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Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/1630/CD

COMMITTEE DRAFT (CD)

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United States of America

SECRETARY:

Ms Hae Choe

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:

☐

Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

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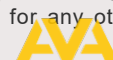
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TITLE:

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

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Documents

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ISO/IEC 80601-2-13:2018(E)

ISO/TC 121/SC 1 **N 1356 1362** // ISO TC 121/SC 1/JWG 1 **N 214-372**

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Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

Voting dates: Start of ballot 7 September 2018, end of ballot: 30 November 2018. Comments to be discussed at a meeting of ISO/TC 121/SC 1/JWG 1, Berlin (Germany), 7 to 9 January 2019

CD stage

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267

268 **Foreword**

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

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

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286 For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and
 287 expressions related to conformity assessment, as well as information about ISO's adherence to the
 288 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see
 289 www.iso.org/iso/foreword.html.

290 This document was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic*
 291 *and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines* and
 292 Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D,
 293 *Electromedical equipment*.

294 This second edition cancels and replaces the first edition (ISO 80601-2-13:2011 including ISO 80601-2-
 295 13:2011/AMD 1:2015 and ISO 80601-2-13:2011/AMD 2:2018), which has been technically revised

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

- 297 – incorporation of the texts of the amendments AMD 1:2015 and AMD 2:2018;
- 298 – incorporation of updates regarding the “2019 amendments” to IEC 60601-1 and its applicable collateral
 299 standards;
- 300 – updates for new editions of the cited standards;
- 301 – addition of requirements on pressure measurement for functional testing at the patient connection port;
- 302 – consideration of anaesthetic workstations using Oxygen 93;
- 303 – amendments to the technical description of an anaesthetic workstation with regard to information about
 304 the end of life of the anaesthetic workstation and its individual components;
- 305 – inclusion of a normative reference to the series of standards ISO 18562 and to the standard ISO 10993-1
 306 on biocompatibility evaluation of breathing gas pathways and on biological evaluation of medical devices
 307 respectively;

- 308 – amendments to the alarm condition for power supply failure by adding simply electronically generated
- 309 alarm signals as another option;

- 310 – for the determination of the A-weighted sound pressure, replacement of the normative reference
- 311 ISO 3746 by ISO 3744:2010;

- 312 – amendments to the requirements on the internal electrical power source;

- 313 – amendments to the requirement on the connection for remote control;

- 314 – amendments to the instructions for use for the anaesthetic gas delivery system and for the anaesthetic
- 315 breathing system;

- 316 – amendments to the requirements on the flow rate adjustment control;

- 317 – revision of the requirements on the reservoir bag connection port;

- 318 – amendments of the constructional requirements of the circle absorber assembly and the information to
- 319 be provided for the inspiratory and expiratory pressure/flow rate characteristics of that item;

- 320 – amendments of the pressure and flow-rate characteristics of the inspiratory and expiratory valves;

- 321 – addition of requirements on ventilation modes;

- 322 – amendments to the requirements on the adjustable pressure limitation protection device;

- 323 – addition of the normative reference to IEC 60601-1-12 for an anaesthetic workstation that is used in an
- 324 emergency medical services environment.

- 325 A list of all parts in the ISO 80601 series can be found on the ISO website.

- 326 Any feedback or questions on this document should be directed to the user's national standards body. A
- 327 complete listing of these bodies can be found at www.iso.org/members.html.

328 Introduction

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

330 — Requirements and definitions: roman type.

331 — Terms defined in Clause 3 of the general standard, in this particular standard and test specifications:
332 italic type.

333 — Informative material appearing outside of tables, such as notes, examples and references: in smaller
334 type. Normative text of tables is also in a smaller type.

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

336 — “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all
337 subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

338 — “subclause” means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all
339 subclauses of Clause 201.7).

340 References to clauses within this document are preceded by the term “Clause” followed by the clause
341 number. References to subclauses within this document are by number only.

342 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any
343 combination of the conditions is true.

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

346 — “shall” means that compliance with a requirement or a test is mandatory for compliance with this
347 document;

348 — “should” means that compliance with a requirement or a test is recommended but is not mandatory for
349 compliance with this document;

350 — “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

353 This document considers both an *anaesthetic workstation* supplied complete and its individual
354 components *in combination with its accessories*. It has been structured to allow *responsible*
355 *organizations* to configure an *anaesthetic workstation* from individual components in conformance with
356 professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, this
357 document identifies particular requirements pertinent to specific *anaesthetic workstation* components,
358 ~~and to their including~~ associated *monitoring equipment*, *alarm system(s)* and *protection device(s)*, and
359 defines the interfaces.

360

361 Figure 201.101 is a graphical representation of the structure of this document and is provided for
 362 informational purposes only.

<i>anaesthetic workstation</i>		
General requirements Clauses 201.1 – 201.17, 201.106, 201.107, 202-212	<i>monitoring equipment, alarm systems and protection devices</i>	Mandatory elements; see also Table AA.1
<i>anaesthetic gas delivery system</i> Clause 201.101		
<i>anaesthetic breathing system</i> Clause 201.102		
<i>anaesthetic gas scavenging system</i> Clause 201.103	<i>monitoring equipment, alarm systems and protection devices</i>	Optionally present; see also Table AA.1
<i>anaesthetic vapour delivery system</i> Clause 201.104		
<i>anaesthetic ventilator</i> Clause 201.105		

363 **Figure 201.101 — Configuration of an *anaesthetic workstation* and corresponding organization of**
 364 **this document**

365

European Foreword

To be inserted in the European Foreword of EN ISO 80601-2-13/A2:2017

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

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

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO/ IEC
ISO 407:2004	EN ISO 407:2004	ISO 407:2004
ISO 594-2:1998	EN 1707:1997 ^a	ISO 594-2:1998 ^a
ISO 2878:2017	-	ISO 2878:2017
ISO 3744:2010	EN ISO 3744:2010	ISO 3744:2010
ISO 4135:2001	EN ISO 4135:2001	ISO 4135:2001
ISO 5145:2017	-	ISO 5145:2017
ISO 5356-1:2015	EN ISO 5356-1:2015	ISO 5356-1:15
ISO 5356-2:2012	EN ISO 5356-2:2012	ISO 5356-2:2012
ISO 5359:2014 + AMD 1:2017	EN ISO 5359:2014 + AMD 1:2017	ISO 5359:2014 + AMD 1:2018
ISO 5360:2016	EN ISO 5360:2016	ISO 5360:2016
ISO 5362:2012	-	ISO 5362:2012
ISO 5367:2014	EN ISO 5367:2014	ISO 5367:2014
ISO 7396-1:2016 + AMD 1:2017	EN ISO 7396-1:2016 + AMD 1:20xx	ISO 7396-1:2016 + AMD 1:2017
ISO 7396-2:2007	EN ISO 7396-2:2007	ISO 7396-2:2007
ISO 8836:20xx	EN ISO 8836:20xx	ISO 8836:20xx
ISO 7000:2014	-	ISO 7000:2014
ISO 7010: + AMD 1:2012 + AMD 2:2012 + AMD 3:2012 + AMD 4:2013 + AMD 5:2014 + AMD 6:2014 + AMD 7:2016 + AMD 8:2017	EN ISO 7010: + A 1:2012 + A 2:2012 + A 3:2012 + A 4:2013 + A 5:2014 + A 6:2014 + A 7:2016 + A 8:20xx	ISO 7010: + AMD 1:2012 + AMD 2:2012 + AMD 3:2012 + AMD 4:2013 + AMD 5:2014 + AMD 6:2014 + AMD 7:2016 + AMD 8:2017

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO/ IEC
ISO 9170-1:2017	EN ISO 9170-1:20xx	ISO 9170-1:2017
ISO 9170-2:2008	EN ISO 9170-2:2008	ISO 9170-1:2008
ISO 10079-1:2015 + AMD 1:2018	EN ISO 10079-1:2015 + AMD 1:20xx	ISO 10079-1:2015 + AMD 1:2018
ISO 10079-3:2014	EN ISO 10079-2:2014	ISO 10079-3:2014
ISO 10524-1:2018	EN ISO 10524-1:20xx	ISO 10524-1:2018
ISO 10993-1:20xx	EN ISO 10993-1:20xx	ISO 10993-1:20xx
ISO 15223-1:2016, corrected version 2017-03	EN ISO 15223-1:2016, corrected version 2017-03	ISO 15223-1:2016, corrected version 2017-03
ISO 18082:2014 + AMD 1:2017	EN ISO 18082:2014 + AMD 1:2017	ISO 18082:2014 + AMD 1:2017
ISO 18562-1:2017	EN ISO 18562-1:20xx	ISO 18562-1:2017
ISO 18562-2:2017	EN ISO 18562-2:20xx	ISO 18562-2:2017
ISO 18562-3:2017	EN ISO 18562-3:20xx	ISO 18562-3:2017
ISO 18562-4:2017	EN ISO 18562-4:20xx	ISO 18562-4:2017
ISO/IEC 80079-20-1:2017	EN ISO 80079-20-1:20xx	ISO/IEC 60079-20-1:2017
ISO 80601-2-55:2018	EN ISO 80601-2-55:2018	ISO 80601-2-55:2018
IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + AMD 1:2012 + AMD 2:20xx	EN 60601-1:2005 + Cor. :2010 + A1:2013 + A2:20xx	IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + AMD 1:2012 + AMD 2:20xx
IEC 60601-1-2:2014 + AMD 1:2018	EN 60601-1-2:2015 + A1:20xx	IEC 60601-1-2:14 + AMD 1:2018
IEC 60601-1-6:2010 + AMD 1:2013 + AMD 2:20xx	EN 60601-1-6:2010 + A1:2015 + A2:20xx	IEC 60601-1-6:2010 + AMD 1:2013 + AMD 2:20xx
IEC 60601-1-8:2006 + AMD 1:2012 + AMD 2:20xx	EN 60601-1-8:2007 A 1:2012 + A2:20xx	IEC 60601-1-8:2006 AMD 1:2012 + AMD 2:20xx
IEC 60601-1-10:2007 + AMD 1:2012 + AMD 2:20xx	EN 60601-1-10:2008 + A1:2013 + A2:20xx	IEC 60601-1-10:2007 + AMD 1:2012 + AMD 2:20xx
IEC 62570:2014	EN 62570:2015	IEC 62570:2014
IEC 62304:20xx	EN 62304:20xx	IEC 62304:20xx
IEC 80601-2-49:2018	EN 80601-2-49:20xx	IEC 80601-2-49:2018
^a Replaced by EN ISO 80369-7:2017 and ISO 80369-7:2016 respectively.		

Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

201.1 Scope, object and related standards

IEC 60601-1:2005 + AMD 1:2012 + AMD 2:20xx, Clause 1 applies, except as follows:

201.1.1 * Scope

Replacement:

This document is applicable to the *basic safety* and *essential performance* of an *anaesthetic workstation* for administering inhalational anaesthesia whilst continuously attended by a professional operator.

This document specifies particular requirements for a complete *anaesthetic workstation* and the following *anaesthetic workstation* components which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant *anaesthetic workstation* components, to form an *anaesthetic workstation* to a given specification:

- *anaesthetic gas delivery system;*
- *anaesthetic breathing system;*
- *anaesthetic gas scavenging system;*
- *anaesthetic vapour delivery system;*
- *anaesthetic ventilator;*
- *monitoring equipment;*
- *alarm system;*
- *protection device.*

NOTE 1 *Monitoring equipment, alarm systems and protection devices* are summarized in Table AA.1.

An *anaesthetic workstation* supplied complete and its individual components are considered as *ME equipment* or *ME systems* with regard to the general standard.

NOTE 2 The applicability of this document is indicated in Table AA.2.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to an *anaesthetic workstation* where the characteristics of those *accessories* can affect the *basic safety* and *essential performance* of the *anaesthetic workstation*.

410 If a clause or subclause is specifically intended to be applicable to *anaesthetic workstation*
 411 components *or its accessories* only, the title and content of that clause or subclause will say so. If
 412 that is not the case, the clause or subclause applies both to an *anaesthetic workstation* and its
 413 individual components *including accessories*, as relevant.

414 *Hazards* inherent in the intended physiological function of an *anaesthetic workstation* and its
 415 individual components *including accessories* within the scope of this document are not covered by
 416 specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

417 NOTE 3 See also 4.2 of the general standard.

418 This document is not applicable to any *anaesthetic workstation* intended for use with flammable
 419 anaesthetic agents, as determined by Annex BB.

420 **201.1.2 Object**

421 *Replacement:*

422 The object of this document is to establish particular *basic safety* and *essential performance*
 423 requirements for an *anaesthetic workstation* and its individual components designed for use in
 424 the *anaesthetic workstation* (as defined in 201.3.211) and its *accessories*.

425 **201.1.3 Collateral standards**

426 *Addition:*

427 This document refers to those applicable collateral standards that are listed in Clause 2 of the
 428 general standard and Clause 201.2 of this document.

429 IEC 60601-1-3:2008, IEC 60601-1-9 + AMD 1:2013, IEC 60601-1-11:2010 + AMD 1: 2018 and
 430 AMD 2:20xx do not apply.

431 **201.1.4 *Particular standards**

432 *Addition:*

433 The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1
 434 (the general standard) with the prefix “201” (e.g. 201.1 in this document addresses the content of
 435 Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is
 436 the final digit(s) of the collateral standard document number (e.g. 202.4 in this document
 437 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 206.4 in this
 438 document addresses the content of Clause 4 of the IEC 60601-1-6 collateral standard, etc.). The
 439 changes to the text of the general standard are specified by the use of the following words:

440 “Replacement” means that the clause or subclause of the general standard or applicable collateral
 441 standard is replaced completely by the text of this document.

442 “Addition” means that the text of this document is additional to the requirements of the general
 443 standard or applicable collateral standard.

444 “Amendment” means that the clause or subclause of the general standard or applicable collateral
 445 standard is amended as indicated by the text of this document.

446 Subclauses, figures or tables which are additional to those of the general standard are numbered
 447 starting from 201.101. However, due to the fact that definitions in the general standard are
 448 numbered 3.1 to 3.154, additional definitions in this document are numbered beginning from
 449 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

450 Subclauses or figures which are additional to those of a collateral standard are numbered starting
 451 from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 206 for
 452 IEC 60601-1-6, etc.

453 The term “this document” is used to make reference to the general standard, any applicable
 454 collateral standards and this particular standard taken together.

455 Where there is no corresponding clause or subclause in this document, the clause or subclause of
 456 the general standard or applicable collateral standard, although possibly not relevant, applies
 457 without modification; where it is intended that any part of the general standard or applicable
 458 collateral standard, although possibly relevant, is not to be applied, a statement to that effect is
 459 given in this document.

460 If an *anaesthetic workstation* is supplied with physiological monitoring, having more than one
 461 applied part on the patient, then IEC 80601-2-49:2018 applies. Measured parameters related to
 462 the inherent function of an anaesthetic workstation (i.e. *airway pressure*, ventilation volume,
 463 oxygen concentration, volatile anaesthetic agent concentration, CO₂/N₂O), including derived and
 464 related parameters such as spontaneous ventilation volume or CO₂ production, are not
 465 considered to be a *physiological monitoring unit* as per IEC 80601-2-49.

466 201.2 Normative references

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

471 IEC 60601-1:2005 + AMD 1:2012 + AMD 2:20xx, Clause 2 applies, except as follows:

472 *Replacement:*

473 *Replace references to ISO 2878, ISO 7000, ISO 7010, ISO 15223-1, IEC 60601-1-2, IEC 60601-1-6 and*
 474 *IEC 60601-1-8, IEC 62304:2006 by the following references:*

475 ISO 2878:2017, *Rubber, vulcanized or thermoplastic — Antistatic and conductive products —*
 476 *Determination of electrical resistance*

477 ISO 7000:2014, *Graphical symbols for use on equipment — Registered symbols*

478 ISO 7010:2011 + AMD 1:2012 + AMD 2:2012 + AMD 3:2012 + AMD 4:2013 + AMD 5:2014 + AMD
 479 6:2014 + AMD7:2016, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

480 ISO 15223-1:2016, corrected version 2017-03, *Medical devices — Symbols to be used with medical device*
 481 *labels, labelling and information to be supplied — Part 1: General requirements*

- 482 IEC 60601-1-2:2014 + AMD 1:2018, *Medical electrical equipment — Part 1-2: General requirements for*
483 *basic safety and essential performance — Collateral standard: Electromagnetic disturbances —*
484 *Requirements and tests*
- 485 IEC 60601-1-6:2010 + AMD 1:2013 + AMD 2:20xx, *Medical electrical equipment — Part 1-6:*
486 *General requirements for basic safety and essential performance — Collateral standard: Usability*
- 487 IEC 60601-1-8:2006 + AMD 2012 + AMD 2:20xx, *Medical electrical equipment — Part 1-8: General*
488 *requirements for basic safety and essential performance — Collateral Standard: General*
489 *requirements, tests and guidance for alarm systems in medical electrical equipment and medical*
490 *electrical systems*
- 491 IEC 62304:20xx, *Medical device software — Software life cycle processes*
- 492 *Addition:*
- 493 ISO 407:2004, *Small medical gas cylinders — Pin-index yoke-type valve connections* [alternative
494 normative reference to ISO 5145]
- 495 ISO 594-2:1998, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical*
496 *equipment — Part 2: Lock fittings*¹
- 497 ISO 3744:2010, *Acoustics - Determination of sound power levels and sound energy levels of noise*
498 *sources using sound pressure - Engineering methods for an essentially free field over a reflecting*
499 *plane*
- 500 ISO 5145:2017, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*
501 [alternative normative reference to ISO 407]
- 502 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and*
503 *sockets*
- 504 ISO 5356-2:2012, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-*
505 *threaded weight-bearing connectors*
- 506 ISO 5359:2014 + AMD 1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies*
507 *for use with medical gases*
- 508 ISO 5360:2016, *Anaesthetic vaporizers — Agent-specific filling systems*
- 509 ISO 5362:2006, *Anaesthetic reservoir bags*
- 510 ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing tubes intended for use with*
511 *anaesthetic apparatus and ventilators*
- 512 ISO 7396-1:2016 + AMD 1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed*
513 *medical gases and vacuum*
- 514 ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

¹ ISO/TC 121/SC 1/JWG 1 will reconsider the reference to ISO 594-2 when ISO 80369-2, *Small bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases applications* becomes available.

- 515 ISO 8836:20XX, *Suction catheters for use in the respiratory tract* ((see question box in the text))
- 516 ISO 9170-1:2017, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with*
517 *compressed medical gases and vacuum*
- 518 ISO 9170-2:2008, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for*
519 *anaesthetic gas scavenging systems* ((see question box in the text))
- 520 ISO 10079-1:2015 + AMD 1:2018, *Medical suction equipment — Part 1: Electrically powered suction*
521 *equipment — Safety requirements* [alternative normative reference to ISO 10079-3] ((see question box
522 *in the text*))
- 523 ISO 10079-3:2014, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or*
524 *pressure source* [alternative normative reference to ISO 10079-1] ((see question box in the text))
- 525 ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and*
526 *pressure regulators with flow-metering devices*
- 527 ISO 10993-1:20xx, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a*
528 *risk management process*
- 529 ISO 18082:2014 + AMD 1:2017, *Anaesthetic and respiratory equipment — Dimensions of non-*
530 *interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*
- 531 ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*
532 *Part 1: Evaluation and testing within a risk management process*
- 533 ISO 18562-2:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare*
534 *applications — Part 2: Tests for emissions of particulate matter*
- 535 ISO 18562-3:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare*
536 *applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)*
- 537 ISO 18562-4:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare*
538 *applications — Part 4: Tests for leachables in condensate*
- 539 ISO/IEC 80079-20-1:2017, *Explosive atmospheres — Part 20-1: Material characteristics for gas and*
540 *vapour classification — Test methods and data* ((see question box in the text))
- 541 ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the*
542 *basic safety and essential performance of respiratory gas monitors*
- 543 IEC 60079-20-1:2017, *Explosive atmospheres — Part 20-1: Material characteristics for gas and*
544 *vapour classification — Test methods and data*
- 545 IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + AMD 1:2012 + AMD 2:20XX, *Medical electrical*
546 *equipment — Part 1: General requirements for basic safety and essential performance*
- 547 IEC 60601-1-10:2007 + AMD 1:2012 + AMD 2:20xx, *Medical electrical equipment — Part 1-10:*
548 *General requirements for basic safety and essential performance — Collateral standard:*
549 *Requirements for the development of physiologic closed-loop controllers*
- 550 IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the*
551 *magnetic resonance environment*

552 IEC 80601-2-49:2018, *Medical electrical equipment — Part 2-49: Particular requirements for the*
553 *basic safety and essential performance of multifunction patient monitoring equipment*

554 **201.3 Terms and definitions**

555 For the purposes of this document, the terms and definitions given in ISO 4135:2001,
556 IEC 60601-1:2005 + AMD 1:2012 + AMD 2:0xx, IEC 60601-1-2:2014 + AMD 1:2018, IEC 60601-1-
557 6:2010 + AMD 1:2013 + AMD 2:20xx, IEC 60601-1-8:2006 + AMD 1:2012 + AMD 2:20xx and the
558 following apply.

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

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

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

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

564 *Addition:*

565 **201.3.201**

566 ***active anaesthetic gas scavenging system***

567 *anaesthetic gas scavenging system* in which gas flow in the *disposal system* results from a *power*
568 *device*

569 Note 1 to entry: Derived from the definition of active system in ISO 4135:2001, definition 7.1.2. In the definition
570 of *active anaesthetic gas scavenging system* in this document it has been clarified that the gas flow of the *disposal*
571 *system* is considered.

572 **201.3.202**

573 ***airway pressure***

574 pressure at the *patient connection port*

575 **201.3.203**

576 ***anaesthetic breathing system***

577 inspiratory and expiratory pathways through which *anaesthetic gas* flows at respiratory
578 pressures between the *fresh-gas inlet*, the *patient connection port* and the *exhaust valve* or *exhaust*
579 *port*

580 Note 1 to entry: Adapted from ISO 4135:2001, definition 4.1.1 by deleting “those” before “inspiratory and
581 expiratory pathways”, by replacing “port” by “*exhaust port*” and by adding “*anaesthetic*” before “gas”.

582 **201.3.203**

583 ***anaesthetic breathing system***

584 inspiratory and expiratory pathways through which *anaesthetic gas* flows at respiratory
585 pressures between the *fresh-gas inlet*, the *patient connection port* and the *exhaust valve* or *exhaust*
586 *port*

587 Note 1 to entry: Adapted from ISO 4135:2001, definition 4.1.1 by deleting “those” before “inspiratory and
588 expiratory pathways”, by replacing “gas” by “*anaesthetic gas*” and by replacing “port” by “*exhaust port*”.

589 **201.3.204**
 590 ***anaesthetic gas***

591 gases and, if present, vapour of a volatile anaesthetic agent, used in anaesthesia

592 Note 1 to entry: In parts of an *anaesthetic breathing system*, *anaesthetic gas* includes gases exhaled by the
 593 *patient*.

594 **201.3.205**
 595 ***anaesthetic gas delivery system***

596 *anaesthetic workstation* component that receives separate supplies of *medical gas(es)* and delivers
 597 mixed gases in concentrations or individual flow rates adjustable by the *operator*

598 Note 1 to entry: An *anaesthetic gas delivery system* can include a means of flow rate adjustment control,
 599 *flowmeters* or a gas mixer and *anaesthetic gas delivery system piping* but does not include vaporizers.

600 **201.3.206**
 601 ***anaesthetic gas delivery system piping***

602 all piping, including unions, from the *unidirectional valves* in the pipeline inlets and from the
 603 outlets of the *pressure regulator(s)* to the means of flow rate adjustment control, as well as the
 604 piping connecting the means of flow rate adjustment control and the piping connecting the
 605 *anaesthetic vapour delivery system* to the *fresh-gas outlet*

606 Note 1 to entry: *Anaesthetic gas delivery system piping* includes piping leading to and from pneumatic loss of
 607 pressure *alarm signal* generators, pressure indicators, the oxygen flush and gas power outlets.

608 **201.3.207**
 609 ***anaesthetic gas scavenging system***

610 *protection device* that is connected to an *anaesthetic breathing system* or to associated equipment
 611 for the purpose of conveying excess *anaesthetic gas* to an appropriate place of discharge

612 Note 1 to entry: Functionally, an *anaesthetic gas scavenging system* comprises three different parts: a *transfer*
 613 *system*, a *receiving system* and a *disposal system*. These three functionally discrete parts can be either separate or
 614 sequentially combined in part or in total. In addition, one or more parts of an *anaesthetic gas scavenging system*
 615 can be sequentially combined with an *anaesthetic breathing system* or an *anaesthetic ventilator*, to include the
 616 *transfer system* or the *transfer and receiving system*.

617 Note 2 to entry: Adapted from ISO 4135:2001, definition 7.1.1 by clarifying that this system is to be considered
 618 a *protection device* and by incorporating minor editorial modifications.

619 **201.3.208**
 620 ***anaesthetic patient valve***

621 valve at the *patient* end of an *anaesthetic breathing system* that has three operating functions:

622 — as a *unidirectional valve* to prevent flow towards the vaporizer during exhalation,

623 — as an inflating valve to permit intermittent positive-pressure ventilation, and

624 — as a *unidirectional exhaust valve* to prevent inhalation of air through the *exhaust port* during
 625 spontaneous ventilation

626 **201.3.209**
 627 ***anaesthetic vapour delivery system***

628 *anaesthetic workstation* component that provides the vapour of a volatile anaesthetic agent in a
 629 calibrated concentration

630 Note to entry: Adapted from ISO 4135:2001, definition 2.2.2 by clarifying that this system is a component of
 631 an *anaesthetic workstation*, that the volatile agent is a volatile anaesthetic agent, and by replacing “controllable
 632 concentration” by “calibrated concentration”.

633 **201.3.210**
 634 ***anaesthetic ventilator***
 635 *anaesthetic workstation* component that is connected via the *anaesthetic breathing system* to the
 636 *patient’s* airway and automatically augments or provides ventilation during anaesthesia

637 **201.3.211**
 638 ***anaesthetic workstation***
 639 system for administering inhalational anaesthesia that contains an *anaesthetic gas delivery system*,
 640 an *anaesthetic breathing system* and any required *monitoring equipment*, *alarm systems*, and
 641 *protection devices*

642 Note to entry: The *anaesthetic workstation* can also include, but is not limited to, one or more of the following:
 643 *anaesthetic vapour delivery system*, *anaesthetic ventilator*, *anaesthetic gas scavenging system*, and any associated
 644 *monitoring equipment*, *alarm systems* and *protection devices*.

645 **201.3.212**
 646 ***breathing tube***
 647 non-rigid tube used to convey *anaesthetic gas* between ~~components~~ **parts** of an *anaesthetic*
 648 *breathing system*

649 Note to entry: Adapted from ISO 4135:2001, definition 4.1.2 by replacing “gases and/or vapours” by
 650 “*anaesthetic gas*”, “breathing system” by “*anaesthetic breathing system*” and “components” by “parts”.

651 **201.3.213**
 652 ***circle absorber assembly***
 653 part of a *circle breathing system* that comprises one or more carbon-dioxide-absorbent
 654 containers, *inspiratory* and *expiratory valves* or other means of ensuring unidirectional gas flow,
 655 two ports for connection to *breathing tubes*, a *fresh-gas inlet*, and a reservoir bag port or an
 656 *anaesthetic ventilator* port or both

657 Note 1 to entry: Adapted from ISO 4135:2001, definition 4.1.9.1 by replacing “circle system” by “*circle breathing*
 658 *system*”, by adding “*inspiratory* and *expiratory valves*” as a means of ensuring unidirectional gas flow.

659 **201.3.214**
 660 ***circle breathing system***
 661 *anaesthetic breathing system* in which the direction of gas flow through inspiratory and expiratory
 662 pathways is unidirectional and in which the two pathways form a circle

663 Note 1 to entry: Adapted from ISO 4135:2001, definition 4.1.9 by adding “anaesthetic” before “breathing system”,
 664 by replacing “circuit” by “circle” and by deleting “and which normally incorporated a carbon dioxide absorber” at
 665 the end of the definition.

666 **201.3.215**
 667 ***danger zone***
 668 any zone within and/or around an *anaesthetic workstation* in which a person is subject to a *risk* to
 669 their health or safety from the powered movement of the *anaesthetic workstation* or its
 670 components

- 671 **201.3.216**
 672 ***delivered volume***
 673 **V_{DEL}**
 674 volume of gas delivered through a *patient connection port* during a breath
- 675 Note 1 to entry: Adapted from ISO 4135:2001, definition 3.4.2 by replacing “inspiratory phase” by “breath”.
- 676 Note 2 to entry: *Delivered volume* is also referred to as tidal volume when all of the *delivered volume* enters the
 677 *patient's* respiratory tract. This is frequently not the case when there is significant *tracheal tube* cuff leakage (as
 678 in neonates) or in non-invasive ventilation.
- 679 **201.3.217**
 680 ***disposal hose***
 681 part of an *anaesthetic gas scavenging system* that conveys excess *anaesthetic gas* from the
 682 *receiving system* to the *disposal system*
- 683 **201.3.218**
 684 ***disposal system***
 685 part of an *anaesthetic gas scavenging system* by means of which the excess *anaesthetic gas* is
 686 conveyed to the point of discharge
- 687 Note 1 to entry: Adapted from ISO 4135:2001, definition 7.1.3 by replacing “the expired and/or excess
 688 anaesthetic gases” by “excess *anaesthetic gas*” and by deleting “from a *receiving system*” before “to the point of
 689 discharge”.
- 690 Note 2 to entry: The point of discharge can be, for example, the exterior of a building or a non-recirculating
 691 extract ventilation system.
- 692 **201.3.219**
 693 ***exhaust port***
 694 port through which waste or excess *anaesthetic gas* is discharged to the atmosphere or to an
 695 *anaesthetic gas scavenging system*
- 696 Note 1 to entry: Adapted from ISO 4135:2001, definition 4.2.1.6 by adding “anaesthetic” before “gas”..
- 697 **201.3.220**
 698 ***exhaust valve***
 699 valve connected to an *exhaust port*
- 700 Note 1 to entry: ISO 4135:2001, definition 4.3.8, modified by replacing “through which excess and/or waste
 701 gas(es) are discharged to atmosphere or to an AGSS.
- 702 Note 2 to entry: An *adjustable pressure-limiting (APL) valve* can be an *exhaust valve*.
- 703 **201.3.221**
 704 ***exhaust flow rate***
 705 flow rate of gas from the *receiving system* at the entry to the *disposal system*
- 706 **201.3.222**
 707 ***fresh gas***
 708 respirable gas delivered to an *anaesthetic breathing system*
- 709 Note 1 to entry: Adapted from ISO 4135:2001, definition 3.1.8 by adding “anaesthetic” before “breathing
 710 system”.

- 711 **201.3.223**
 712 ***fresh-gas inlet***
 713 port through which *fresh gas* enters the *anaesthetic breathing system*
- 714 Note 1 to entry: Adapted from ISO 4135:2001, definition 4.2.1.5 by replacing “is supplied to the breathing
 715 system” by “enters the *anaesthetic breathing system*”.
- 716 **201.3.224**
 717 ***fresh-gas outlet***
 718 port through which *fresh gas* is delivered from the *anaesthetic gas delivery system*
- 719 Note 1 to entry: Adapted from ISO 4135:2001, definition 4.2.1.1 by replacing “the mixture of an anaesthetic gas
 720 and vapour is delivered from the anaesthetic machine” by “*fresh gas* is delivered from the *anaesthetic gas delivery*
 721 *system*”.
- 722 **201.3.225**
 723 ***high-flow transfer and receiving system***
 724 *transfer and receiving system* that connects to a *high-flow-rate disposal system*
- 725 **201.3.226**
 726 ***induced flow rate***
 727 flow rate at the inlet of the *transfer system*, that is generated by the *disposal system*
- 728 * **201.3.227**
 729 ***interchangeable anaesthetic vapour delivery system***
 730 *anaesthetic vapour delivery system* that
 731 — by design is intended to be used with different *anaesthetic workstations*, and
 732 — can be exchanged by the clinical *user* without the use of *tools* and without the need for
 733 specific tests
- 734 **201.3.228**
 735 ***low-flow transfer and receiving system***
 736 *transfer and receiving system* that connects to a *low-flow-rate disposal system*
- 737 **201.3.229**
 738 ***maximum exhaust flow rate***
 739 largest *exhaust flow rate* that can be accommodated without exceeding the specified limitations
 740 for *induced flow rate*
- 741 **201.3.230**
 742 ***maximum limited pressure***
 743 highest pressure at the *patient connection port* during *normal use* and under a *single fault*
 744 *condition*
- 745 ~~NOTE — Adapted from ISO 4135:2001, definitions 3.3.3 and 3.3.4.~~
- 746 **201.3.231**
 747 ***minimum exhaust flow rate***
 748 smallest *exhaust flow rate* that ensures that the specified limit of *spillage* to atmosphere is not
 749 exceeded
- 750 ((Sec Note: includes a requirement))

- 751 **201.3.232**
 752 **monitoring equipment**
 753 *anaesthetic workstation* component that continuously or continually measures and displays the
 754 value of a variable to the *operator*
- 755 **201.3.233**
 756 **patient connection port**
 757 port of an *anaesthetic breathing system*, intended for connection to the connector of an airway
 758 device
- 759 Note 1 to entry: Adapted from ISO 4135:2001, definition 4.2.1.2 by replacing "opening at the patient end of a
 760 breathing system" by "port of an *anaesthetic breathing system*" and by replacing "of an airway device" by "to the
 761 connector of an airway device".
- 762 EXAMPLE *Patient connection port* can connect to a *tracheal tube*, *tracheostomy tube*, face mask or
 763 supraglottic device.
- 764 **201.3.234**
 765 **power device**
 766 ~~component~~ **part** of the *disposal system* of an *active anaesthetic gas scavenging system* that
 767 generates the *exhaust flow rate*
- 768 **201.3.235**
 769 **power supply**
 770 source of energy other than that generated directly by the human body or by gravity that makes
 771 the device function
- 772 EXAMPLE *Supply mains*, *internal electrical power source*, compressed gas from a *medical gas pipeline system*
 773 or cylinder.
- 774 **201.3.236**
 775 **protection device**
 776 ~~device~~ **component of an *anaesthetic workstation*** that without intervention by the *operator*,
 777 protects the *patient*, *operator* or others from hazardous output due to incorrect delivery or
 778 removal of energy or substances
- 779 **201.3.237**
 780 **receiving system**
 781 part of an *anaesthetic gas scavenging system* that provides an interface between the *transfer*
 782 *system* and the *disposal system*
- 783 **201.3.238**
 784 **spillage**
 785 volume of *anaesthetic gas* that cannot be accommodated by the *anaesthetic gas scavenging system*
 786 over a specified period
- 787 **201.3.239**
 788 **transfer system**
 789 ~~component~~ **part** of an *anaesthetic gas scavenging system*, which can incorporate a transfer tube,
 790 that transfers *anaesthetic gas* from the *exhaust port* of an *anaesthetic breathing system*, or
 791 associated equipment to the *receiving system*

792 **201.3.240**
 793 **y-piece**
 794 three-way connector with a *patient connection port* and two ports for connection to *breathing*
 795 *tubes*

796 [SOURCE: ISO 4135:2001, 4.2.2.2]

797 **201.4 General requirements**

798 IEC 60601-1:2005 + AMD 1:2012, Clause 4 applies, except as follows:

799 **201.4.3 * Essential performance**

800 *Addition:*

801 Additional *essential performance* requirements are identified in the subclauses listed in
 802 Table 201.101.

803 **Table 201.101 — Distributed essential performance requirements**

Requirement	Subclause
Oxygen flow under all conditions except the failure of the oxygen supply (pipeline or cylinder) to the <i>anaesthetic workstation</i> or generation of a <i>technical alarm condition</i>	201.12.4.107.2 (oxygen supply failure <i>protection device</i>) 201.101.2 (interruption of the electrical <i>power supply</i>) 201.101.8 (oxygen flush)
Delivery of a non-hypoxic gas mixture to the <i>patient</i> or generation of a <i>technical alarm condition</i>	201.11.8.102 (<i>alarm condition for power supply failure</i>) 201.11.8.103 (<i>internal electrical power source</i>) 201.12.4 (protection against hazardous output) 201.101.4.2.3 (reverse flow and cross flow <i>protection device</i>) 201.101.7 (gas mixers) 201.101.8 (oxygen flush)
Non-delivery of excessive concentrations of a volatile anaesthetic agent or generation of a <i>technical alarm condition</i>	201.104.2 (delivered vapour concentration) 201.12.4.103.3 (anaesthetic agent <i>monitoring equipment</i>)
<i>Airway pressure</i> monitoring and associated alarm	201.12.4.109 (<i>airway pressure monitoring equipment</i>)

804 **201.4.10 Power supply**

805 *Addition:*

806 **201.4.10.101* Requirements for pneumatic power input**

807 The *anaesthetic workstation* or its individual components *including accessories* shall operate and
 808 meet the requirements of this document throughout the *rated* range of inlet pressures and shall

809 not cause an unacceptable *risk* under the *single fault condition* to a maximum pressure of
810 1 000 kPa (10 bar).

811 If the *anaesthetic workstation* or its individual components *including accessories* is/are intended
812 to be connected to either

813 — a *medical gas pipeline system* complying with ISO 7396-1:2016 + AMD 1:2017 *via terminal units*
814 *complying with ISO 9170-1:2017* and flexible hose connections complying with ISO 5359:2014 +
815 AMD 1:2017, or

816 Sec. Note: Deletion of the text (*via terminal units complying with ISO 9170-1:2017*) because reference
817 to ISO 9170-1 is already covered by ISO 7396-1.

818 — a *pressure regulator* complying with ISO 10524-1:2018,

819 then

820 — the *rated* range of inlet pressures shall cover the range specified in those standards,

821 — the time-weighted average input flow (over 10 s) required by the *anaesthetic workstation* or all
822 individual *anaesthetic workstation* components for each gas shall not exceed 60 l/min at a
823 pressure of 280 kPa measured at the gas inlet port, with the oxygen flush not activated,

824 — the transient input flow shall not exceed the equivalent of 200 l/min for 3 s.

825 NOTE 1 Internal *pressure regulators* can be required to accommodate the *rated* range of inlet pressure and
826 the *single fault condition* of maximum inlet pressure.

827 NOTE 2 Flow values are expressed under STPD conditions (Standard Temperature and Pressure Dry); see
828 201.7.4.3.

829 *Check compliance by functional testing in normal use and under normal condition with the most*
830 *adverse operating settings (e.g. highest driving gas consumption, highest fresh gas delivery and*
831 *highest rated gas consumption at any gas power supply output, if provided, but without activating*
832 *the oxygen flush).*

833 **201.5 General requirements for testing *ME equipment***

834 IEC 60601-1:2005 + AMD 1:2012, Clause 5 applies, except as follows:

835 *Addition:*

836 **201.5.101 Additional general requirements for testing of *anaesthetic*** 837 ***workstations and anaesthetic workstation components including accessories***

838 **201.5.101.1 Test conditions**

839 The ambient temperature for the duration of each test should be between 20 °C and 25 °C, except
840 where otherwise stated.

841 **201.5.101.2 Test equipment**

842 The accuracy of the test equipment used to carry out measurements shall be better than or equal
843 $\pm 5\%$ of the variable to be measured for each device in the measurement setup, except where
844 otherwise stated. Dry air should be used as the test gas, except where otherwise stated.

845 Pressure measuring equipment for functional testing at the *patient connection port* shall have a
846 response time of 200 ms maximum (200 ms to reach 90% of the final reading) and a minimum
847 sample rate of 10 ms.

848 **201.5.101.3 * Gas flow rate and leakage specifications**

849 Gas flow rate, volume and leakage specifications in this document are expressed at STPD
850 (Standard Temperature and Pressure Dry) except for those associated with the *anaesthetic*
851 *breathing system*, which are expressed at BTPS (Body Temperature and Pressure Saturated).

852 NOTE 1 For the purposes of this document, STPD is 101,3 kPa at an operating temperature of 20 °C.

853 NOTE 2 For the purposes of this document, BTPS is local atmospheric pressure and a relative humidity of
854 100 % at an operating temperature of 37 °C.

855 *Correct all test measurements to STPD or BTPS, as appropriate.*

856 **201.6 Classification of ME equipment or ME systems**

857 IEC 60601-1:2005 + AMD 2:20xx, Clause 6 applies.

858 **210.7 ME equipment identification, marking and documents**

859 IEC 60601-1:2005 + AMD 1:2012 + AMD 2:20xx, Clause 7 applies, except as follows:

860 **201.7.2 Marking on the outside of ME equipment or ME equipment parts**

201.7.2.3 * Consult accompanying documents

861 *Replace the existing subclause by the following:*

862 The *anaesthetic workstation* and its individual components shall be marked with the safety sign
863 for the mandatory action: "follow instructions for use", ISO 7010-M002 (see IEC 60601-
864 1:2005+TC1, Table D.2, number 10).

865 NOTE One safety sign is sufficient on the *anaesthetic workstation* to cover all components that are described
866 in the instructions for use of the *anaesthetic workstation*.

867 *Add the following subclause:*

868 **201.7.2.21 * Mass of mobile equipment**

869 *Replace the existing subclause by the following:*

870 The *anaesthetic workstation* shall be legibly marked with its maximum mass in kilograms [see
871 also 201.101.1.1 k)].

872 *Addition:*

201.7.2.101 Marking with year of manufacture or use-by date

873 The *anaesthetic workstation* and its *operator-detachable* components or their packaging shall be
874 marked with the following:

875 a) year of manufacture or

876 b) use-by date, if applicable, ~~see~~ symbol 5.1.4 of ISO 15223-1:2016 (Table 201.D.2.101,
877 symbol 1).

878 NOTE The *manufacturer's* attention is drawn to the importance of consistent use of indication for single-use
879 devices.

880 c) for an *anaesthetic workstation* intended to be used in the magnetic resonance (MR)
881 environment,

882 — IEC 62570:2014, 7.3.1 (with two options: Table 201.D.2.101, symbol 7 or symbol 8) for an
883 “MR Safe” *anaesthetic workstation*, or

884 — IEC 62570:2014, 7.3.2 (see Table 201.D.2.101, symbol 9) for an “MR Conditional” *anaesthetic*
885 *workstation*, in accordance with IEC 62570.

886 *Check compliance by visual inspection.*

887 201.7.2.102 Operator-accessible gas-specific inlet and outlet

888 Each *operator-accessible gas-specific* inlet and outlet shall be marked with the gas name or
889 chemical symbol in accordance with Table 6 of ISO 5359:2014 + AMD 1: 2017. If colour coding is
890 used it shall be in accordance with Table 6 of ISO 5359:2014 + AMD 1:2017.

891 *Check compliance by visual inspection.*

892 201.7.2.103 * Operator-accessible gas power supply outlet

893 Each *operator-accessible gas power supply* outlet shall be marked with the *rated* output pressure
894 and *rated* flow rate.

895 EXAMPLE 1 280 kPa - 600 kPa, 20 l/min.

896 EXAMPLE 2 280 kPa - 600 kPa, 20 l/min - 40 l/min.

897 *Check compliance by visual inspection.*

898 201.7.2.104 ~~Devices~~ Components, parts and accessories containing phthalates

899 If parts of the *anaesthetic workstation* or its individual components in contact with gas to be
900 inhaled by the *patient* contain phthalates, which are known to be carcinogenic, mutagenic or toxic
901 to reproduction, the *anaesthetic workstation* and its individual components shall be marked
902 accordingly.

903 NOTE 1 The symbol given in Reference [18] can be used.

904 NOTE 2 For information, see Directive 1272/2008/EC, Annex VI, part 3 [23].

905 *Check compliance by visual inspection*

906 **201.7.2.105 Cylinder and pipeline pressure indicators**

907 All cylinder and pipeline pressure indicators shall be identified with the gas name or the chemical
908 symbol in accordance with Table 6 of ISO 5359:2014 + AMD 1:2017. If colour coding is used it
909 shall be in accordance with Table 6 of ISO 5359:2014 + AMD 1:2017.

910 *Check compliance by visual inspection.*

911 **201.7.4.2 * Control devices**

912 *Addition:*

913 Each *gas-specific* flow rate adjustment control of an *anaesthetic gas delivery system* shall be
914 identified with the gas that it controls by the gas name or the chemical symbol in accordance with
915 Table 6 of ISO 5359:2014 + AMD 1:2017. If colour coding is used it shall be in accordance with
916 Table 6 of ISO 5359:2014 + AMD 1:2017. Each flow rate adjustment control of an *anaesthetic gas*
917 *delivery system* shall be marked with an indication of how to increase and decrease the gas flow
918 rate. If applicable, the point of reference for reading the flow rate indication shall be identified.

919 NOTE A multifunctional control that can be used to control multiple items is not considered a *gas-specific*
920 control.

921 The oxygen flush control shall be marked with one of the following:

922 — “Oxygen Flush”, or

923 — “O₂ Flush”, or

924 — “O₂ +”.

925 **201.7.4.3 * Unit of measure**

926 *Addition:*

927 All gas volume, flow and leakage specifications shall be expressed as STPD, except those
928 associated with the *anaesthetic breathing system*, which shall be expressed as BTPS.

929 NOTE 1 For the purposes of this document, STPD is 101,3 kPa at an operating temperature of 20 °C.

930 NOTE 2 For the purposes of this document, BTPS is local atmospheric pressure and a relative humidity of
931 100 % at an operating temperature of 37 °C.

932 **201.7.9.1 General**

933 *Replacement:*

934 *Replace the first dash with:*

935 — name or trade name and address of

- 936 — the *manufacturer*, and
- 937 — where the *manufacturer* does not have an address within the locale, an authorized
- 938 representative within the locale,

939 to which the *responsible organization* can refer;

940 **201.7.9.2.1 General**

941 *Addition:*

942 ~~The instructions for use shall contain the date of issue or the latest revision.~~ ((covered by

943 IEC 60601-1, 7.9.3.19))

944 For *anaesthetic workstations* not supplied complete, the instructions for use shall contain, as far

945 as applicable, information about the *monitoring equipment*, *alarm systems* and *protection devices*

946 required by this document and how to connect them.

947 **201.7.9.2.2 * Warnings and safety notices**

948 *Addition:*

949 The instructions for use shall contain a statement to the effect that, in case of *anaesthetic*

950 *workstation* failure, the lack of immediate access to appropriate alternative means of ventilation

951 can result in *patient* injury.

952 EXAMPLE An alternative means of ventilation would be a self-inflating, manually-powered *resuscitator*

953 (see ISO 10651-4:2002) with mask.

954 **201.7.9.2.8 * Start-up procedure**

955 *Amendment:*

956 *Delete the given EXAMPLE and add the following text at the end of the subclause:*

957 The instructions for use shall contain at least one *operator* pre-use checklist.

958 EXAMPLE 1 Beginning of day or shift pre-use checklist.

959 EXAMPLE 2 Between *patients* pre-use checklist.

960 NOTE Attention is drawn to additional pre-use checklists required by regional or national medical

961 associations or authorities with jurisdiction.

962 Electronic displays integral to, or provided with, the *anaesthetic workstation* or its individual

963 components may be used to provide such a pre-use checklist.

964 **201.7.9.2.101 Additional requirements for the instructions for use ((previously**

965 **under 201.7.9.2.14))**

966 *Addition:*

967 The instructions for use of the *anaesthetic workstation* and its individual components shall

968 include the following:

- 969 aa) information on the method of enabling the *anaesthetic workstation* or its individual components,
 970 including the *monitoring equipment*, *alarm systems* and *protection devices*, required by this
 971 document; this information may form part of the pre-use checklist (see 201.7.9.2.8);
- 972 bb) the conditions under which the measured values are displayed, e.g. BTPS, STPD;
- 973 cc) where an *anaesthetic workstation* is not supplied complete, a statement to the effect that whoever
 974 assembles the *anaesthetic workstation* from individual components shall provide the pre-use
 975 checklist for the *anaesthetic workstation* (see 201.7.9.2.8);
- 976 dd) where applicable, a statement to the effect that a malfunction of the *medical gas pipeline system*
 977 can cause one or more *anaesthetic workstations* other *anaesthetic workstation* components
 978 connected to the *medical gas pipeline system* to stop their operation simultaneously; this is not
 979 applicable to *anaesthetic workstations* that only use cylinders for gas supply;
- 980 ee) where applicable, disclosure of the presence of all natural rubber latex-based ~~components~~ parts
 981 and *accessories* and their location (see also Symbol 5.4.5 in ISO 15223-1:2016);
- 982 ff) where applicable, whether the *anaesthetic workstation* or its individual components and
 983 *accessories* is/are suitable for use in a magnetic resonance imaging (MRI) environment and any
 984 related restrictions;
- 985 gg) if an *anaesthetic workstation* or its individual components and *accessories* is/are used for the
 986 treatment of children or treatment of pregnant or nursing women, the *residual risk* from
 987 phthalates that are carcinogenic, mutagenic or toxic to reproduction;
- 988 hh) for single-use *accessories* to the *anaesthetic workstation* or its individual components and
 989 *accessories* disclosure of the *risks* associated with reusing; this information may be given upon
 990 request.
- 991 ii) if the ~~device~~ *anaesthetic workstation or its individual* components is/are suitable for O₂ 93,
 992 restrictions and consequences, e. g. possible argon accumulation.

993 *Check compliance by inspection of the instructions for use.*

994 **201.7.9.3 Technical description**

995 *Addition:*

996 **201.7.9.3.1 General**

997 *Addition:*

998 The technical description shall include information to allow the *responsible organization* to assess
 999 when the *anaesthetic workstation* and its individual components is approaching the end of its life.
 1000 (e.g. in terms of years of service or number of uses), assuming that the preventative inspection,
 1001 maintenance and calibration is performed according to the *accompanying documentation*.

1002 *Check compliance by inspection of the technical description.*

1003 **201.7.9.3.101 Components**

1004 The technical description shall describe the maximum weight of components, as well as the height
 1005 of and length of arms on which these components may be mounted on the *anaesthetic workstation*

1006 or its individual components so as not to compromise the stability requirements tested in
1007 IEC 60601-1:2005 + AMD 1:2012, Clause 9.

1008 *Check compliance by inspection of the technical description.*

1009 **201.7.9.3.102 *Anaesthetic workstations intended to be mounted to a wall or***
1010 ***ceiling pendant***

1011 For *anaesthetic workstations* intended to be mounted to a wall or a ceiling pendant and that are
1012 not considered *mobile equipment* and consequently need not comply with the requirement on
1013 moving over a threshold in 201.9.4.2.4.3, the technical description shall contain a warning to the
1014 effect of: "Warning: This device, when removed from its wall or ceiling mount, does not meet the
1015 stability requirements of ISO/IEC 80601-2-13 and IEC 60601-1 respectively. Special caution has
1016 to be taken." The technical description shall contain any additional handling instructions
1017 necessary to allow transport with an acceptable *risk* according to the *risk management file*.

1018 *Check compliance by inspection of the technical description.*

1019 **201.8 Protection against electrical hazards from *ME equipment***

1020 IEC 60601-1:2005 + AMD 1:2012 + AMD 2:20XX, Clause 8 applies, except as follows:

1021 **201.8.11.3 *Power supply cords***

1022 *Addition:*

1023 **201.8.11.3.101 * Additional requirements for *power supply cords***

1024 Unless the *anaesthetic workstation* or its individual components automatically switch over to an
1025 *internal electrical power source* (see 201.11.8.102) or the functionality of the complete *anaesthetic*
1026 *workstation* can be restored in less than 30 s following the restoration of power, the *power supply*
1027 *cord* of the *anaesthetic workstation* or its individual components shall be a non-detachable cord or
1028 shall be protected against accidental disconnection.

1029 *Check compliance by inspection. For an anaesthetic workstation and its individual components*
1030 *provided with an appliance coupler, subject the detachable power supply cord to an axial pull of*
1031 *force for 1 min as shown in Table 201.102. During the test, the mains connector shall not become*
1032 *disconnected from the appliance inlet, and the ~~ME equipment~~ anaesthetic workstation and its*
1033 *individual components shall continue to function normally.*

Table 201.102 — Force of axial pull

Mass (m) of ME equipment kg	Pull force N
$m \leq 1$	30
$1 < m \leq 4$	60
$m > 4$	100

201.9 Protection against mechanical hazards of ME equipment and ME systems

IEC 60601-1:2005 + AMD 1:2012 + AMD 2:20xx, Clause 9 applies, except as follows:

201.9.2 Mechanical hazards associated with moving parts

201.9.2.1 General

Addition:

Where the direction of movement of a moving part needs to be known in order to avoid a hazardous situation, the direction of movement shall be marked on the moving part or its housing.

Check compliance by visual inspection.

Additional subclauses:

201.9.2.101 Maintenance points

Any maintenance points shall be located outside *danger zones* and adjustment, maintenance, repair, cleaning and servicing operations shall be possible when the *anaesthetic workstation* is not being operated.

Where this is not achievable, alternative means of *risk* mitigation, e.g. alarming and information of safety and training, are permitted to reduce the *risk* to acceptable levels.

Check compliance by inspection of the risk management file and usability engineering file.

201.9.2.102 * Lighting

Anaesthetic workstations shall be supplied with lighting where the absence thereof causes an unacceptable *risk*.

NOTE Attention is drawn to areas of shadows likely to cause nuisance, irritating dazzles, dangerous stroboscopic effects on moving parts, to internal parts requiring frequent inspection and adjustment, and to maintenance areas.

Check compliance by inspection of the risk management file and usability engineering file.

201.9.2.103 * Integrated seating

Where a seat for the *operator* is an integral part of the *anaesthetic workstation*, the seat shall

- 1061 — enable the *operator* to maintain a stable position,
- 1062 — be adaptable for the *operator's* distance from the control device,
- 1063 — be adaptable for the *operator*, e.g. arm length, height, etc.,
- 1064 — be designed to minimize transmission of vibrations to the *operator*,
- 1065 — withstand maximum operational stresses, and
- 1066 — be provided with slip-resistant footrests where no floor is underneath the *operator*.
- 1067 *Check compliance by functional testing.*

1068 **201.9.2.104 * Arrangement of control positions**

1069 For *anaesthetic workstations* which contain one or more *danger zones*

- 1070 — the *operator* shall be able to ensure, from each control position, that no one is in the *danger*
1071 *zone(s)*, or
- 1072 — the control system shall be designed in such a way that starting is prevented while someone is in
1073 the *danger zone*, or
- 1074 — an audible or visual *alarm signal* shall be given long enough before the *anaesthetic workstation* is
1075 started to allow anyone wholly or partially in a *danger zone* to leave the area.

1076 Where there is more than one control position for an *anaesthetic workstation*, the control systems
1077 shall be designed in such a way that the use of one of them precludes the use of the others, except
1078 for stop controls and emergency stops.

1079 When an *anaesthetic workstation* has two or more operating positions, each position shall be
1080 provided with all the required control devices without the *operators* hindering or putting each
1081 other into a *hazardous situation*.

1082 *Check compliance by visual inspection and functional testing.*

1083 **201.9.4 Instability hazards**

1084 **201.9.4.2.4.3 Movement over a threshold**

1085 *Addition:*

1086 *Anaesthetic workstations* that are intended only to be used when mounted to a wall or pendant,
1087 but may need to be removed from the wall or pendant for service or at initial installation, are not
1088 considered *mobile equipment* and the threshold test specified in IEC 60601-1:2005 + AMD 1:2012,
1089 9.4.2.4.3 does not apply. Such non-*mobile anaesthetic workstations machines* can use small casters
1090 to aid service and installation of the device. See also 201.7.9.3.102.

1091 **201.10 Protection against unwanted and excessive radiation hazards**

1092 IEC 60601-1:2005 + AMD 1:2012 + AMD 2:20xx, Clause 10 applies.

1093 **201.11 Protection against excessive temperatures and other hazards**

1094 IEC 60601-1:2005 + AMD 1:2012 + AMD 2:20xx, Clause 11 applies, except as follows:

1095 **201.11.6.3 Spillage on ME equipment and ME systems**

1096 *Replacement:*

1097 The *anaesthetic workstation* and its individual **components, parts and accessories** shall be so
1098 constructed that *spillage* does not wet parts which, when wetted, pose an unacceptable *risk*.

1099 *Check compliance by the following test:*

1100 *Test the anaesthetic workstation and its individual components, parts and accessories under the*
1101 *least favourable specified working conditions, but in accordance with the instructions for use. Pour a*
1102 *quantity of 200 ml of normal tap water steadily on an arbitrary point on the top surface of the*
1103 *anaesthetic workstation and its individual components, parts and accessories, for approximately*
1104 *15 s, from a height not exceeding 5 cm. After the test, the anaesthetic workstation and its individual*
1105 *components, parts and accessories shall comply with all the requirements of this document for*
1106 *normal condition.*

1107 **201.11.6.8 Compatibility with substances used with the ME equipment**

1108 *Addition:*

1109 The *anaesthetic workstation* and its individual **components, parts and accessories** shall be
1110 designed and manufactured to minimize health *risks* due to particles and substances leached or
1111 leaking from the *anaesthetic workstation* or its individual **components, parts and accessories**
1112 during *normal use*. Particular attention shall be paid to the toxicity of materials and their
1113 compatibility with substances and gases with which they come into contact during *normal use*.

1114 NOTE 1 Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction.

1115 *Check compliance by the tests as given in ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017,*
1116 *ISO 18562-4:2017, and ISO 10993-1:20xx.*

1117 NOTE 2 Attention is drawn to anaesthetic gases that may contribute to leaching.

1118 **201.11.8 Interruption of the power supply/supply mains to ME equipment**

1119 *Addition:*

1120 **201.11.8.101 * General requirements**

1121 The instructions for use shall describe the functioning of the *anaesthetic workstation* or its
1122 individual components after interruption of the *power supply*, and where applicable following a
1123 switchover to an *internal electrical power source*. Particular emphasis shall be placed on the flow
1124 rate and composition of the *fresh gas* and the behaviour of any *operator-accessible gas power*
1125 *supply outlet* under these circumstances.

1126 *Check compliance by inspection of the instructions for use.*

1127 **201.11.8.102 * Alarm condition for power supply failure**

1128 The *anaesthetic workstation* shall be equipped with an *alarm system* that includes a *power supply*
1129 *failure alarm signal* that indicates when the *power supply* is outside the range specified by the
1130 *manufacturer*. The *alarm signals* for the *power supply failure alarm condition* shall be

1131 — generated for at least 7 s if pneumatically generated, **or**

1132 — generated for at least 7 s if generated by **basic electronics** (e.g. piezo buzzer supplied by a gold
1133 cap) or

1134 — at least 5 bursts and a *high priority* alarm that complies with IEC 60601-1-8, + AMD 1:2012 +
1135 AMD 2:20xx, if electronically generated.

1136 EXAMPLE The Ritchie Whistle is a pneumatic alarm sound generator.

1137 NOTE 1 The *power supply failure technical alarm condition* applies to the *supply mains*, an *internal electrical*
1138 *power source* or pneumatic (driving) *power supply*.

1139 NOTE 2 The 7 s duration of the *alarm signals* for the *power supply failure alarm condition* is measured
1140 exclusive of any *interburst interval*.

1141 The A-weighted sound pressure level shall be at least 2 dB above a white background sound level
1142 of 55 dB when tested as described in ISO 3744:2010.

1143 If the normal operation of the *anaesthetic workstation* or its individual components is maintained
1144 by the automatic switchover to an *internal electrical power source* or alternate pneumatic *power*
1145 *supply*, the *power supply failure high priority technical alarm condition* shall not occur. Any such
1146 switchover to an *internal electrical power source* or alternate pneumatic *power supply* shall be
1147 indicated by an *information signal* or a *low priority technical alarm condition*.

1148 *Check compliance by functional testing.*

1149 **201.11.8.103 * Internal electrical power source**

1150 If the *anaesthetic workstation* or its individual components has/have an *internal electrical power*
1151 *source*,

1152 a) it shall provide at least 30 min of back-up time necessary for normal operation;

1153 b) it/they shall be equipped with:

1154 1) a means of determining the state of the *internal electrical power source*; this means may be
1155 qualitative;

1156 EXAMPLE 1 An indication of the remaining time provided by the *internal electrical power source*.

1157 EXAMPLE 2 An indication of the percentage of the remaining capacity provided by the *internal electrical*
1158 *power source*.

1159 EXAMPLE 3 A gauge of the remaining capacity provided by the *internal electrical power source*.

1160 NOTE An uncalibrated gauge that only indicates the state of the power source could be qualitative.

1161 2) an *alarm system* that detects a *technical alarm condition* with *medium priority*, at least 10 min
1162 prior to the loss of function, and *high priority* at least 5 min prior to the loss of function

1163 c) the instructions for use shall include the following:

1164 1) the operational time of a new *internal electrical power source* when fully charged;

1165 NOTE With the passage of time, the operational time may decrease.

1166 2) the conditions under which 201.11.8.103 a) is maintained;

1167 3) the behaviour after a switchover to the *internal electrical power source*;

1168 4) the behaviour while the *internal electrical power source* is recharging.

1169 *Check compliance by functional testing and inspection of the instructions for use.*

1170 **201.11.101 Packaging systems for components intended to be sterilized**

1171 Packaging systems shall be designed to maintain components at their intended level of
1172 cleanliness and to reduce the *risk* of microbial contamination.

1173 *Check compliance by inspection.*

1174 **201.12 Accuracy of controls and instruments and protection against hazardous** 1175 **outputs**

1176 IEC 60601-1:2005 + AMD 1:2012, Clause 12 applies, except as follows:

1177 **201.12.4 Protection against hazardous output**

1178 *Addition:*

1179 **201.12.4.101 * Accidental adjustment of operating controls**

1180 A means of protection against accidental adjustment of operating controls that can create a
1181 *hazardous situation* shall be provided. This includes the accidental turning off of the *anaesthetic*
1182 *workstation* or its individual components.

1183 If a selector switch or control is provided to change from one mode to another, it shall be bi-
1184 stable.

1185 EXAMPLE 1 Requiring a confirmation step can be one method.

1186 EXAMPLE 2 Manual/automatic ventilation selector switch, vaporiser selector switch, *circle absorber*
1187 *assembly* bypass mechanism.

1188 The *usability* of the means of protection shall be evaluated in the *usability engineering process*
1189 according to IEC 60601-1-6:2010 + AMD 1:2013 + AMD 2:20xx.

1190 *Check compliance by functional testing and inspection of the usability engineering file.*

1191 **201.12.4.102 * Additional requirements for anaesthetic workstations**

1192 The *anaesthetic workstation* shall be equipped with the following *monitoring equipment, alarm*
 1193 *systems, and protection devices*. If not so equipped, the instructions for use shall contain a
 1194 statement to the effect that the *anaesthetic workstation* is to be equipped with the following
 1195 *monitoring equipment, alarm systems, and protection devices* complying with this document,
 1196 before being put into service and shall describe how to connect these ~~items~~ components:

- 1197 — *airway pressure monitoring equipment* complying with 201.12.4.109;
- 1198 — *maximum limited pressure protection device* complying with 201.102.2.1 (*anaesthetic breathing*
 1199 *system*) or 201.105.2.1 (*anaesthetic ventilator*);
- 1200 — *adjustable pressure limitation protection device* complying with 201.102.2.2 (*anaesthetic*
 1201 *breathing system*) or 201.105.2.2 (*anaesthetic ventilator*);
- 1202 — *exhaled volume monitoring equipment* complying with 201.12.4.104;
- 1203 — *alarm system* with *anaesthetic breathing system integrity alarm condition* complying with
 1204 201.12.4.105;
- 1205 — *carbon dioxide monitoring equipment* complying with 201.12.4.103.1;
- 1206 — *oxygen monitoring equipment* complying with 201.12.4.103.2;
- 1207 — *anaesthetic agent monitoring equipment* with *halogenated agent monitoring equipment* if the
 1208 *anaesthetic gas delivery system* is designed to be equipped with an *anaesthetic vapour delivery*
 1209 *system* complying with 201.12.4.103.3;
- 1210 — *anaesthetic breathing system* *continuing-positive-pressure alarm condition* complying with
 1211 201.12.4.106;
- 1212 — *oxygen supply failure alarm system* and *protection device* complying with 201.12.4.107.1 and
 1213 201.12.4.107.2 respectively;
- 1214 — *hypoxic mixture delivery selection protection device* complying with 201.12.4.107.3;
- 1215 — *protection device* for the workplace environment (*anaesthetic gas scavenging system*) if the
 1216 *anaesthetic gas delivery system* is equipped with means to deliver nitrous oxide or is designed to
 1217 be equipped with an *anaesthetic vapour delivery system* complying with 201.12.4.108.
- 1218 *Manufacturers* of individual components shall make available information regarding how to
 1219 connect these items to the *anaesthetic workstation*.

1220 *Check compliance by inspection and, if applicable, inspection of the instructions for use.*

1221 NOTE See also Table AA.1.

1222 **201.12.4.103 Respiratory gas monitoring equipment**

1223 **201.12.4.103.1 Carbon dioxide monitoring equipment**

1224 *Carbon dioxide monitoring equipment* shall comply with ISO 80601-2-55:2018.

1225 *Check compliance by application of the tests of ISO 80601-2-55:2018.*