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Medical electrical equipment —

Part 2-90:
Particular requirements for basic safety and essential performance of ventilatory high-flow therapy equipment

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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

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

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

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

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

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This is the first edition of ISO 80601-2-90.

Introduction

Respiratory high-flow therapy equipment has been used successfully for years with neonatal *patients*. In recent years there is more information about treating adults with *respiratory high-flow therapy equipment* when it is used as an intermediate therapy to improve oxygenation in adult critical care *patients*, respiratory care units and for palliative care. The use of *respiratory high-flow therapy equipment* continues to increase as it is easily set up and is well tolerated by *patients*.

Since the outbreak of COVID-19 in China in January of 2020, its spread has been rapid and fierce. In hospitals across the world, all kinds of *respiratory high-flow therapy equipment* have been widely used. More and more new *manufacturers* of *respiratory high-flow therapy equipment* have rapidly emerged. Neither international nor national standards are available for *respiratory high-flow therapy equipment*. With the spread of the epidemic globally, the demand for this document is clear and very urgent.

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

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

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

— The air entering the *gas intake port* by the *respiratory high-flow therapy equipment* might be contaminated. What measures are needed to avoid or reduce the contamination of the *gas pathways*.

— The input oxygen source pressure might be unstable.

— When the pressure of the oxygen source is insufficient, is there an additional gas source, such as adding an additional oxygen input to maintain the delivered oxygen concentration?

— When the oxygen concentration of the *respiratory high-flow therapy equipment* does not reach the set value, does the *respiratory high-flow therapy equipment* need to generate an *alarm condition*?

— Is the *respiratory high-flow therapy equipment* easy to install and adjust by *operators* wearing multiple layers of protective clothing and gloves?

— Are the *markings* and displays of the *respiratory high-flow therapy equipment* clear enough for *operators* whose vision is blurred due to aerosol on their goggles?

— To reduce unnecessary *risk* of infection and reduce the burden on the *operators*, *respiratory high-flow therapy equipment* needs to remain stable, reducing the need for frequent *operator* adjustment.

— For the *respiratory high-flow therapy equipment* used in an infected area, after one *patient's* use, before the next *patient's* use or before the *respiratory high-flow therapy equipment* is transferred to a non-infected area, the *respiratory high-flow therapy equipment* needs *cleaning* and *disinfection,* including the surface of the *enclosure* and the internal *gas pathways*.

— The risk of infectious exhaled gas.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *test specifications: 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.

— *terms defined in Clause 3 of the general standard*[1]*, in this document or as noted: small capitals*.

In referring to the structure of this document, the term

— "clause" means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 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 particular document are by number only.

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

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

— "shall" means that conformance with a requirement or a test is mandatory for conformance with this document;

— "should" means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability;

— "must" is used express an external constraint.

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

The ISO and IEC 80601 family of documents are also parts of the IEC 60601 family of documents.

[1] The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*.

Medical electrical equipment

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

This document applies to the *basic safety* and *essential performance* of *respiratory high-flow therapy equipment,* as defined in 201.3.219, hereafter also referred to as *ME equipment*, in combination with its *accessories*:

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

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

EXAMPLE 1 *Patients* with Type 1 Respiratory Failure who exhibit a reduction in arterial blood oxygenation or *patients* who would benefit from reduced work of breathing, as needed in Type 2 Respiratory Failure, where arterial carbon dioxide is high.

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

NOTE 1 In the *home healthcare environment*, the *supply mains* is often not reliable.

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

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

EXAMPLE 2 Breathing sets, connectors, water traps, expiratory valve, *humidifier*, *breathing system filter*, external electrical power source, *distributed alarm system*.

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.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 2 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for:

— *ventilators* or *accessories* for *ventilator-dependent patients* intended for critical care applications, which are given in ISO 80601-2-12[15];

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13[16];

— *ventilators* or *accessories* intended for the emergency medical services environment, which are given in ISO 80601-2-84[21][2];

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment,* which are given in ISO 80601-2-72[18];

— ventilatory support equipment or *accessories* intended for *patients* with ventilatory impairment, which are given in ISO 80601-2-79[19];

— ventilatory support equipment or *accessories* intended for *patients* with ventilatory insufficiency, which are given in ISO 80601-2-80[20];

— sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70[17];

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

— high-frequency jet *ventilators* (HFJVs)[32], which are given in ISO 80601-2-87[22];

— gas mixers for medical use, which are given in ISO 11195[11];

— high-frequency oscillatory *ventilators* (HFOVs), which are given in ISO 80601-2-87[22]; and

— cuirass or "iron-lung" ventilation equipment.

NOTE 3 *Respiratory high-flow therapy equipment* can be incorporated into any of the above equipment, in which case those standards would be applicable for those *ventilation-modes*.

This document is a particular standard in the IEC 60601 and IEC/ISO 80601 series of documents.

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 *respiratory high-flow therapy equipment,* as defined in 201.3.202, and its *accessories*.

NOTE 1 *Accessories* are included because the combination of the *respiratory high-flow therapy equipment* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of the *respiratory high-flow therapy equipment*.

NOTE 2 This document has been prepared to address the relevant International Medical Device Regulators Forum (IMDRF) *essential principles* and labelling guidances as indicated in Annex CC.

NOTE 3 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex DD.

NOTE 4 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[27] as indicated in Annex EE.

201.1.3 Collateral standards

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

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

[2] Under preparation. Stage at the time of publication: ISO/DIS 80601-2-84:2017.

IEC 60601-1-2:2014+AMD1:2020+AMD2:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 211 respectively. IEC 60601-1-3[23] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

IEC 60601-1:2005, 1.4 is replaced by:

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, including the 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 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this particular 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 “2xx”, where xx is the final digits 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, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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

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

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

Subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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

201.2 Normative references

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

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

NOTE 2 Informative references are listed in the Bibliography.

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

278 *Replacement:*

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

280 *Addition:*

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

283 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

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

285 ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical*
286 *gases*

287 ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

288 ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and*
289 *vacuum*

290 ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical*
291 *devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical*
292 *devices and guidance on the selection of standards*

293 ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device*
294 *manufacturer for the processing of medical devices*

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

297 ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

298 ISO 20417:2020, *Medical devices — Information to be supplied by the manufacturer*

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

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

302 ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General*
303 *requirements*

304 ISO 80369-7:2020, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors*
305 *for intravascular or hypodermic applications*

306 ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and*
307 *essential performance of respiratory gas monitors*

ISO 80601-2-74:—[3], *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: 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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7396-1:2016, ISO 8836:2014, ISO 16142-1:2016, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 20417:2020, ISO 23328-2:2002, IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 62366-1:2015 as indicated in Annex FF and the following apply.

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

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

— ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An alphabetized index of defined terms is found Annex FF.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 3 applies, except as follows:

Addition:

201.3.201
airway device
device intended to provide a *gas pathway* to and from the *patient's* trachea

[SOURCE: ISO 4135:—[5], 3.8.1.1]

201.3.202
airway pressure
P_{aw}
pressure at the *patient-connection port*

[SOURCE: ISO 4135:—[5], 3.1.4.39.1]

201.3.203
body temperature pressure, saturated
BTPS
ambient atmospheric pressure, at a temperature of 37 °C, and a relative humidity (201.3.220) of 100 %

[SOURCE: ISO 4135:—[5], 3.1.1.7]

[3] Under preparation. Stage at the time of publication: ISO/DIS 80601-2-74:2020

201.3.204
breathing system
inspiratory and expiratory *gas pathways* through which gas flows at respiratory pressures and continuously or intermittently in fluid communication with the *patient's* respiratory tract during any form of mechanical ventilation or respiratory therapy

[SOURCE: ISO 4135:—[5], 3.6.1.1, modified —notes deleted.]

201.3.205
exhaust port
opening or openings through which exhaust gas is discharged

[SOURCE: ISO 4135:—[5], 3.1.4.9, modified —notes deleted.]

201.3.206
flow-direction-sensitive component
component or *accessory* through which gas flow is in one direction only for proper functioning or *patient* safety

[SOURCE: ISO 4135:—[5], 3.1.4.13, modified —replaced "must be" with "is".]

201.3.207
fresh gas
respiratory gas delivered to a *breathing system*

Note 1 to entry: In a circle system, the *fresh gas* is all respirable gas delivered into the circle system (including anaesthetic gases and vapours). This may include oxygen or air delivered into a vapourizer, and it will also include the vapour generated by the vapourizer.

Note 2 to entry: In a ventilator, the *fresh gas* is all respirable gas delivered into the *breathing system* (which may be at a point within the ventilator).

[SOURCE: ISO 4135:—[5], 3.1.1.13, modified —replaced "VBS" with "*breathing system*".]

201.3.208
gas intake port
port through which gas is drawn for use by the *patient*

[SOURCE: ISO 4135:—[5], 3.1.4.19]

201.3.209
gas output port
port of the *medical electrical equipment* or device through which gas is delivered at respiratory pressures to an *operator*-detachable part of a *breathing system*

[SOURCE: ISO 4135:—[5], 3.1.4.20]

201.3.210
healthcare professional
individual with appropriate training, knowledge and skills who provides preventive, curative, promotional or rehabilitative health care services in a systematic way to people, families or communities

EXAMPLE *Healthcare professional operator*.

Note 1 to entry: The *healthcare professional operator* is the supervising clinician or the *healthcare professional* responsible for the treatment of a *patient* on *respiratory high-flow therapy equipment*.

[SOURCE: ISO 4135:—[5], 3.1.6.2, modified — added example and note.]

201.3.211
high-flow nasal cannula
patient interface comprising nasal prongs designed for the administration of oxygen or fresh gas above an appropriate threshold for the *patient* size

Note 1 to entry: A flow of greater than 6 l/min is considered as high flow for adults. For paediatric *patients*, a lower threshold might be applicable[39][49].

[SOURCE: ISO 4135:—[5], 3.8.6.3]

201.3.212
high-pressure inlet
inlet to which gas is supplied at a pressure exceeding 100 kPa above ambient

[SOURCE: ISO 4135:—[5], 3.1.4.22]

201.3.213
humidifier
ME equipment that adds water in the form of droplets or vapour, or both, to the inspired gas

Note 1 to entry: This term includes vaporizing, bubble-through and ultrasonic *humidifiers* and active heat and moisture exchangers (HMEs).

[SOURCE: ISO 4135:—[5], 3.7.2.1]

201.3.214
inlet connector
connector on an inlet

EXAMPLE Connection on a low-flow nasal cannula that connects to the outlet of oxygen therapy tubing.

Note 1 to entry: An *inlet connector* can be gas-specific, but this should be indicated with the post-coordinated term gas-specific *inlet connector*.

[SOURCE: ISO 4135:—[5], 3.1.4.24.1]

201.3.215
mask
device which provides a non-invasive interface between the *patient's* airway and a *patient-connection port* or other connection to a source of respirable gas

[SOURCE: ISO 4135:—[5], 3.8.6.4]

201.3.216
maximum limited pressure
$P_{Lim,max}$
highest *airway pressure* that can occur during *normal use* or under *single fault condition*

[SOURCE: ISO 4135:—[5], 3.1.4.39.3]

201.3.217
monitoring equipment
ME equipment or part that continuously or continually measures and indicates the value of a variable to the *operator*