



SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-90:2025
01-februar-2025

Medicinska električna oprema - 2-90. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za respiratorno terapijo z velikim pretokom (ISO/DIS 80601-2-90:2024)

Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment (ISO/DIS 80601-2-90:2024)

Medizinische elektrische Geräte - Teil 2-90: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Geräten für die Beatmungstherapie mit hohem Durchfluss (ISO/DIS 80601-2-90:2024)

Appareils électromédicaux - Partie 2-90: Exigences particulières pour la sécurité de base et les performances essentielles des équipements de thérapie respiratoire à haut débit (ISO/DIS 80601-2-90:2024)

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Ta slovenski standard je istoveten z: prEN ISO 80601-2-90

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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oSIST prEN ISO 80601-2-90:2025

en,fr,de



DRAFT International Standard

ISO/DIS 80601-2-90

Medical electrical equipment — Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

Appareils électromédicaux —

*Partie 2-90: Exigences particulières pour la sécurité de base
et les performances essentielles des équipements de thérapie
respiratoire à haut débit*

ICS: 11.040.10

ISO/TC 121/SC 3

Secretariat: **ANSI**

Voting begins on:
2024-12-06

Voting terminates on:
2025-02-28

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

Reference number
ISO/DIS 80601-2-90:2024(en)

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Published in Switzerland

1	Contents	
2	Contents	iii
3	Introduction	viii
4	201.1 Scope, object and related standards	1
5	201.1.1 Scope	1
6	201.1.2 Object	2
7	201.1.3 Collateral standards	3
8	201.1.4 Particular standards	3
9	201.2 Normative references	4
10	201.3 Terms and definitions	6
11	201.4 General requirements	21
12	201.4.3 Essential performance	21
13	201.4.3.101 Additional requirements for essential performance	21
14	201.4.5 Alternative risk control measures or test methods for ME equipment or	
15	ME system	22
16	201.4.6 ME equipment or ME system parts that contact the patient	22
17	201.4.11.101 Additional requirements for pressurized gas input	23
18	201.4.11.101.1 Overpressure requirement	23
19	201.4.11.101.2 Compatibility requirement	23
20	201.5 General requirements for testing of ME equipment	24
21	201.5.101 Additional requirements for the general requirements for testing of	
22	ME equipment	24
23	201.5.101.1 Respiratory high-flow therapy equipment test conditions	24
24	201.5.101.2 Gas flowrate specifications	24
25	201.5.101.3 Respiratory high-flow therapy equipment testing errors	24
26	201.6 Classification of ME equipment and ME systems	25
27	201.7 ME equipment identification, marking and documents	25
28	201.7.1.101 Information supplied by the manufacturer	25
29	201.7.2.4.101 Additional requirements for accessories	25
30	201.7.2.18 External gas source	26
31	201.7.4.3 Units of measurement	27
32	201.7.9.2.1 General	Error! Bookmark not defined.
33	201.7.9.2.1.101 Additional general requirements	27
34	201.7.9.2.2.101 Additional requirements for warnings and safety notices	27
35	201.7.9.2.8.101 Additional requirements for start-up procedure	29
36	201.7.9.2.9.101 Additional requirements for operating instructions	30
37	201.7.9.2.9.101.1 Lay operator operating instructions	30
38	201.7.9.2.9.101.2 Healthcare professional operator operating instructions	31
39	201.7.9.2.12 Cleaning, disinfection and sterilization	31
40	201.7.9.2.13.101 Additional requirements for maintenance	32
41	201.7.9.2.14.101 Additional requirements for accessories, supplementary equipment,	
42	used material	32
43	201.7.9.3.1.101 Additional general requirements	32
44	201.7.9.3.101 Additional requirements for the technical description	33
45	201.8 Protection against electrical hazards from ME equipment	33
46	201.9 Protection against mechanical hazards of ME equipment and ME systems	33
47	201.9.4.3.101 Additional requirements for instability from unwanted lateral movement	33

ISO/DIS 80601-2-90:2024(en)

48	201.9.6.2.1.101	Additional requirements for audible acoustic energy.....	33
49	201.10	Protection against unwanted and excessive radiation <i>hazards</i>	34
50	201.11	Protection against excessive temperatures and other <i>hazards</i>	35
51	201.11.1.2.2	<i>Applied parts</i> not intended to supply heat to a <i>patient</i>	35
52	201.11.6.6	<i>Cleaning and disinfection</i> of <i>ME equipment</i> or <i>ME system</i>	35
53	201.11.6.7	<i>Sterilization</i> of <i>ME equipment</i> or <i>ME system</i>	36
54	201.11.7	<i>Biocompatibility</i> of <i>ME equipment</i> and <i>ME systems</i>	36
55	201.11.8.101	Additional requirements for interruption of the power supply/ <i>supply mains</i> to <i>ME equipment alarm condition</i>	37
56	201.11.8.101.1	<i>Alarm conditions</i>	37
57	201.11.8.101.2	Alternative power supply/ <i>supply mains</i>	39
58	201.12	Accuracy of controls and instruments and protection against hazardous outputs.....	39
59	201.12.1	Accuracy of controls and instruments.....	39
60	201.12.1.101	<i>Continuous flow breathing-therapy mode</i>	40
61	201.12.1.101.1	Flowrate accuracy.....	40
62	201.12.1.101.2	Accuracy of delivered oxygen concentration.....	42
63	201.12.2.101	<i>Usability</i> of <i>ME equipment</i>	43
64	201.12.4	Protection against hazardous output.....	44
65	201.12.4.101	Oxygen monitor.....	44
66	201.12.4.102	<i>Maximum limited pressure protection device</i>	45
67	201.12.4.103	Flowrate monitoring.....	45
68	201.12.4.104	<i>Obstruction alarm condition</i>	46
69	201.12.4.105	<i>SpO₂ monitoring equipment</i>	46
70	201.12.101	Protection against accidental adjustments.....	47
71	201.13	<i>Hazardous situations</i> and fault conditions for <i>ME equipment</i>	47
72	201.13.2.101	Additional specific <i>single fault conditions</i>	48
73	201.13.101	Failure of one gas supply to <i>respiratory high-flow therapy equipment</i>	48
74	201.13.102	Independence of delivery control function and related <i>risk control</i> measures.....	48
75	201.14	<i>Programmable electrical medical systems (PEMS)</i>	49
76	201.15	Construction of <i>ME equipment</i>	50
77	201.15.101	Mode of operation.....	50
78	201.15.102	Delivered oxygen concentration.....	50
79	201.15.103	Pre-use check.....	51
80	201.16	<i>ME systems</i>	51
81	201.16.1.101	Additional general requirements for <i>ME systems</i>	51
82	201.16.2	<i>Accompanying documents</i> of an <i>ME system</i>	52
83	201.17	Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	52
84	201.101	Gas connections.....	52
85	201.101.1	Connections to an inlet.....	52
86	201.101.1.1	<i>Low-pressure hose assembly</i>	52
87	201.101.2	<i>Breathing system connectors</i>	52
88	201.101.2.1	General.....	52
89	201.101.2.2	Other named ports.....	53
90	201.101.2.2.1	General.....	53
91	201.101.2.2.2	<i>Patient-connection port</i>	53
92	201.101.2.2.6	<i>Gas pathway connection port</i>	54
93	201.101.2.2.7	Monitoring probe port.....	Error! Bookmark not defined.
94	201.101.2.2.8	Temperature sensor port.....	54
95	201.101.2.2.9	Nebulization port.....	54
96			

97	201.101.3	Oxygen inlet connector	55
98	201.101.4	Gas intake port	55
99	201.102	Requirements for the <i>breathing system</i> and <i>accessories</i>	55
100	201.102.1	General	55
101	201.102.2	Labelling	55
102	201.102.3	Breathing sets	56
103	201.102.4	Humidification system	56
104	201.102.5	Breathing system filter (BSF)	56
105	201.102.6	Airway devices	56
106	201.103	Indication of duration of operation	57
107	201.104	Functional connection	57
108	201.104.1	General	57
109	201.104.2	Connection to an electronic health record	57
110	201.104.3	Connection to a <i>distributed alarm system</i>	57
111	201.104.4	Connection for remote control	58
112	201.105	Power supply cords	58
113	201.106	Respiratory high-flow therapy equipment security	58
114	202	Electromagnetic disturbances — Requirements and tests	58
115	202.4.3.1	Compliance criteria	59
116	202.5.2.2.1	Requirements applicable to all <i>ME equipment</i> and <i>ME systems</i>	59
117	202.8.1.101	Additional general requirements	59
118	206	Usability	59
119	208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	61
120			
121	208.6.5.4.2	Selection of <i>default alarm preset</i>	61
122	208.6.12.2	Operator alarm system logging	62
123	211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	63
124			
125	211.7.4.7	Additional requirements for <i>cleaning, disinfection</i> and <i>sterilization</i>	63
126	211.10.1.1	General requirements for mechanical strength	63
127		Annexes	63
128		Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	64
129			
130		Annex D (informative) <i>Symbols on marking</i>	72
131		Annex AA (informative) Particular guidance and rationale	74
132	AA.1	General guidance	74
133	AA.2	Rationale for particular clauses and subclauses	74
134		Annex BB (informative) Data interface requirements	92
135	BB.1	Background and purpose	92
136	BB.2	Data definition	93
137		Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances	96
138		Annex DD (informative) Terminology — Alphabetized index of defined terms	100
139			

ISO/DIS 80601-2-90:2024(en)

140 Foreword

141 ISO (the International Organization for Standardization) and IEC (the International Electrotechnical
142 Commission) form the specialized system for worldwide standardization. National bodies that are
143 members of ISO or IEC participate in the development of International Standards through technical
144 committees established by the respective organization to deal with particular fields of technical activity.
145 ISO and IEC technical committees collaborate in fields of mutual interest. Other international
146 organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the
147 work.

148 The procedures used to develop this document and those intended for its further maintenance are
149 described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the
150 different types of document should be noted. This document was drafted in accordance with the editorial
151 rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives or
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161 expressions related to conformity assessment, as well as information about ISO's adherence to the World
162 Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT),
163 see www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

164 This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory*
165 *equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and
166 Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC D,
167 *Particular medical equipment, software, and systems*, in collaboration with the European Committee for
168 Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in
169 accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

170 This second edition cancels and replaces the first edition (ISO 80601-2-90:2021), which has been
171 technically revised.

172 The main changes are as follows:

- 173 — updated normative references;
- 174 — clarified *system recovery* requirements;
- 175 — added *cybersecurity* requirements; and
- 176 — added requirements for *SpO₂ monitoring equipment*.

177 A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO and IEC
178 websites.

179 Any feedback or questions on this document should be directed to the user's national standards body. A
180 complete listing of these bodies can be found at www.iso.org/members.html and [www.iec.ch/national-](http://www.iec.ch/national-committees)
181 [committees](http://www.iec.ch/national-committees).

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182 **Introduction**

183 *Respiratory high-flow therapy equipment* has been used successfully for years with neonatal *patients*. In
 184 recent years there is more information about treating adults with *respiratory high-flow therapy*
 185 *equipment* when it is used as an intermediate therapy to improve oxygenation in adult critical care
 186 *patients*, respiratory care units and for palliative care. *High-flow therapy equipment* is also used in the
 187 treatment of chronic respiratory disease to reduce exacerbation, improve physiological outcomes and
 188 quality of life^{[31][44][45][48]} ¹. The use of *respiratory high-flow therapy equipment* continues to increase as it
 189 is easily set up and is well tolerated by *patients*.

190 Since the outbreak of COVID-19 in January of 2020, its spread has been rapid and fierce. In hospitals
 191 across the world, all kinds of *respiratory high-flow therapy equipment* have been widely used. In general,
 192 there is a trend to use more non-invasive respiratory therapy. More and more new *manufacturers* of
 193 *respiratory high-flow therapy equipment* have rapidly emerged. Neither international nor national
 194 standards are available for *respiratory high-flow therapy equipment*. With the spread of the epidemic
 195 globally, the demand for this document is clear and very urgent.

196 The first *respiratory high-flow therapy equipment* was constructed by the connection of a *humidifier*,
 197 air/oxygen mixer/blender, flowmeter, breathing tube and cannula. Based on the improvement in
 198 technical integration in recent years, there are several technical routes for *respiratory high-flow therapy*
 199 *equipment* on the market. *Respiratory high-flow therapy equipment* is not fully covered by the existing
 200 standards for *humidifiers*, gas mixers for medical use, flowmeters or *ventilators*.

201 This document addresses the *basic safety* and *essential performance* requirements of *respiratory high-*
 202 *flow therapy equipment*, including *risks* related to oxygen (e.g., fires, incorrect oxygen concentration,
 203 incorrect flow delivery, etc.).

204 Specifically, the following *risks* and related requirements were considered in the development of this
 205 document.

- 206 — Contaminated air entering the *gas intake port* of the *respiratory high-flow therapy equipment*.
- 207 — Instability of gas supply from a *high-pressure inlet*.
- 208 — Insufficient pressure from a *high-pressure inlet*, and subsequent effects on oxygen delivered to the
 209 *patient*.
- 210 — Insufficient oxygen being delivered to the *patient*, and related *alarm condition*.
- 211 — *Usability* by *operators* wearing personal protective equipment (such as gloves and blurred visors),
 212 when setting up equipment, or viewing or changing settings.
- 213 — Instability of output delivered to *patients*, necessitating frequent *operator* adjustment.
- 214 — *Processing* of equipment, including the surface of the *enclosure* and internal *gas pathways*,
 215 particularly after use on infectious *patients*.
- 216 — Infectious exhaled gas.
- 217 — Overheating of *respiratory high-flow therapy equipment*.
- 218 — Insufficient flow capability from a *medical gas pipeline system*, and subsequent effects on oxygen
 219 supply to other *patients* in a care area.

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

- 221 — requirements and definitions: roman type;

¹ Numbers in square brackets refer to the Bibliography.

- 222 — *terms defined in Clause 3 of the general standard, in this document or as noted: italic type;*
- 223 — informative material appearing outside of tables, such as notes, examples and references: in smaller type.
224 Normative text of tables is also in a smaller type.
- 225 In referring to the structure of this document, the term:
- 226 — “clause” means one of the five numbered divisions within the table of contents, inclusive of all
227 subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- 228 — “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses
229 of Clause 201).
- 230 References to clauses within this document are preceded by the term “Clause” followed by the clause
231 number. References to subclauses within this particular document are by number only.
- 232 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination
233 of the conditions is true.
- 234 For the purposes of this document, the auxiliary verb:
- 235 — “shall” indicates a requirement;
- 236 — “should” indicates a recommendation;
- 237 — “may” indicates a permission;
- 238 — “can” is used to describe a possibility or capability; and
- 239 — “must” is used express an external constraint.
- 240

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241 **Medical electrical equipment —**

242 **Part 2-90:**

243 **Particular requirements for basic safety and essential**
244 **performance of respiratory high-flow therapy equipment**

245 **201.1 Scope, object and related standards**

246 Clause 1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

247 NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

248 **201.1.1 Scope**

249 *Replacement:*

250 NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

251 This document applies to the *basic safety* and *essential performance* of *respiratory high-flow therapy*
252 *equipment*, as defined in 201.3.262, hereafter also referred to as *ME equipment* or *ME system*, in
253 combination with its *accessories*:

254 — intended for use with *patients* who can breathe spontaneously; and

255 — intended for *patients* who would benefit from improved alveolar gas exchange; and who would
256 benefit from receiving high-flow humidified respiratory gases, which can include a *patient* whose
257 upper airway is bypassed.

258 EXAMPLE 1 *Patients* with Type 1 Respiratory Failure who exhibit a reduction in arterial blood oxygenation.

259 EXAMPLE 2 *Patients* who would benefit from reduced work of breathing, as needed in Type 2 Respiratory
260 Failure, where arterial carbon dioxide is high.

261 EXAMPLE 3 *Patients* requiring humidification to improve mucociliary clearance.

262 *Respiratory high-flow therapy equipment* can be intended for use in the *home healthcare environment* or
263 intended for use in professional healthcare facilities.

264 NOTE 2 In the *home healthcare environment*, the *supply mains* is often not reliable.

265 *Respiratory high-flow therapy equipment* can be:

266 — fully integrated *ME equipment*; or

267 — a combination of separate items forming a *ME system*.

268 This document also applies to other types of respiratory equipment when that equipment includes a
269 respiratory high-flow therapy mode.

270 NOTE 3 This document and ISO 80601-2-12 are applicable to a critical care *ventilator* with a high-flow therapy
271 mode.

ISO/DIS 80601-2-90:2024(en)

272 *Respiratory high-flow therapy equipment can be transit-operable.*

273 This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to
274 the *respiratory high-flow therapy equipment*, where the characteristics of those *accessories* can affect the
275 *basic safety* or *essential performance* of the *respiratory high-flow therapy equipment*.

276 EXAMPLE 4 Breathing sets, *connectors*, *humidifier*, *breathing system filter*, external electrical power source,
277 *distributed alarm system*, *high-flow nasal cannula*, tracheal tube, tracheostomy tube, face *mask* and supra-laryngeal
278 airway.

279 NOTE 4 *Accessories* are assessed with the relevant clauses of this document when configured as part of
280 *respiratory high-flow therapy equipment*.

281 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems*
282 only, the title and content of that clause or subclause will say so. If that is not the case, the clause or
283 subclause applies both to *ME equipment* and to *ME systems*, as relevant.

284 *Hazards* inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope
285 of this document are not covered by specific requirements in this document except in the general
286 standard, 7.2.13 and 8.4.1.

287 NOTE 5 Additional information can be found in the general standard, 4.2.

288 This document does not specify the requirements for:

289 — *ventilators* or *accessories* for *ventilator-dependent patients* intended for critical care applications,
290 which are given in ISO 80601-2-12;

291 — *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13;

292 — *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given
293 in ISO 80601-2-84;

294 — *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare*
295 *environment*, which are given in ISO 80601-2-72;

296 — ventilatory support equipment or *accessories* intended for *patients* with ventilatory impairment,
297 which are given in ISO 80601-2-79;

298 — ventilatory support equipment or *accessories* intended for *patients* with ventilatory insufficiency,
299 which are given in ISO 80601-2-80;

300 — sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70;

301 — continuous positive airway pressure (CPAP) *ME equipment*;

302 — high-frequency jet *ventilators* (HFJVs)^[33], which are given in ISO 80601-2-87;

303 — gas mixers for medical use, which are given in ISO 11195;

304 — flowmeters, which are given in ISO 15002;

305 — high-frequency oscillatory *ventilators* (HFOVs), which are given in ISO 80601-2-87; and

306 — cuirass or “iron-lung” ventilation equipment.

307 This document is a particular standard in the IEC 60601 series, the IEC 80601 series and the ISO 80601
308 series.

309 **201.1.2 Object**

310 *Replacement:*