101.2 provides the method of calculating the  $SpO_2$  ACCURACY of PULSE OXIMETER EQUIPMENT.

Note 2 to entry: Additional information is found in Annex CC.

[SOURCE: ISO 3534-2:2006<sup>[3]</sup>, 3.3.1, modified — Replaced note 1 to note 3 with new notes and 'or measurement result and the true' with 'and an accepted reference'.]