



SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-23:2024
01-julij-2024

Medicinska električna oprema - 2-23. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za skozikožno (transkutano) nadzorovanje delnega (parcialnega) krvnega tlaka

Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

Medizinische elektrische Geräte - Teil 2-23: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten für die transkutane Partialdrucküberwachung

Appareils électromédicaux - Partie 2-23: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de surveillance de la pression partielle transcutanée

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Ta slovenski standard je istoveten z: prEN IEC 80601-2-23:2024

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62D/2133/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

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62D/2037A/RR

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: <input type="checkbox"/> Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: <input type="checkbox"/> EMC <input type="checkbox"/> ENVIRONMENT <input type="checkbox"/> QUALITY ASSURANCE <input checked="" type="checkbox"/> SAFETY	
<input checked="" type="checkbox"/> SUBMITTED FOR CENELEC PARALLEL VOTING Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	<input type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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TITLE:

Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

PROPOSED STABILITY DATE: 2030

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment**

FOREWORD

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International standard IEC 60601-2-23 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This fourth edition cancels and replaces the third edition published in 2011. This edition constitutes a technical revision to align with Amendment 1:2012 and Amendment 2:2020 of IEC 60601-1:2005, new versions of collateral standards and amendments thereto.

Further it includes the following technical changes:

- Expansion of the scope to the EMERGENCY MEDICAL SERVICE ENVIRONMENT and HOME HEALTHCARE ENVIRONMENT
- Changed ESSENTIAL PERFORMANCE in Table 201.101
- Changed requirement for ingress protection

- 159 – Added PRIMARY OPERATING FUNCTIONS
- 160 – Added requirements for ALARM SYSTEM logging
- 161

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162 The text of this particular standard is based on the following documents:

FDIS	Report on voting
62DXX/FDIS	62D/XX/RVD

163
164 Full information on the voting for the approval of this particular standard can be found in the
165 report on voting indicated in the above table.

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

167 In this standard, the following print types are used:

- 168 – Requirements and definitions: roman type.
169 – *Test specifications: italic type.*
170 – Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
171 Normative text of tables is also in a smaller type.
172 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS
173 NOTED: SMALL CAPITALS.

174 In referring to the structure of this standard, the term

- 175 – “clause” means one of the twenty numbered divisions within the table of contents,
176 inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
177 – “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all
178 subclauses of Clause 7).

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

181 In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any
182 combination of the conditions is true.

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

- 185 – “shall” means that compliance with a requirement or a test is mandatory for compliance
186 with this standard;
187 – “should” means that compliance with a requirement or a test is recommended but is not
188 mandatory for compliance with this standard;
189 – “may” is used to describe a permissible way to achieve compliance with a requirement or
190 test.

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

193 A list of all parts of the IEC 60601 series, published under the general title *Medical electrical*
194 *equipment*, can be found on the IEC website.

195

196 The committee has decided that the contents of this publication will remain unchanged until
197 the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data
198 related to the specific publication. At this date, the publication will be

- 199 • reconfirmed,
200 • withdrawn,
201 • replaced by a revised edition, or
202 • amended.

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

208 The National Committees are requested to note that for this document the stability date
209 is 20xx.

210 This text is included for the information of the national committees and will be deleted at the
211 publication stage.

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214

INTRODUCTION

215 This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of
216 TRANSCUTANEOUS PARTIAL PRESSURE MONITORS. It amends and supplements
217 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020:
218 *Medical electrical equipment – Part 1: General requirements for basic safety and essential*
219 *performance*, hereinafter referred to as the general standard.

220 The aim of this fourth edition is to bring this particular standard up to date with reference to
221 the edition 3.2 of the general standard and new versions of collateral standards and
222 amendments thereto through technical changes.

223 The requirements of this particular standard take priority over those of the general standard
224 and collateral standards.

225 A “General guidance and rationale” for the more important requirements of this particular
226 standard is included in Annex AA. It is considered that knowledge of the reasons for these
227 requirements will not only facilitate the proper application of the standard but will, in due
228 course, expedite any revision necessitated by changes in clinical practice or as a result of
229 developments in technology. However, Annex AA does not form part of the requirements of
230 this document.

231

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

240 **201.1 Scope, object and related standards**

241 Clause 1 of the general standard¹ applies, except as follows:

242 **201.1.1 * Scope**

243 *Replacement:*

244 This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of
245 TRANSCUTANEOUS PARTIAL PRESSURE MONITORS as defined in 201.3.203 hereinafter also
246 referred to as ME EQUIPMENT or ME SYSTEM.

247 This document applies to TRANSCUTANEOUS PARTIAL PRESSURE MONITORS intended for use in
248 professional healthcare facilities in the EMERGENCY MEDICAL SERVICE ENVIRONMENT or the
249 HOME HEALTHCARE ENVIRONMENT.

250 This standard applies to TRANSCUTANEOUS PARTIAL PRESSURE MONITORS used with adults,
251 children and neonates, and it includes the use of these devices in foetal monitoring during
252 birth.

253 This standard does not apply to haemoglobin saturation oximeters or to devices applied to
254 surfaces of the body other than the skin (for example conjunctiva, mucosa).

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

258 The clause or subclause applies to ME EQUIPMENT, as default. For ME EQUIPMENT with the
259 corresponding safety measure or function not completely integrated into the ME EQUIPMENT but
260 instead implemented in an ME SYSTEM, the ME EQUIPMENT MANUFACTURER shall specify in the
261 ACCOMPANYING DOCUMENTS which functionality and safety requirements shall be provided by
262 the ME SYSTEM to comply with this standard. The ME SYSTEM has to be verified accordingly.

263 HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within
264 the scope of this document are not covered by specific requirements in this document.

265 NOTE See also 4.2 of the General Standard.

266 **201.1.2 Object**

267 *Replacement:*

268 The object of this particular standard is to establish BASIC SAFETY and
269 ESSENTIAL PERFORMANCE requirements for TRANSCUTANEOUS PARTIAL PRESSURE MONITORS as
270 defined in 201.3.203.

¹ The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*