



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 10651-4:2021**  
**01-september-2021**

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**Pljučni ventilatorji - 4. del: Posebne zahteve za naprave za oživljanje, ki jih upravlja uporabnik (ISO/DIS 10651-4:2021)**

Lung ventilators - Part 4: Particular requirements for user-powered resuscitators (ISO/DIS 10651-4:2021)

Beatmungsgeräte - Teil 4: Anforderungen an anwenderbetriebene Wiederbelebungsgeräte (Handbeatmungsgeräte) (ISO/DIS 10651-4:2021)

Ventilateurs pulmonaires - Partie 4 : Exigences relatives aux ressuscitateurs à puissance motrice manuelle (ISO/DIS 10651-4:2021)

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**Ta slovenski standard je istoveten z: prEN ISO 10651-4**

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**ICS:**

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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# DRAFT INTERNATIONAL STANDARD

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ISO/TC 121/SC 3

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2021-09-29

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## Lung ventilators —

### Part 4: Particular requirements for user-powered resuscitators

*Ventilateurs pulmonaires —**Partie 4: Exigences relatives aux ressuscitateurs à puissance motrice manuelle*

ICS: 11.040.10

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## ISO 10651-4:2021(E)

104 **Foreword**

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

112 The procedures used to develop this document and those intended for its further maintenance are  
 113 described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the  
 114 different types of ISO documents should be noted. This document was drafted in accordance with the  
 115 editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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

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

122 For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and  
 123 expressions related to conformity assessment, as well as information about ISO's adherence to the World  
 124 Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see  
 125 [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

126 This document was prepared by Technical Committee ISO/TC 121, *Anesthetic and respiratory*  
 127 *equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*.

128 This second edition cancels and replaces the first edition (ISO 10651-4:2002<sup>[7]1</sup>), which has been  
 129 technically revised.

130 The main changes compared to the previous edition are as follows:

- 131 — clarified scope and indicated that the requirements include specified *accessories*;
- 132 — normative references updated from ENs to current ISO standards;
- 133 — updated defined terms to be consistent with current ISO standards;
- 134 — specified test conditions;
- 135 — specified calculation and disclosure of measurement uncertainty;
- 136 — harmonized storage and operating environmental conditions with current ISO standards;
- 137 — added requirements for *shelf-life* and *expected lifetime*;
- 138 — harmonized *information supplied by the manufacturer* with ISO 20417 and ISO 15223-1;

<sup>1</sup> Figures in square brackets refer to the Bibliography.



- 139 — added requirements for the oxygen inlet connector;
- 140 — clarified ventilatory testing requirements;
- 141 — clarified *delivered oxygen concentration* performance requirements;
- 142 — added *processing* requirements;
- 143 — added *biocompatibility* requirements;
- 144 — added *usability* requirements;
- 145 A list of all parts in the ISO 10651 series can be found on the ISO website.
- 146 Any feedback or questions on this document should be directed to the user's national standards body. A  
147 complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

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**ISO 10651-4:2021(E)**148 **Introduction**

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

150 — “clause” means one of the fourteen numbered divisions within the table of contents, inclusive  
151 of all subdivisions (e.g. Clause 10 includes subclauses 10.3, 10.4, etc.);152 — “subclause” means a numbered subdivision of a clause (e.g. 10.3, 10.4 and 10.5 are all  
153 subclauses of Clause 10).154 References to clauses within this document are preceded by the term “Clause” followed by the clause  
155 number. References to subclauses within this document are by number only.156 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination  
157 of the conditions is true.158 The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2. For the  
159 purposes of this document, the auxiliary verb:

160 — “shall” indicates a requirement;

161 — “should” indicates a recommendation;

162 — “may” indicates a permission;

163 — “can” is used to describe a possibility or capability; and

164 — “must” indicates an external constraint.

165 Annex B contains a guide to the *marking and labelling* requirements in this document.166 Annex C contains a summary of the *symbols* referenced in this document.167 Requirements in this document have been decomposed so that each requirement is uniquely delineated.  
168 This is done to support automated requirements tracking.

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# Lung ventilators — Part 4: Particular requirements for user-powered resuscitators

## 1 Scope

This document specifies requirements for *user-powered resuscitators* intended for use with all age groups and which are intended to provide *lung* ventilation to *patients* whose breathing is inadequate. *User-powered resuscitators* are designated according to ideal body mass range.

NOTE 1 *Patients* being treated with a *resuscitator* can be *ventilator-dependent*.

Example *user-powered resuscitators* include:

— self-inflating bag *resuscitators* intended to be squeezed by the *user's* hand and refilled by elastic recoil; and

NOTE 2 Self-inflating bag *resuscitators* are generally *transit-operable*.

— flow-inflating bag *resuscitators* intended to be squeezed by the *user's* hand and refilled by a flow from a medical gas source.

This document is also applicable to those *accessories* that are intended for use with *resuscitators* where the characteristics of those *accessories* can affect the *safety* of the *user-powered resuscitator*.

Examples of such *accessories* include such as *masks*, *PEEP* valves, capnometric indicators, manometers, metronomes, flow restrictors, filters, gas refill valves, oxygen gas mixers, connectors, point-of-use packaging, electronic feedback devices, electronic sensors and transmission of data to other equipment.

This document does not specify the requirements for:

— gas-powered emergency resuscitators, which are given in ISO 10651-5<sup>[8]</sup>;

— electrically-powered resuscitators;

— gas powered resuscitators for *professional healthcare facilities*; and

— anaesthetic reservoir bags, which are given in ISO 5362<sup>[4]</sup>.

NOTE 3 This document has been prepared to address the relevant *essential principles*<sup>[22]</sup> and labelling<sup>[23]</sup> guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex D.

NOTE 4 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016<sup>[11]</sup> as indicated in Annex E.

NOTE 5 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745<sup>[21]</sup> as indicated in Annex F.

## 2 Normative references

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

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

205 NOTE 2 Informative references are listed in the Bibliography.

206 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and*  
207 *sockets*

208 ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk*  
209 *management process*

210 ISO 11195:2018, *Gas mixers for medical use — Stand-alone gas mixers*

211 ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a*  
212 *sterilizing agent and the development, validation and routine control of a sterilization process for medical*  
213 *devices*

214 ISO 17664-1:—<sup>2</sup>, *Processing of health care products — Information to be provided by the medical device*  
215 *manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

216 ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device*  
217 *manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

218 ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*  
219 *Part 1: Evaluation and testing within a risk management process*

220 ISO 20417:2021, *Medical devices -- Information to be provided by the manufacturer*

221 ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use: — Part 1: Salt test method*  
222 *to assess filtration performance*

223 ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use: — Part 2: Non-filtration*  
224 *aspects*

225 ISO 80369-2:—<sup>3</sup>, *Small-bore connectors for liquids and gases in healthcare applications — Part 2:*  
226 *Connectors for breathing systems and driving gases applications*

227 IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical*  
228 *devices*

229 IEC Guide 115:—<sup>4</sup>, *Application of uncertainty of measurement to conformity assessment activities in the*  
230 *electrotechnical sector*

### 231 3 Terms and definitions

232 For the purposes of this document, the following terms and definitions apply.

<sup>2</sup> Under preparation. Stage at the time of publication: ISO/FDIS 17664-1:2020.

<sup>3</sup> Under preparation. Stage at the time of publication: ISO/DIS 80369-2:2021.

<sup>4</sup> Under preparation. Stage at the time of publication: ISO/DV 115:2020.

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

234 — ISO Online browsing platform: available at <https://www.iso.org/obp>

235 — IEC Electropedia: available at <http://www.electropedia.org/>

236 NOTE An alphabetized index of defined terms is found in Annex G.

### 237 3.1

#### 238 **accessory**

239 item, intended specifically by its *manufacturer*, to be used together with one or more *medical devices* to  
240 specifically enable or assist those *medical devices* to be used in accordance with their *intended use*

241 Note 1 to entry: An *accessory* is typically a consumable or separate item for use with one or more *medical devices*.

242 Note 2 to entry: Some *authorities having jurisdiction* consider an *accessory* to be a *medical device*.

243 Note 3 to entry: Some *authorities having jurisdiction* have a different definition of *accessory*.

244 [SOURCE: ISO 20417:2021, 3.1]

### 245 3.2

#### 246 **accompanying information**

247 information accompanying or marked on a *medical device* or *accessory* for the *user* or those accountable  
248 for the installation, use, *processing*, maintenance, decommissioning and disposal of the *medical device* or  
249 *accessory*, particularly regarding safe use

250 Note 1 to entry: The *accompanying information* shall be regarded as part of the *medical device* or *accessory*.

251 Note 2 to entry: The *accompanying information* can consist of the *label*, *marking*, *instructions for use*, *technical*  
252 *description*, installation manual, quick reference guide, etc.

253 Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve  
254 auditory, visual, or tactile materials and multiple media types (e.g., CD/DVD-ROM, USB stick, website).

255 [SOURCE: ISO 20417:2021, 3.2, modified —deleted note 4.]

### 256 3.3

#### 257 **airway pressure**

258 pressure at the *patient-connection port*, relative to ambient pressure unless otherwise specified

259 Note 1 to entry: In addition to its direct reference, this term or its symbol  $P_{aw}$ , displayed in various character styles,  
260 is only used, in context or by qualification, to designate this concept as a measured quantity.

261 Note 2 to entry: The site(s) of actual measurement(s) may be anywhere in the *ventilator breathing system*, providing  
262 that the indicated value is referenced to that at the *patient-connection port*.

263 Note 3 to entry: This is the generic term for this fundamental concept. Post-coordinated terms, for example, peak  
264 inspiratory pressure and baseline *airway pressure*, are used in particular contexts.

265 Note 4 to entry: Although providing no explicit indication as to where along the *patient's* airway this pressure is  
266 measured, this term, along with its symbol, has become widely adopted as referencing the pressure at the point at  
267 which *artificial ventilation* equipment is connected to the *patient's* airway or to an *airway device*. This is the final  
268 site where a common and replicable pressure can be continuously monitored, conveniently, before breathing gas  
269 enters the *patient*.

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270 Note 5 to entry: A pressure measured in the *patient's* airway at a site other than at the *patient-connection port* is  
271 referred to in this document as a respiratory pressure.

272 [SOURCE: ISO 19223:2019<sup>[13]</sup>, 3.6.1 modified — deleted notes 6 and 7.]

273 **3.4**  
274 ***atmospheric temperature and pressure***  
275 ***ATP***

276 expressed at ambient atmospheric pressure and temperature

277 **3.5**  
278 ***bag inlet valve***

279 valve activated by the sub-atmospheric pressure in the *compressible unit* of the *resuscitator* to refill the  
280 *compressible unit* with gas at ambient pressure

281 [SOURCE: ISO 4135:—<sup>[4]</sup>, 3.6.1.3.1]

282 **3.6**  
283 ***bag refill valve***

284 valve, with no manual trigger, activated by the sub-atmospheric pressure in the *compressible unit* of the  
285 *resuscitator* to refill the *compressible unit* from a pressurized gas source

286 [SOURCE: ISO 4135:—<sup>[13]</sup>, 3.6.1.3.2]

287 **3.7**  
288 ***BAP***

289 quantity by which the baseline *airway pressure* is set to be positively offset from the ambient pressure

290 [SOURCE: ISO 19223:2019<sup>[13]</sup>, 3.10.2, modified — deleted notes.]  
291 [https://standards.iteh.ai/catalog/standards/sist/bc9d91d0-173e-418d-b61c-  
aaf440f30708/osist-pren-iso-10651-4-2021](https://standards.iteh.ai/catalog/standards/sist/bc9d91d0-173e-418d-b61c-aaf440f30708/osist-pren-iso-10651-4-2021)

292 **3.8**  
293 ***biocompatibility***

294 ability to be in contact with a living system without producing an unacceptable adverse effect

295 Note 1 to entry: Medical devices may produce some level of adverse effect, but that level may be determined to be  
296 acceptable when considering the benefits provided by the medical device.

297 [SOURCE: ISO 18562-1:2016, 3.2]

298 **3.9**  
299 ***breathing system filter***  
300 ***BSF***

301 device intended to reduce transmission of particulates, including microorganisms, in a breathing system

302 [SOURCE: ISO 4135:—<sup>[13]</sup>, 3.6.1.5]

303 **3.10**  
304 ***cleaning***

305 removal of contaminants to the extent necessary for further *processing* or for *intended use*

306 Note 1 to entry: *Cleaning* consists of the removal, usually with detergent and water, of adherent soil (e.g. blood,  
307 protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a *medical device*  
308 by a manual or automated *process* that prepares the items for safe handling or further *processing*.

309 [SOURCE: ISO 17664-1:—, 3.1]

309 **3.11**310 ***clearly legible***

311 capable of being read by a person with normal vision

312 [SOURCE: ISO 20417:2021, 3.4]

313 **3.12**314 ***compressible unit***315 part of a *user-powered resuscitator* e.g. a bag or bellows that, when squeezed by the *user*, delivers a volume  
316 of gas317 [SOURCE: ISO 4135:—<sup>[13]</sup>, 3.4.1.11, modified —replaced 'compressed' by 'squeezed'.]318 **3.13**319 ***delivered oxygen concentration***320 concentration of oxygen in the gas delivered to a *patient*321 [SOURCE: ISO 4135:—<sup>[13]</sup>, 3.1.1.14, modified —deleted example.]322 **3.14**323 ***disinfection***324 *process* to reduce the number of viable microorganisms to a level previously specified as being  
325 appropriate for a defined purpose326 [SOURCE: ISO 17664-1:—<sup>[13]</sup>, 3.3]327 **3.15**328 ***e-documentation***329 any form of electronically accessible *information supplied by the manufacturer* related to a *medical device*  
330 or *accessory*

331 EXAMPLE CD/DVD-ROM, USB stick, website.

332 [SOURCE: ISO 20417:2021, 3.6, modified —deleted note 1.]

333 **3.16**334 ***essential principles***335 ***essential principles of safety and performance***336 fundamental high-level requirements that when complied with ensure a medical device is safe and  
337 performs as intended338 [SOURCE: ISO 16142-1:2016<sup>[11]</sup>, 3.3]339 **3.17**340 ***exhaust port***341 port of the medical equipment or device from which gas is discharged to the atmosphere during *normal*  
342 *use*, either directly or via an anaesthetic gas scavenging system343 Note 1 to entry: A *resuscitator* may have more than one *exhaust port*.344 [SOURCE: ISO 19223:2019<sup>[13]</sup>, 3.14.2, modified —added note.]345 **3.18**346 ***expected lifetime***347 time period specified by the *manufacturer* during which the *medical device* or *accessory* is expected to  
348 remain safe and effective for use