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DIN EN ISO 80601-2-61
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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); English version EN ISO 80601-2-61:2019, English translation of DIN EN ISO 80601-2-61:2019-09

Medizinische elektrische Geräte –
Teil 2-61: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Pulsoximetriegeräten (ISO 80601-2-61:2017, korrigierte Fassung 2018-02);
Englische Fassung EN ISO 80601-2-61:2019,
Englische Übersetzung von DIN EN ISO 80601-2-61:2019-09

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);
Version anglaise EN ISO 80601-2-61:2019,
Traduction anglaise de DIN EN ISO 80601-2-61:2019-09

Document comprises 103 pages

Translation by DIN-Sprachendienst.

In case of doubt, the German-language original shall be considered authoritative.

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A comma is used as the decimal marker.

National foreword

This document (EN ISO 80601-2-61:2019) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" (Secretariat: ANSI, USA) in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" (Secretariat: BSI, United Kingdom), with the active participation of German experts.

The responsible German body involved in its preparation was *DIN-Normenausschuss Rettungsdienst und Krankenhaus* (DIN Standards Committee Rescue Services and Hospital), Working Committee NA 053-03-01 AA "Anaesthesia and artificial respiration".

The DIN documents corresponding to the international documents referred to in this document are as follows:

ISO 3534-2:2006	DIN ISO 3534-2:2013-12
ISO 3744:2010	DIN EN ISO 3744:2011-02
ISO 4135:2001	DIN EN ISO 4135:2002-03
ISO 7000	DIN ISO 7000
ISO 9000:2015	DIN EN ISO 9000:2015-11
ISO 11073-10404:2010	DIN EN ISO 11073-10404:2011-07
ISO 13732-1:2006	DIN EN ISO 13732-1:2008-12
ISO 14155:2011	DIN EN ISO 14155:2012-01
ISO 14937:2009	DIN EN ISO 14937:2010-03
ISO 15223-1:2016	DIN EN ISO 15223-1:2017-04
ISO 80601-2-61:2011	DIN EN ISO 80601-2-61:2012-01
IEC 60068-2-27:2008	DIN EN 60068-2-27 (VDE 0468-2-27):2010-02
IEC 60068-2-31:2008	DIN EN 60068-2-31 (VDE 0468-2-31):2009-04
IEC 60068-2-64:2008	DIN EN 60068-2-64 (VDE 0468-2-64):2009-04
IEC 60529:2013	DIN EN 60529 (VDE 0470-1):2014-09
IEC 60601-1-2:2014	DIN EN 60601-1-2 (VDE 0750-1-2):2016-05
IEC 60601-1-3:2008	DIN EN 60601-1-3 (VDE 0750-1-3):2014-06
IEC 60601-1-6:2016	DIN EN 60601-1-6 (VDE 0750-1-6):2016-02
IEC 60601-1-8:2006	DIN EN 60601-1-8 (VDE 0750-1-8):2014-04
IEC 60601-1-10:2007	DIN EN 60601-1-10 (VDE 0750-1-10):2016-04
IEC 60601-1-11:2015	DIN EN 60601-1-11 (VDE 0750-1-11):2016-04
IEC 60601-1-12:2014	DIN EN 60601-1-12 (VDE 0750-1-12):2016-01
IEC 60825-1:2014	DIN EN 60825-1 (VDE 0837-1):2015-07
IEC 60825-2:2004	DIN EN 60825-2 (VDE 0837-2):2011-06
IEC 62366:2007	DIN EN 62366 (VDE 0750-241):2008-09
IEC 62366-1:2015	DIN EN 62366-1 (VDE 0750-241-1):2017-07
IEC/TR 60721-4-7:2001+AMD1:2003	DIN 40046-721-7:2004-11

Amendments

This standard differs from DIN EN ISO 80601-2-61 (VDE 0750-2-61):2012-01 as follows:

a) requirements for pulse oximeter equipment for use in the home healthcare environment have been included;

b) requirements for pulse oximeter equipment for use in the emergency medical services environment have been included;

c) the requirements for the degree of protection (IP classification) of pulse oximeter equipment have been revised;

d) requirements for the data interface have been included;

e) in the informative Annex AA, rationale on single requirements have been updated;

f) the Bibliography has been updated due to the progress in the knowledge of hypoxaemia, electronic health records and alarm systems;

g) the informative Annex ZA for the presentation of the relationship of clauses of the standard and the essential requirements of EU Directive 93/42/EEC regarding medical devices has been deleted;

h) the standard has been editorially revised.

Previous editions

DIN EN 865: 1997-05
DIN EN ISO 9919 (VDE 0750-2-54): 2005-09, 2009-09
DIN EN ISO 80601-2-61 (VDE 0750-2-61): 2012-01

National Annex NA
(informative)

Bibliography

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DIN EN 60068-2-27 (VDE 0468-2-27):2010-02, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock (IEC 60068-2-27:2008)*

DIN EN 60068-2-31 (VDE 0468-2-31):2009-04, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimen (IEC 60068-2-31:2008)*

DIN EN 60068-2-64 (VDE 0468-2-64):2009-04, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008)*

DIN EN 60529 (VDE 0470-1):2014-09, *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989 + A1:1999 + A2:2013)*

DIN EN 60601-1-2 (VDE 0750-1-2):2016-05, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests (IEC 60601-1-2:2014)*

DIN EN 60601-1-3 (VDE 0750-1-3):2014-06, *Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008 + A1:2013)*

DIN EN 60601-1-6 (VDE 0750-1-6):2016-02, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability (IEC 60601-1-6:2010 + A1:2013)*

DIN EN 60601-1-8 (VDE 0750-1-8):2014-04, *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 (IEC 60601-1-8:2006 + A1:2012)*

DIN EN 60601-1-10 (VDE 0750-1-10):2016-04, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers (IEC 60601-1-10:2007 + A1:2013)*

DIN EN 60601-1-11 (VDE 0750-1-11):2016-04, *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 60601-1-11:2015)*

DIN EN 60601-1-12 (VDE 0750-1-12):2016-01, *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 intended for use in the emergency medical services environment (IEC 60601-1-12:2014)*

DIN EN 60721-3-7, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities — Section 7: Portable and non-stationary use*

DIN EN 60825-1 (VDE 0837-1):2015-07, *Safety of laser products — Part 1: Equipment classification and requirements (IEC 60825-1:2014)*

DIN EN 60825-2 (VDE 0837-2):2011-06, *Safety of laser products — Part 2: Safety of optical fibre communication systems (OFCS) (IEC 60825-2:2004 + A1:2006 + A2:2010)*

DIN EN 62366 (VDE 0750-241):2008-09, *Medical devices — Application of risk management to medical devices (ISO 62366:2007)*

DIN EN 62366-1 (VDE 0750-241-1):2017-07, *Medical devices — Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016)*

DIN EN ISO 3744:2011-02, *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 3744:2010)*

DIN EN ISO 4135:2002-03, *Anaesthetic and respiratory equipment — Vocabulary (ISO 4135:2001)*

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

DIN EN ISO 11073-10404:2011-07, *Health informatics — Personal health device communication — Part 10404: Device specialization — Pulse oximeter (ISO/IEEE 11073-10404:2010)*

DIN EN ISO 13732-1:2008-12, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces (ISO 13732-1:2006)*

DIN EN ISO 14155:2012-01, *Clinical investigation of medical devices for human subjects — Good clinical practice (ISO 14155:2011 + Cor. 1:2011)*

DIN EN ISO 14937:2010-03, *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 14937:2009)*

DIN EN ISO 15223-1:2017-04, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*

DIN EN ISO 9000:2015-11, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2015)*

DIN EN ISO 80601-2-61:2012-01, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011)*

DIN ISO 3534-2:2013-12, *Statistics — Vocabulary and symbols — Part 2: Applied statistics (ISO 3534-2:2006)*

DIN ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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EUROPEAN STANDARD

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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)

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Medizinische elektrische Geräte — Teil 2-61: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Pulsoximetriegeräten (ISO 80601-2-61:2017, korrigierte Fassung 2018-02)

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

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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Contents

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.

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).

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

This document was prepared jointly by 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*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition of ISO 80601-2-61 cancels and replaces the first edition (ISO 80601-2-61:2011), which has been technically revised. It includes an alignment with Amendment 1 of both the third edition of IEC 60601-1 and the second edition of IEC 60601-1-8, as well as the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, the second edition of IEC 60601-1-11 and IEC 60601-1-12.

The most significant changes are the following modifications:

– updated rationale (Annex AA) and references related to advances in the understanding of hypoxaemia, electronic health records and ALARM SYSTEMS;

– ingress protection changed from IPX1 to IPX2;

and the following additions:

– Clause 211, requirements for use in the HOME HEALTHCARE ENVIRONMENT;

– Clause 212, requirements for use in the emergency medical services (EMS) environment;

– Annex HH, Data interface requirements.

This corrected version of ISO 80601-2-61:2017 incorporates the following correction:

– headers have been corrected.

A list of all the parts of the ISO/IEC 80601 series is available on the ISO website.