Irish Standard
I.S. EN ISO 80601-2-61:2011

Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2 -61:2011)

I.S. EN ISO 80601-2-61:2011

Incorporating amendments/corrigenda/National Annexes issued since publication:

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-61

April 2011

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Supersedes EN ISO 9919:2009

English Version

Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011)

Appareils électromédicaux - Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls (ISO 80601-2-61:2011)

Medizinische elektrische Geräte - Teil 2-61: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Pulsoximetriegeräten (ISO 80601-2-61:2011)

This European Standard was approved by CEN on 17 March 2011.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (EN ISO 80601-2-61:2011) 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 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

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 ISO 9919:2009.

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, see informative Annex ZA, which is an integral part of this document.

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 and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-61:2011 has been approved by CEN as a EN ISO 80601-2-61:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

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 to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

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

Clause(s)/sub-clause(s) of this European standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
all	1, 2, 3	
201.4	1, 2, 3, 6	
201.4.3	1, 2	
201.4.101	2, 3	
201.4.102	3, 6	
201.4.103	6, 9.1	
201.7	12.9, 13	
201.7.2.3	13.2, 13.3 j), 13.3 k)	
201.7.2.9	2, 9.1, 13.1	
201.7.2.13.101	13.3 k)	
201.7.2.17.101	8.3, 13.1, 13.2, 13.3 b), 13.3 d), 13.3 f), 13.5	
201.7.2.101	9.1, 12.4, 13.2, 13.3 b), 13.3 d), 13.3 e), 13.3 f), 13.3 k), 13.5	
201.7.2.4.101	13.3 e), 13.3 i)	
201.7.4.3	10.3	
201.7.9.1	13.3.a)	
201.7.9.2.1.101	6, 13.6	
201.7.9.2.1.101 a), 201.7.9.2.1.101 b)	13.4	
201.7.9.2.1.101 c)	11.4.1, 13.6 j)	
201.7.9.2.1.101 d)	13.6 b)	
201.7.9.2.1.101 e)	13.6 b), 13.6 p)	
201.7.9.2.1.101 f)	13.4	

Table ZA.1 — *(continued)*

Clause(s)/sub-clause(s) of this European standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.7.9.2.1.101 g)	13.6 c)	
201.7.9.2.1.101 h)	13.6 h)	
201.7.9.2.1.101 i)	13.6 q)	
201.7.9.2.2.101	13.6 c), 13.6 d)	
201.7.9.2.8.101	13.6 i)	
201.7.9.2.9.101 b)	13.6 a)	
201.7.9.2.9.101 c), d) & e)	13.6 a), 13.6 b)	
201.7.9.2.14.101 a) & b)	13.6 c)	
201.7.9.2.14.101 c)	7.5	
201.7.9.2.14.101 d)	13.6 g)	
201.7.9.3.1.101	13.6 d)	
201.8	12.6, 12.7.4	
201.9	12.7.1	
201.10	11.2.1, 11.2.2	
201.11	6, 7.1, 7.2, 7.3, 7.5, 8.1, 8.2, 8.4, 8.6, 9.3, 12.7.5, 12.8.2	
201.11.6.5.101	7.6	
201.11.8.101	4, 12.2, 12.3	
201.12.1	6, 10.1, 6a	
201.12.4	6	
201.12.4.101	9.1, 10.1, 10.2	
201.12.4.102	10.1, 10.2, 12.4	
201.14	12.1, 12.1 a)	
201.15	12.7	
201.15.3.5.101	4, 5, 9.2, 12.7.1	
201.101.1	2, 3, 4, 5, 6, 6 a), 7.1, 7.6, 8.3, 9.1, 9.2, 10.1, 11.1.1, 11.2.2, 12.5, 12.6, 12.7.1, 12.7.5	
201.101.2	9.1, 13.1	
201.102	10.2	
202	9.2, 11.3.1, 12.5	
208	2, 6, 9.1, 10.2, 12.2, 12.3, 12.4	

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

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I.S. EN ISO 80601-2-61:2011

INTERNATIONAL STANDARD

ISO 80601-2-61

First edition
2011-04-01

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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

ISO 80601-2-61 was prepared by a Joint Working Group of Technical Committee 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, *Electromedical equipment*.

This first edition of ISO 80601-2-61 cancels and replaces the second edition of ISO 9919:2005, which has been revised to harmonize it with the third edition of IEC 60601-1:2005.

In this standard, 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, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

— “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— “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.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This standard covers BASIC SAFETY and ESSENTIAL PERFORMANCE requirements achievable within the limits of existing technology.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the reasoning of the committee 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.

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, Clause 1 applies, except as follows:

201.1.1 * Scope

Subclause 1.1 of The general standard is replaced by:

This International Standard 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.

This International Standard 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 standard are not covered by specific requirements in this standard except in 201.11 and in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

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

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

This International Standard is not applicable to remote or slave (secondary) devices that display SpO_2 values that are located outside of the PATIENT ENVIRONMENT.

201.1.2 Object

Subclause 1.2 of The general standard is replaced by:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PULSE OXIMETER EQUIPMENT [as defined in 201.3.216] and its ACCESSORIES.