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

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Appareils électromédicaux —

Partie 2-90: Exigences particulières pour la sécurité de base et
les performances essentielles des équipements de thérapie

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This draft is submitted to a parallel vote in ISO and in IEC.

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Foreword

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

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 document 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 and IEC 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) or the IEC list of patent declarations received (see patents.iec.ch).

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

For an explanation of 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 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

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

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. *High-flow therapy equipment* is also used in the treatment of chronic respiratory disease to reduce exacerbation, improve physiological outcomes and quality of life^{[30][43][44][47]} ¹. 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. In general, there is a trend to use more often non-invasive respiratory therapy. 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, flowmeter, 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, flowmeters 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.

- Contaminated air entering the *gas intake port* of the *respiratory high-flow therapy equipment*.
- Instability of gas supply from a *high-pressure inlet*.
- Insufficient pressure from a *high-pressure inlet*, and subsequent effects on oxygen delivered to the patient.
- Insufficient oxygen being delivered to the patient, and related *alarm condition*.
- *Usability* by operators wearing personal protective equipment (such as gloves and blurred visors), when setting up equipment, or viewing or changing settings.
- Instability of output delivered to patients, necessitating frequent operator adjustment.
- *Processing* of equipment, including the surface of the enclosure and internal *gas pathways*, particularly after use on infectious patients.
- Infectious exhaled gas.
- Overheating of *respiratory high-flow therapy equipment*.

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;

¹ Numbers in square brackets refer to the Bibliography.

- 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 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.

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 to 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.

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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

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

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

201.1.1 * Scope

Replacement:

This document applies to the *basic safety and essential performance of respiratory high-flow therapy equipment*, as defined in 201.3.220, hereafter also referred to as *ME equipment* or *ME system*, 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, which can include a *patient* whose upper airway is bypassed.

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

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

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

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:

- fully integrated *ME equipment*; or
- a combination of separate items forming a *ME system*.

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

NOTE 2 This standard and ISO 80601-2-12^[14] are applicable to a critical care *ventilator* with a high-flow therapy mode.

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

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 the general standard, 7.2.13 and 8.4.1.

NOTE 3 Additional information can be found in the general standard, 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^[14];
- *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13^[15];
- *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84^[20];
- *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72^[17];
- ventilatory support equipment or *accessories* intended for *patients* with ventilatory impairment, which are given in ISO 80601-2-79^[18];
- ventilatory support equipment or *accessories* intended for *patients* with ventilatory insufficiency, which are given in ISO 80601-2-80^[19];
- sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70^[16];
- continuous positive airway pressure (CPAP) *ME equipment*;
- high-frequency jet *ventilators* (HFJVs)^[31], which are given in ISO 80601-2-87^[21];
- gas mixers for medical use, which are given in ISO 11195^[9];
- flowmeters, which are given in ISO 15002^[11];
- high-frequency oscillatory *ventilators* (HFOVs), which are given in ISO 80601-2-87^[21]; and
- cuirass or “iron-lung” ventilation equipment.

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

201.1.2 Object

Replacement:

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^[26] as indicated in Annex EE.

201.1.3 Collateral standards

Amendment (add after existing text):

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.

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^[22] 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, 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.

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

Replacement:

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

Addition:

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

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

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

ISO 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

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

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

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

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

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

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

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

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

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

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

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

ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

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

ISO 80601-2-74:—², *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*

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201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7396-1:2016+AMD1:2017, ISO 8836:2014, ISO 16142-1:2016, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 20417:2021, 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.

201.3.201

airway device

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

[SOURCE: ISO 4135:—^[5], 3.8.1.2]

² Under preparation. Stage at the time of publication: ISO/FDIS 80601-2-74:2021.

201.3.202

airway pressure

P_{aw}

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

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

[SOURCE: ISO 4135:—^[5], 3.1.4.41.1]

201.3.203

body temperature pressure, saturated

BTPS

ambient atmospheric pressure, at a temperature of 37 °C, and a relative humidity of 100 %

[SOURCE: ISO 4135:—^[5], 3.1.1.7]

201.3.204

breathing system

pathways through which gas flows to or from the *patient* at respiratory pressures and continuously or intermittently in fluid communication with the *patient's* respiratory tract during any form of artificial ventilation or respiratory therapy

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

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201.3.205

exhaust port

port through which exhaust gas is discharged to the atmosphere or to an anaesthetic gas scavenging system

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[SOURCE: ISO 4135:—^[5], 3.1.4.11, modified —notes deleted.]

201.3.206

flow-direction-sensitive component

component or *accessory* through which gas flow has to be in one direction only for proper functioning or *patient* safety

[SOURCE: ISO 4135:—^[5], 3.1.4.15]

201.3.207

fresh gas

respirable gas delivered to a *breathing system*

[SOURCE: ISO 4135:—^[5], 3.1.1.16, modified —notes deleted.]

201.3.208

gas intake port

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

[SOURCE: ISO 4135:—^[5], 3.1.4.21]

201.3.209**gas output port**

port of the device through which gas is delivered at respiratory pressures to a *user*-detachable part of a *breathing system*

[SOURCE: ISO 4135:—^[5], 3.1.4.22]

201.3.210**healthcare professional**

individual with appropriate certification, 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^{[36][49]}.

[SOURCE: ISO 4135:—^[5], 3.8.6.3, modified — added cross references.]

201.3.212**high-pressure inlet**

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

[SOURCE: ISO 4135:—^[5], 3.1.4.24]

201.3.213**humidifier**

device that adds water in the form of droplets or vapour, or both, to the inspired gas

Note 1 to entry: This term includes vaporising, 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], 3.1.4.26.1]