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 80601-2-61:2011)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-61:2011 sisaldab Euroopa standardi EN ISO 80601-2-61:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-61:2011 consists of the English text of the European standard EN ISO 80601-2-61:2011.
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 01.04.2011.	Date of Availability of the European standard is 01.04.2011.
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.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-61

April 2011

ICS 11.040.10

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.

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

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Ref. No. EN ISO 80601-2-61:2011: E

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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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.

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

201.1.3 Collateral standards

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

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

IEC 60601-1-3 does not apply.

NOTE Additional requirements for ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT are found in IEC 60601-1-11.

201.1.4 Particular standards

Subclause 1.4 of The general standard is replaced by:

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

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

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

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 208.6 in this particular standard addresses the content of Clause 6 of the 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 particular standard.

"Addition" means that the text of this particular standard 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 particular standard.

Subclauses or figures which 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 which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 206 for IEC 60601-1-6, etc.

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

Where there is no corresponding section, clause or subclause in this particular standard, 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 standard.

