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Part 2-94: Particular requirements for basic safety and essential performance of inhalational therapy nebulizer equipment

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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.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

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/2186/CD

COMMITTEE DRAFT (CD)

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62D/2041/NP, 62D/2090A/RVN

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Safety	

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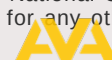
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TITLE:

Medical electrical equipment - Part 2-94: Particular requirements for basic safety and essential performance of inhalational therapy nebulizer equipment

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Documents

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Medical electrical equipment — Part 2-94: Particular requirements for basic safety and essential performance of inhalational therapy nebulizer equipment

Appareils électro médicaux — Partie 2-94: Exigences particulières pour la sécurité de base et les performances essentielles de l'équipement de nébulisation de thérapie par inhalation

CD stage

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49 Foreword

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

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

61 Attention is drawn to the possibility that some of the elements of this document may be the subject of
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63 patent rights identified during the development of the document will be in the Introduction and/or on
64 the ISO list of patent declarations received (see www.iso.org/patents).

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

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

71 This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory*
72 *equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and
73 Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D,
74 *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN)
75 Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the
76 Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

77 A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

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

Introduction

Inhalational therapy *nebulizing systems* are widely used to deliver drugs and vaccines in an aerosol form to humans through the respiratory system. *Nebulizers* are also used for diagnostic purposes using radioisotopes for lung challenge tests. These drugs can be in the form of a solution, suspension or emulsion. Aerosol inhalation is the preferred route of administration for some drugs. Some drugs are intended for treatment of systemic diseases and other drugs are intended to treat respiratory diseases. To achieve the intended treatment, aerosol particles have to be deposited in specific parts of the respiratory tract. Different size particles tend to deposit in different parts of the respiratory system; therefore, the performance profile and the *intended use* of the *nebulizer* are defined by the *manufacturer* and specified in the *accompanying documentation*.

The details of *nebulizers* (e.g., the test methods for aerosol output) aerosol output rate, and particle sizing are given in ISO 27427, *Anaesthetic and respiratory equipment — Nebulizing systems and components*.

The document is intended to cover the *basic safety* and *essential performance* of complete *nebulizing system*, intended to alleviate the symptoms of *patients* by delivering an inhalational therapy to the respiratory tract of the *patient*. *Nebulizing systems* are intended for use in the *home healthcare environment* by *lay operators* as well as in *professional healthcare facilities*.

The objectives of this document are to ensure the electrical, pneumatic, mechanical safety as well as the *biocompatibility* of the materials of the components that come into contact with the human body and compatibility between the materials of the components and the dispensed liquid of:

- *nebulizing systems* which can be powered by gas (e.g., compressors, pipeline systems, cylinders);
- electrically powered *nebulizing systems* [e.g., spinning disc, ultrasonic, vibrating mesh (active and passive), and capillary devices]; and
- manually powered *nebulizing systems*.

In this document, the following print types are used:

- Requirements and definitions: roman type
- *Test specifications and terms defined in clause 3 of the general standard, in this document or as noted: italic type;*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

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

- “clause” means one of the four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.1, 201.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 201.101, 201.102 and 201.102.1 are all subclauses of Clause 201).

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

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

118 For the purposes of this document, the auxiliary verb:

119 — “shall” indicates a requirement;

120 — “should” indicates a recommendation;

121 — “may” indicates a permission;

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

123 — “must” is used to express an external constraint.

124 Annex C contains a guide to the *marking* and labelling requirements in this document.

125 Annex D contains a summary of the *symbols* referenced in this document.

Medical electrical equipment —

Part 2-9x:

Particular requirements for the basic safety and essential performance of inhalational therapy nebulizer equipment

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

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

This document is applicable to the *basic safety and essential performance* of a *nebulizing system*, that includes *nebulizing equipment and a nebulizer*, intended to alleviate the symptoms of *patients* by delivering an inhalational therapy to the respiratory tract of the *patient*. A *Nebulizing system* is typically intended for use in the *home healthcare environment* by *lay operators* as well as *use* in *professional healthcare facilities*.

This document includes:

- *nebulizers in nebulizing systems* which are powered by *pressurized gas*; and
- electrically powered *nebulizers in nebulizing systems* [e.g., spinning disc, ultrasonic, vibrating mesh (active and passive), and capillary devices].

This document includes *nebulizing systems* used during spontaneous breathing (e.g., handheld equipment applied via a mouthpiece) as well as systems which are included into a ventilatory breathing system of a ventilatory support equipment or ventilators for ventilator dependent *patients*.

This document includes *nebulizing systems* intended for use with adults, children, neonates and premature born.

This document includes *nebulizing systems* intended for the supply of drugs within ventilatory breathing systems.

This document does not apply to drug-specific *nebulizers* or their components (e.g., metered dose inhalers, metered liquid inhalers, dry powder inhalers).

This document does not apply to nebulizing systems without nebulizing equipment.

EXAMPLE A *nebulizer* using the inspiratory flow of gas to the *patient* as an energy source.

This document does not specify the requirements for respiratory *humidifiers*, the requirements for which are given in ISO 80601-2-74 or ISO 20789.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to *nebulizing systems*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *nebulizing systems*.

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

NOTE See also 4.2 of the general standards.

201.1.2 Object

IEC 60601-1:2005, 1.2 is replaced by:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for a *nebulizing system* (as defined in 201.3.231)

NOTE 1 This document has been prepared to address the relevant *essential principles*^[17] and labelling^[18] guidance's of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex BB.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745^[16] as indicated in Annex CC.

201.1.3 Collateral standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.3 applies with the following addition:

IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 apply as modified in Clauses 202 and 206 respectively. IEC 60601-1-3:2008+AMD1:2013 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular *ME equipment* under consideration.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1+AMD1:2012+AMD2:2020 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the

190 IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by
191 the use of the following words:

192 "Replacement" means that the clause or subclause of the general standard or applicable collateral
193 standard is replaced completely by the text of this document.

194 "Addition" means that the text of this document is additional to the requirements of the general standard
195 or applicable collateral standard.

196 "Amendment" means that the clause or subclause of the general standard or applicable collateral
197 standard is amended as indicated by the text of this document.

198 Subclauses, figures or tables which are additional to those of the general standard are numbered starting
199 from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through
200 3.139, additional definitions in this document are numbered beginning from 201.3.201. Additional
201 annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

202 Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting
203 from 20x, where "x" is the number of the collateral standard (e.g. 202 for IEC 60601-1-2, 211 for
204 IEC 60601-1-11, etc.)

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

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

211 **201.2 Normative references**

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

215 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2 applies, except as follows:

216 *Addition:*

217 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources*
218 *using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

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

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

223 ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device*
224 *manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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

227 ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*
228 *Part 1: Evaluation and testing within a risk management process*

ISO 20417:1, *Medical devices — Information to be supplied by the manufacturer*

ISO 27427:2023, *Anaesthetic and respiratory equipment — Nebulizing systems and components*

ISO 80369-1:2, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

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

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-11:2015+AMD 1:2020 and the following apply.

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

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

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

Addition:

201.3.201

accompanying information

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

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

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

¹ Under preparation. Stage at the time of publication: ISO/DIS 20417:2024.

² Under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2024.

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

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

262 **201.3.202**

263 **airway pressure**

264 P_{aw}

265 pressure at the *patient-connection port* or at the distal outlet of the equipment where there is no *patient-*
266 *connection port*

267 Note 1 to entry: The *airway pressure* can be derived from pressure measurements made anywhere within
268 the equipment.

269 [SOURCE: ISO 4135:2022, 3.1.4.41.1]

270 **201.3.203**

271 **airway pressure accuracy**

272 degree of correspondence between the pressure set on the *nebulizing system* and the actual (true) *airway*
273 *pressure*

274 Note 2 to entry: An *auto CPAP* mode may be bi-level.

275 **201.3.204**

276 **automatic start function**

277 feature by which a *nebulizing system* automatically starts the therapy based on when the *patient* is
278 connected to the equipment

279 Note 1 to entry: A *nebulizing system* may provide an *automatic start function*.

280 Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

281 **201.3.205**

282 **automatic stop function**

283 feature by which a *nebulizing system* automatically stops the therapy when the *patient* is disconnected
284 from the equipment

285 Note 1 to entry: A *nebulizing system* may provide an *automatic stop function*.

286 Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

287 **201.3.206**

288 **benefit**

289 positive impact or desirable outcome of the use of a *medical device* on the health of an individual, or a
290 positive impact on *patient* management or public health

291 Note 1 to entry: *Benefits* can include positive impact on clinical outcome, the *patient's* quality of life, outcomes
292 related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or positive impact on public
293 health.

294 [SOURCE: ISO 14971:2019, 3.2]

295 **201.3.207**

296 **biocompatibility**

297 ability of a *medical device*, *accessory* or material to perform with an appropriate host response in a specific
298 application

299 Note 1 to entry: A *medical device* or *accessory* may produce some level of adverse effect, but that level may be
300 determined to be acceptable when considering the *benefit* provided.

301 [SOURCE: ISO 10993-1:2018, 3.1, modified — added “*accessory*” and note.]

302 **201.3.208**

303 **breathing gas pathway**

304 pathway between the *intake* and the *patient-connection port*

305 **201.3.209**

306 **breathing system filter**

307 **BSF**

308 device intended to reduce transmission of particulates, including microorganisms, in *breathing systems*

309 [SOURCE: ISO 23328-2:2002, 3.1]

310 **201.3.210**

311 **breathing tube**

312 non-rigid tube used to convey gases or vapours within the *user-detachable* section of a *breathing system*

313 [SOURCE: ISO 4135:2022, 3.1.4.41.1, modified —deleted note.]

314 **201.3.211**

315 **cleaning**

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

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

320 [SOURCE: ISO 17664-2:2021, 3.1, modified — replaced 'and/or' with 'or'.]

321 **201.3.212**

322 **connector**

323 fitting to join two or more components

324 [SOURCE: ISO 4135:2022, 3.1.4.5, modified — deleted note.]

325 **201.3.213**

326 **disinfection**

327 *process* to reduce the number of viable microorganisms to a level previously specified as being
328 appropriate for a defined purpose