

**SLOVENSKI STANDARD**  
**SIST EN IEC 80601-2-26:2020/oprA1:2021**  
**01-november-2021**

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**Dopolnilo A1 - Medicinska električna oprema - 2-26. del: Posebne zahteve za osnovno varnost in bistvene lastnosti elektroencefalografov**

Amendment 1 - Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph

Medizinische elektrische Geräte - Teil 2-26: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektroenzephalographen

Appareils électromédicaux - Partie 2-26: Exigences particulières pour la sécurité de base et les performances essentielles des électroencéphalographes

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**Ta slovenski standard je istoveten z: EN IEC 80601-2-26:2020/prA1:2021**

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**ICS:**

11.040.55      Diagnostična oprema      Diagnostic equipment

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62D/1897/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:

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CLOSING DATE FOR VOTING:

2021-12-03

SUPERSEDES DOCUMENTS:

62D/1833/RR

IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
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 <input type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING <b>Attention IEC-CENELEC parallel voting</b> 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.	
This document is still under study and subject to change. It should not be used for reference purposes.	
Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.	

TITLE:

**Amendment 1 - Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph**

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

IEC 80601-2-26 amendment is to align to the Amendment projects of the IEC 60601-1 series. Please see IEC 62D/1808/INF and 62D/1828/AC for more information.

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

### MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

#### FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 80601-2-26 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 publication is published as a double logo standard.

This document cancels and replaces the third edition of IEC 60601-2-26 published in 2012. This edition constitutes a technical revision to align with Amendment 1:2012 of IEC 60601-1:2005, new versions of collateral standards and amendments thereto.

98 The text of this standard is based on the following documents of IEC:

FDIS	Report on voting
62D/xxxx/FDIS	62D/xxxx/RVD

99  
100 Full information on the voting for the approval of this document can be found in the report on  
101 voting indicated in the above table. In ISO, the standard has been approved by xxx  
102 P members out of yyy having cast a vote.

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

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

- 105 – requirements and definitions: roman type;
- 106 – *test specifications*: italic type;
- 107 – informative material appearing outside of tables, such as notes, examples and references: in smaller type.  
108 Normative text of tables is also in a smaller type;
- 109 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS  
110 NOTED: SMALL CAPITALS.

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

- 112 – "clause" means one of the seventeen numbered divisions within the table of contents,  
113 inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- 114 – "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all  
115 subclauses of Clause 7).

116 References to clauses within this document are preceded by the term "Clause" followed by  
117 the clause number. References to subclauses within this particular standard are by number  
118 only.

119 In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any  
120 combination of the conditions is true.

121 The verbal forms used in this document conform to usage described in Clause 7 of the  
122 ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- 123 – "shall" means that compliance with a requirement or a test is mandatory for compliance  
124 with this document;
- 125 – "should" means that compliance with a requirement or a test is recommended but is not  
126 mandatory for compliance with this document;
- 127 – "may" is used to describe a permissible way to achieve compliance with a requirement or  
128 test.

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

131 A list of all parts of the 80601 International Standard, published under the general title  
132 *Medical electrical equipment*, can be found on the IEC website.

133 The committee has decided that the contents of this document will remain unchanged until the  
134 stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to  
135 the specific document. At this date, the document will be

- 136 • reconfirmed,
- 137 • withdrawn,
- 138 • replaced by a revised edition, or
- 139 • amended.

140 NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing  
141 organizations may need a transitional period following publication of a new, amended or revised IEC publication in  
142 which to make products in accordance with the new requirements and to equip themselves for conducting new or  
143 revised tests. It is the recommendation of the committees that the content of this publication be adopted for  
144 implementation nationally not earlier than 3 years from the date of publication.

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147

## INTRODUCTION

148 This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of  
149 ELECTROENCEPHALOGRAPHS. It amends and supplements IEC 60601-1:2005 and  
150 IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements*  
151 *for basic safety and essential performance*, hereinafter referred to as the general standard.

152 The aim of this document is to bring this particular standard up to date with reference to the  
153 edition 3.1 of the general standard and new versions of collateral standards and amendments  
154 thereto through technical changes.

155 The requirements of this particular standard take priority over those of the general standard.

156 A general guidance and rationale for the more important requirements of this particular  
157 standard is included in Annex AA. It is considered that knowledge of the reasons for these  
158 requirements will not only facilitate the proper application of the standard but will, in due  
159 course, expedite any revision necessitated by changes in clinical practice or as a result of  
160 developments in technology. However, Annex AA does not form part of the requirements of  
161 this document.

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## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

#### 171 **201.1 Scope, object and related standards**

172 Clause 1 of the general standard<sup>1</sup> applies, except as follows:

##### 173 **201.1.1 \* Scope**

174 *Replacement:*

175 This part of the 80601 International Standard applies to the BASIC SAFETY and  
176 ESSENTIAL PERFORMANCE of ELECTROENCEPHALOGRAPHS as defined in 201.3.204, hereafter also  
177 referred to as ME EQUIPMENT or ME SYSTEM. This document is applicable to  
178 ELECTROENCEPHALOGRAPHS intended for use in professional healthcare facilities, the  
179 EMERGENCY MEDICAL SERVICES ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

180 This document does not cover requirements for other equipment used in  
181 electroencephalography such as:

- 182 – phono-photoc stimulators;
- 183 – EEG data storage and retrieval;
- 184 – ME EQUIPMENT particularly intended for monitoring during electroconvulsive therapy.

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

188 The clause or subclause applies to ME EQUIPMENT, as default. For ME EQUIPMENT with the  
189 corresponding safety measure or function not completely integrated into the ME EQUIPMENT but  
190 instead implemented in an ME SYSTEM, the ME EQUIPMENT MANUFACTURER specifies in the  
191 ACCOMPANYING DOCUMENTS which functionality and safety requirements are provided by the  
192 ME SYSTEM to comply with this document. The ME SYSTEM is verified accordingly.

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

195 NOTE See also 4.2 of the general standard.

##### 196 **201.1.2 Object**

197 *Replacement:*

198 The object of this particular standard is to establish particular BASIC SAFETY and  
199 ESSENTIAL PERFORMANCE requirements for ELECTROENCEPHALOGRAPHS as defined in 201.3.204.

<sup>1</sup> 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*

### 200 **201.1.3 Collateral standards**

201 *Addition:*

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

204 IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010,  
205 IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply as modified in  
206 Clause 202 and 206, respectively. IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-10 do not  
207 apply. All other published collateral standards in the IEC 60601-1 series apply as published.

### 208 **201.1.4 Particular standards**

209 *Replacement:*

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

214 A requirement of a particular standard takes priority over the general standard and collateral  
215 standards.

216 For brevity, IEC 60601-1, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are  
217 referred to in this particular standard as the general standard. Collateral standards are  
218 referred to by their document number.

219 The numbering of clauses and subclauses of this particular standard corresponds to that of  
220 the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content  
221 of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x"  
222 where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this  
223 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral  
224 standard, etc.). The changes to the text of the general standard and applicable collateral  
225 standards are specified by the use of the following words:

226 "*Replacement*" means that the clause or subclause of the general standard or applicable  
227 collateral standard is replaced completely by the text of this particular standard.

228 "*Addition*" means that the text of this particular standard is additional to the requirements of  
229 the general standard or applicable collateral standard.

230 "*Amendment*" means that the clause or subclause of the general standard or applicable  
231 collateral standard is amended as indicated by the text of this particular standard.

232 Subclauses, figures or tables which are additional to those of the general standard are  
233 numbered starting from 201.101. However due to the fact that definitions in the general  
234 standard are numbered 3.1 through 3.147, additional definitions in this document are  
235 numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and  
236 additional items aa), bb), etc.

237 Subclauses, figures or tables which are additional to those of a collateral standard are  
238 numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for  
239 IEC 60601-1-2, etc.

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

242 Where there is no corresponding clause or subclause in this particular standard, the clause or  
 243 subclause of the general standard or applicable collateral standard, although possibly not  
 244 relevant, applies without modification; where it is intended that any part of the general  
 245 standard or applicable collateral standard, although possibly relevant, is not to be applied, a  
 246 statement to that effect is given in this particular standard.

## 247 **201.2 Normative references**

248 NOTE Informative references are listed in the Bibliography.

249 Clause 2 of the general standard applies, except as follows:

### 250 *Replacement:*

251 IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic*  
 252 *safety and essential performance – Collateral standard: Electromagnetic disturbances –*  
 253 *Requirements and tests*  
 254 IEC 60601-1-2:2014/AMD1:2020

255 IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic*  
 256 *safety and essential performance – Collateral standard: Usability*  
 257 IEC 60601-1-6:2010/AMD1:2013  
 258 IEC 60601-1-6:2010/AMD2:2020

### 259 *Addition:*

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260 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic*  
 261 *safety and essential performance*  
 262 IEC 60601-1:2005/AMD1:2012  
 263 IEC 60601-1:2005/AMD2:2020

264 IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for*  
 265 *basic safety and essential performance – Collateral standard: Requirements for medical*  
 266 *electrical equipment and medical electrical systems used in the home healthcare environment*  
 267 IEC 60601-1-11:2015/AMD1:2020

268 IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for*  
 269 *basic safety and essential performance – Collateral standard: Requirements for medical*  
 270 *electrical equipment and medical electrical systems intended for use in the emergency*  
 271 *medical services environment*  
 272 IEC 60601-1-12:2014/AMD1:2020

273 IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the*  
 274 *basic safety and essential performance of high frequency surgical equipment and high*  
 275 *frequency surgical accessories*

## 276 **201.3 Terms and definitions**

277 For the purpose of this document, the terms and definitions given in IEC 60601-1:2005,  
 278 IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014,  
 279 IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013,  
 280 IEC 60601-1-6:2010/AMD2:2020, IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020,  
 281 IEC 60601-1-12:2014, IEC 60601-1-12:2014/AMD1:2020, IEC 60601-2-2:2017 and the  
 282 following apply.

283 ISO and IEC maintain terminological databases for use in standardization at the following  
 284 addresses:

- 285 • IEC Electropedia: available at <http://www.electropedia.org/>
- 286 • ISO Online browsing platform: available at <http://www.iso.org/obp>

287 NOTE An index of defined terms is found beginning on page 36.

288 *Addition:*

289 **201.3.201**

290 **CHANNEL**

291 hardware and/or software selection of a particular electroencephalographic voltage between  
292 ELECTRODES for purposes of display, recording, or transmission

293 **201.3.202**

294 **ELECTRODE**

295 sensor that is applied to the scalp, cerebral cortex, or subdural locations to detect electrical  
296 activity of the brain

297 **201.3.203**

298 **ELECTROENCEPHALOGRAPH**

299 **EEG**

300 presentation (on screen or paper) of the variation with time of voltages taken from  
301 ELECTRODES, whose positions are specified

302 **201.3.204**

303 **ELECTROENCEPHALOGRAPH**

304 ME EQUIPMENT OR ME SYSTEM to produce an ELECTROENCEPHALOGRAPH

305 **201.3.205**

306 **LEAD WIRE**

307 cable connected between an ELECTRODE and either a PATIENT CABLE or the  
308 ELECTROENCEPHALOGRAPH

309 **201.3.206**

310 **NEUTRAL ELECTRODE**

311 reference point for differential amplifiers and/or interference suppression circuits

312 **201.3.207**

313 **PATIENT CABLE**

314 multiwire cable or junction box used to connect LEAD WIRES to the ELECTROENCEPHALOGRAPH

315 **201.4 General requirements**

316 Clause 4 of the general standard applies, except as follows:

317 **201.4.3 ESSENTIAL PERFORMANCE**

318 *Additional subclause:*

319 **201.4.3.101 \* Additional ESSENTIAL PERFORMANCE requirements**

320 Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in  
321 Table 201.101.