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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

ICS: 11.040.10

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This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

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INTERNATIONAL ORGANIZATION for STANDARDISATION**MEDICAL ELECTRICAL EQUIPMENT –
Part 2-61: Particular requirements for the basic safety and
essential performance of pulse oximetry equipment****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. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

ISO 80601-2-61 was prepared by 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, *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 of ISO 80601-2-61^[1] (2011). This edition of ISO 80601-2-61 constitutes a technical revision and 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.

¹ Numbers in square brackets refer to the Bibliography.

95 The most significant changes are the following modifications:

- 96 – Updated Rationale (Annex AA) and references related to advances in our understanding of hypoxia,
97 electronic health records and ALARM SYSTEMS;

98 and the following additions:

- 99 – Clause 211, requirements for use in the HOME HEALTHCARE ENVIRONMENT
100 – Clause 212, requirements for use in the emergency medical services (EMS) environment
101 – Annex HH, Data interface requirements

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103

European Foreword

104 The following referenced documents are indispensable for the application of this document. For undated
105 references, the latest edition of the referenced document (including any amendments) applies. For dated
106 references, only the edition cited applies. However, for any use of this standard "within the meaning of
107 Annex ZA", the user should always check that any referenced document has not been superseded and that
108 its relevant contents can still be considered the generally acknowledged state-of-art.

109 When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a
110 normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the
111 foreword and the Annexes ZZ.

112 NOTE The way in which these references documents are cited in normative requirements determines the extent
113 (in whole or in part) to which they apply.

114 Table – Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 7000 (database)	—	ISO 7000 (database)
ISO 14155:2011	EN ISO 14155:2011+AC:2011	ISO 14155:2011
ISO 14937:2009	—	ISO 14937:2009
ISO 15223-1:— ²	prEN ISO 15223-1:—	ISO 15223-1:—
IEC 60068-2-27:2008+A1:2013	EN 60068-2-27:2009+A1:—	IEC 60068-2-27:2008+A1:2013
IEC 60068-2-31:2008	EN 60068-2-31:2008	IEC 60068-2-31:2008
IEC 60068-2-64:2008	EN 60068-2-64:2008	IEC 60068-2-64:2008
IEC 60601-1:2005+A1:2012	EN 60601-1:2006+A1:2013 +AC:2014+A12:2014	IEC 60601-1:2005+A1:2012
IEC 60601-1-2:2014	EN 60601-1-2:—1	IEC 60601-1-2:2014
IEC 60601-1-6:2010 +A1:2013	EN 60601-1-6:2010+A1:—11	IEC 60601-1-6:2010 +A1:20131
IEC 60601-1-8:2006+A1:2012	EN 60601-1-8:2007 +A1:2013 +AC:2014	IEC 60601-1-8:2006 +A1:2012
IEC 60601-1-11:2015	EN 60601-1-11:2015	IEC 60601-1-11:2015
IEC 60601-1-12:2014	EN 60601-1-12:2015	IEC 60601-1-12:2014
IEC 60417 (database)	—	IEC 60417 (database)
IEC 60529:2013	EN 60529:—	IEC 60529:2013
IEC 60825-1:2014	EN 60825-1:2014	IEC 60825-1:2014

² Under preparation. Stage at the time of publication: ISO FDIS 15223-1:2016.

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
IEC 60825-2:2004+A1:2006+A2:2010	EN 60825-2:2004+A1:2007+A2:2010	IEC 60825-2:2004+A1:2006+A2:2010

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INTRODUCTION

116

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

120 The committees recognized the need to revise the first edition of this document due to the publication of
121 the first edition of IEC 60601-1-12, as well as the fourth edition of IEC 60601-1-2, the second edition of
122 IEC 60601-1-11 and the first Amendments to both the third edition of IEC 60601-1, the third edition of
123 IEC 60601-1-6 and the second edition of IEC 60601-1-8.

124 Annex AA contains a rationale for some of the requirements. It is included to provide additional insight
125 into the reasoning of the committee that led to a requirement and identifying the HAZARDS that the
126 requirement addresses.

127 Annex BB is a literature survey relevant to the determination of the maximum safe temperature of the
128 interface between a PULSE OXIMETER PROBE and a PATIENT'S tissue.

129 Annex CC discusses both the formulae used to evaluate the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT
130 measurements, and the names that are assigned to those formulae.

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

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

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

135 Annex GG describes concepts of PULSE OXIMETER EQUIPMENT response time.

136 Annex HH describes data interface requirements.

137 Annex II contains Reference to the Essential Principles formerly found in Annex HH.

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

139 In this document, the following print types are used:

140 – Requirements and definitions: roman type

141 – *Test specifications: italic type*

142 – Informative material appearing outside of tables, such as notes, examples and references: in smaller type
143 Normative text of tables is also in a smaller type

144 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD³ IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS

145 In referring to the structure of this document, the term

³ 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

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

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

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

152 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination
153 of the conditions is true.

154 The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives,
155 Part 2. For the purposes of this document, the auxiliary verb:

156 – “shall” means that compliance with a requirement or a test is mandatory for compliance with this
157 document;

158 – “should” means that compliance with a requirement or a test is recommended but is not mandatory
159 for compliance with this document; and

160 – “may” is used to describe a permissible way to achieve compliance with a requirement or test.

161 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates
162 that there is guidance or rationale related to that item in Annex AA.

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

170

171 **Medical Electrical Equipment — Part 2-61: Particular**
172 **requirements for basic safety and essential performance of**
173 **pulse oximeter equipment**

174 **201.1 Scope, object and related standards**

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

176 **201.1.1 * Scope**

177 *Replacement:*

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

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

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

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

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

193 HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the
194 scope of this document are not covered by specific requirements in this document except in
195 201.11 and in 7.2.13 and 8.4.1 of the general standard.

196 NOTE 1 See also 4.2 of the general standard.

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

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

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

202 This document is not applicable to pulse haemoglobin monitors.

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

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

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

210 **201.1.2 Object**

211 Subclause 1.2 of the general standard is replaced by:

212 The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE
213 requirements for PULSE OXIMETER EQUIPMENT [as defined in 201.3.203] and its ACCESSORIES.

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

217 **201.1.3 Collateral standards**

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

219 This document refers to those applicable collateral standards that are listed in Clause 2 of the
220 general standard⁴ and Clause 201.2 of this document.

221 IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and IEC 60601-1-12 apply as
222 modified in Clauses 202, 206, 208, 211 and 212 respectively. IEC 60601-1-3² does not apply. All
223 other published collateral standards in the IEC 60601-1 series apply as published.

224 **201.1.4 Particular standards**

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

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

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

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

⁴ The general standard is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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

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

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

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

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

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

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

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

259 **201.2 Normative references**

260 The following documents are referred to in the text in such a way that some or all of their content
261 constitutes requirements of this document. For dated references, only the edition cited applies.
262 For undated references, the latest edition of the referenced document (including any
263 amendments) applies.

264 NOTE 1 The way in which these referenced documents are cited in normative requirements determines
265 the extent (in whole or in part) to which they apply.

266 NOTE 2 Informative references are listed in the Bibliography.

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

268 *Replacement:*