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Enote za oskrbo v medicini (ISO/DIS 11197:2018)

Medical supply units (ISO/DIS 11197:2018)

Gaines techniques à usage médical (ISO/DIS 11197:2018)

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ISO/DIS 11197:2018(E)**35 Foreword**

36 ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies
37 (ISO member bodies). The work of preparing International Standards is normally carried out through ISO
38 technical committees. Each member body interested in a subject for which a technical committee has been
39 established has the right to be represented on that committee. International organizations, governmental and non-
40 governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International
41 Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

42 The procedures used to develop this document and those intended for its further maintenance are described in
43 the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO
44 documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC
45 Directives, Part 2. www.iso.org/directives

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

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

52 For an explanation on the meaning of ISO specific terms and expressions related to conformity
53 assessment, as well as information about ISO's adherence to the WTO principles in the Technical
54 Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

55 The committee responsible for this document is ISO/TC 121.

56 ISO 11197 was prepared by the European Committee for Standardization (CEN) Technical Committee
57 CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with ISO Technical Committee TC 121,
58 *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*, in accordance with the Agreement
59 on technical cooperation between ISO and CEN (Vienna Agreement).

60 This fourth edition cancels and replaces the third edition (ISO 11197:2016), which has been technically revised.

61 Introduction

62 Many healthcare facilities use surface-mounted or recessed containment systems and ENCLOSURES for
63 accommodating and displaying essential PATIENT care services. These are known as MEDICAL SUPPLY UNITS.

64 This International Standard specifies requirements for MEDICAL SUPPLY UNITS manufactured in factories or
65 assembled from components on site.

66 It is intended for use by those persons involved in the design, construction, inspection, testing, maintenance and
67 operation of healthcare facilities as well as those manufacturing, assembling and installing MEDICAL SUPPLY UNITS.

68 Persons involved in the design, manufacture, installation, maintenance and testing of equipment intended to be
69 connected to MEDICAL GAS, MEDICAL DEVICE GAS, VACUUM, ANAESTHETIC GAS SCAVENGING and/or PLUME EXTRACTION SYSTEMS
70 should be aware of the contents of this document.

71 This International Standard is a particular standard, based on IEC 60601-1:2005+A1:2012. IEC 60601-
72 1:2005+A1:2012 is the basic standard for the safety of all MEDICAL ELECTRICAL EQUIPMENT used by or under the
73 supervision of qualified personnel in the general medical and PATIENT environment; it also contains certain
74 requirements for reliable operation to ensure safety.

75 IEC 60601-1:2005+A1:2012 has associated collateral standards and particular standards. The collateral standards
76 include requirements for specific technologies and/or HAZARDS and apply to all applicable equipment, such as
77 medical systems, ELECTROMAGNETIC COMPATIBILITY (EMC), radiation protection in diagnostic X-ray equipment,
78 software, etc. The particular standards apply to specific equipment types, such as medical electron accelerators,
79 high frequency surgical equipment, hospital beds, etc.

80 NOTE Definitions of collateral standard and particular standard can be found in IEC 60601:2005+A1:2012.

81 For an explanation of the special numbering in this document and more on the terms “collateral”, “particular” and
82 “general” standards, see 201.1.3, 201.1.4, and 201.1.5.

83 Annex AA contains rationale statements for some of the requirements of this International Standard. It is included
84 to provide additional insight into the reasoning that led to the requirements and recommendations that have been
85 incorporated in this International Standard. The clauses and subclauses marked with (*) after their number have a
86 corresponding rationale contained in Annex AA.

87

88 Medical supply units

90 201.1 Scope, object and related standards

91 *IEC 60601-1:2005+A1:2012, Clause 1 applies except as follows:*

92 201.1.1 Scope

93 *IEC 60601-1:2005+A1:2012, 1.1 is replaced by:*

94 This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL SUPPLY UNITS, hereafter
95 also referred to as ME EQUIPMENT.

96 This International Standard applies to MEDICAL SUPPLY UNITS manufactured within a factory or assembled on site,
97 including cabinetry and other ENCLOSURES, which incorporate PATIENT care services.

98 NOTE 1 A party that assembles on site various components intended for PATIENT care services into an ENCLOSURE is
99 considered the MANUFACTURER of the MEDICAL SUPPLY UNIT.

100 HAZARDS inherent in the intended function of ME EQUIPMENT or ME SYSTEMS within the scope of this International
101 Standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of IEC 60601-
102 1:2005+A1:2012 (see 201.1.4).

103 NOTE 2 See also IEC 60601-1:2005+A1:2012, 4.2.

104 201.1.2 Object

105 *IEC 60601-1:2005+A1:2012, 1.2 is replaced by:*

106 The object of this International Standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE
107 requirements for MEDICAL SUPPLY UNITS as defined in 201.3.103.

108 201.1.3 Related standards

109 201.1.3.1 Collateral standards

110 *IEC 60601-1:2005+A1:2012, 1.3 applies with the following addition:*

111 This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005+A1:2012,
112 Clause 2 as well as 201.2 of this particular standard.

113 IEC 60601-1-3:2008, IEC 60601-1-8:2006+A1:2012, IEC 60601-1-9:2007, and IEC 60601-1-10:2007+A1:2013 do not
114 apply.

115 NOTE Collateral standards are referred to by their document numbers.

116 **201.1.3.2 Particular standards**

117 *IEC 60601-1:2005+A1:2012, 1.4 applies with the following additions:*

118 The numbering of sections, clauses and subclauses of this particular standard corresponds to that of IEC 60601-
119 1:2005+A1:2012 with the prefix “201” (e.g. 201.1 in this standard addresses the content of IEC 60601-
120 1:2005+A1:2012 Clause 1) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the
121 collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the
122 IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the
123 IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005+A1:2012 are specified by the
124 use of the following words:

125 — “Replacement” means that the clause or subclause of IEC 60601-1:2005+A1:2012 or applicable
126 collateral standard is replaced completely by the text of this particular standard.

127 — “Addition” means that the text of this particular standard is additional to the requirements of
128 IEC 60601-1:2005+A1:2012 or applicable collateral standard.

129 — “Amendment” means that the clause or subclause of IEC 60601-1:2005+A1:2012 or applicable
130 collateral standard is amended as indicated by the text of this particular standard.

131 Subclauses or figures which are additional to those of IEC 60601-1:2005+A1:2012 are numbered starting from
132 201.101. Additional Annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

133 Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where
134 “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

135 The term “this standard” is used to make reference to IEC 60601-1:2005+A1:2012, any applicable collateral
136 standards and this particular standard taken together.

137 Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or
138 subclause of IEC 60601-1:2005+A1:2012 or applicable collateral standard, although possibly not relevant, applies
139 without modification; where it is intended that any part of IEC 60601-1:2005+A1:2012 or applicable collateral
140 standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular
141 standard.

142 **201.2 Normative references**

143 The following documents, in whole or in part, are normatively referenced in this document and are indispensable for
144 its application. For dated references, only the edition cited applies. For undated references, the latest edition of the
145 referenced document (including any amendments) applies.

146 NOTE Informative references are listed in the Bibliography on page 25.

147 *IEC 60601-1:2005+A1:2012, Clause 2 applies and IEC 60601-1-2:2014, Clause 2 applies, with the following additions:*

148 IEC 60364-5-54:2011, *Electrical installations of buildings — Part 5-54: Selection and erection of electrical*
149 *equipment; Earthing arrangements, protective conductors and protective bonding conductors*

150 IEC 60364-7-710:2002, *Electrical installations of buildings — Part 7-710: Requirements for special*
151 *installations or locations; Medical locations*

152 IEC 60529:1989+AMD1:1999 +AMD2:2013 CSV/COR2:2015, *Degrees of protection provided by enclosures*
153 *(IP Code)*

154 IEC 60598-1:2014, *Luminaires — Part 1: General requirements and tests*

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- 155 IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety*
156 *and essential performance*
- 157 IEC 60601-1-2:2014 *Medical electrical equipment — Part 1-2: General requirements for basic safety and*
158 *essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*
- 159 IEC 60601-1-3:2008, *Medical electrical equipment — Part 1: General requirements for safety 3. Collateral*
160 *Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment*
- 161 IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and*
162 *essential performance — Collateral standard: Usability*
- 163 IEC 60601-1-8:2006+A1:2012, *Medical electrical equipment — Part 1-8: General requirements for basic*
164 *safety and essential performance — Collateral Standard: General requirements, test and guidance for alarm*
165 *systems in medical electrical equipment and medical electrical systems*
- 166 IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and*
167 *essential performance — Collateral Standard: Requirements for environmentally conscious design*
- 168 IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and*
169 *essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop*
170 *controllers*
- 171 IEC 61386-1:2008, *Conduit systems for cable management — Part 1: General requirements*
- 172 IEC 61950:2007, *Cable management systems — Specifications for conduit fittings and accessories for cable*
173 *installations for extra-heavy duty electrical steel conduit*
- 174 ISO 32
- 175 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources*
176 *using sound pressure — Engineering methods for an essentially free field over a reflecting plane*
- 177 ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical*
178 *gases*
- 179 ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and*
180 *vacuum*
- 181 ISO 7396-2:2008, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*
- 182 ISO 9170-1:2017, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with*
183 *compressed medical gases and vacuum*
- 184 ISO 9170-2:2008, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic*
185 *gas scavenging systems*
- 186 ISO 14971:2012, *Medical devices — Application of risk management to medical devices*
- 187 ISO 16571:2014, *Systems for evacuation of plume generated by medical devices*
- 188 EN 50174-1:2009 + A2:2014, *Information technology. Cabling installation — Part 1: Installation specification and*
189 *quality assurance*
- 190 EN 50174-2:2009+ A2:2014, *Information technology. Cabling installation — Part 2: Installation planning and practices*
191 *inside buildings*

192 **201.3 Terms and definitions**

193 For the purpose of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, ISO 16571:2014,
194 ISO 7396-1:2016 and the following apply.

195 NOTE An alphabetical index of defined terms is found at the end of this document.

196 *Replacement of 3.26:*

197 **201.3.26**

198 **ENCLOSURE**

199 surrounding case constructed to provide a degree of protection to personnel against accidental contact
200 with live parts and also the enclosed equipment against specified environmental conditions

201 Note 1 to entry: See IEC 61950:2007, 3.15.

202 Note 2 to entry: An ENCLOSURE can be subdivided into COMPARTMENTS.

203 *Addition:*

204 **201.3.63**

205 **MEDICAL ELECTRICAL EQUIPMENT**

206 **ME EQUIPMENT**

207 MEDICAL SUPPLY UNITS may be connected to more than one SUPPLY MAINS.

208 *Addition:*

209 **201.3.67**

210 **MULTIPLE SOCKET-OUTLET**

211 Note: MEDICAL SUPPLY UNITS are not considered **MULTIPLE SOCKET OUTLETS**

212 <https://standards.iteh.ai/catalog/standards/sist/14562ea3-492c-49f0-99a7-f059026e7b9e/sist-en-iso-11197-2020>

213 **201.3.201**

214 **MEDICAL SUPPLY UNIT**

215 Permanently installed ME EQUIPMENT intended to supply electric power, communication means (telephone,
216 call systems, etc.), data transmission, lighting, and/or MEDICAL GASES, MEDICAL DEVICE GASES and/or
217 liquids, an ANAESTHETIC GAS SCAVENGING SYSTEM and/or a PLUME EVACUATION SYSTEM to medical areas of a
218 healthcare facility

219 Note 1 to entry: MEDICAL SUPPLY UNITS can include ME EQUIPMENT or ME SYSTEMS or parts thereof. MEDICAL
220 SUPPLY UNITS can also consist of modular sections for electrical supply, lighting for therapy or illumination,
221 communication, supply of MEDICAL GASES, MEDICAL DEVICE GASES and liquids, PLUME EVACUATION SYSTEMS and
222 ANAESTHETIC GAS SCAVENGING SYSTEMS. Some typical examples of MEDICAL SUPPLY UNITS are bed head service
223 modules, ceiling pendants, beams, booms, columns, pillars, enclosures for area shut off valve boxes of the
224 MEDICAL GAS pipeline system, joinery, cabinetry, concealed COMPARTMENTS on or in a wall and prefabricated
225 walls.

226 Note 2 to entry: Examples of configurations are given in Figures 201.103, 201.104 and 201.105.

227 **201.3.202**

228 **JUNCTION POINT**

229 connection point(s) between the MEDICAL SUPPLY UNIT and the inter-connecting system(s) already installed.

ISO/DIS 11197:2018(E)230 **201.3.203**231 **COMPARTMENT**

232 An area within an ENCLOSURE which is created by separating barriers, walls and covers forming its own
233 cellular section.

234 **201.4 General requirements**

235 *IEC 60601-1:2005+A1:2012, Clause 4 applies.*

236 **201.4.2.3.1 Hazards identified in the 60601-1 series**

237 The MANUFACTURER shall undertake all tests as defined or referenced within this standard and Annex BB,
238 and record the results. National standards may also apply which require test and record keeping.

239 **201.5 General requirements for testing ME EQUIPMENT**

240 *IEC 60601-1:2005+A1:2012, Clause 5 applies with the following additions:*

241 **201.5.9.2.3 Actuating mechanisms**

242 All external surfaces shall conform to a degree of protection against direct contact in normal operation of
243 at least IP2X or IPXXB. See IEC 60529:1989+AMD1:1999+AMD2:2013 CSV/COR2:2015.

244 This level of protection to live parts shall not be compromised during maintenance of the MEDICAL GAS
245 PIPELINE SYSTEMS, ANAESTHETIC GAS SCAVENGING SYSTEMS, PLUME EVACUATION SYSTEMS or liquid pipeline systems,
246 e.g. by the provision of covers, barriers or individual protection with a degree of protection of at least IP2X
247 or IPXXB. See IEC 60529:1989+AMD1:1999+AMD2:2013 CSV/COR2:2015.

248 If requested by the healthcare facility (e.g. in psychiatric or paediatric units or prison healthcare facilities),
249 the MANUFACTURER shall provide means to prevent inadvertent or unauthorized dismantling of MEDICAL
250 SUPPLY UNITS.

251 **201.5.101 MEDICAL SUPPLY UNIT test results**

252 The MANUFACTURER shall test each MEDICAL SUPPLY UNIT. The test results shall be recorded and presented to
253 the RESPONSIBLE ORGANIZATION on request.

254 **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

255 *IEC 60601-1:2005+A1:2012, Clause 6 applies, with the following additions:*

256 **201.6.1 Protection against electric shock**

257 A MEDICAL SUPPLY UNIT shall be designed and constructed as CLASS I.

258 **201.7 ME EQUIPMENT identification, marking and documents**

259 *IEC 60601-1:2005+A1:2012, Clause 7 applies, with the following additions:*