



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-90:2021. It is identical to ISO 80601-2-90:2021.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment (ISO 80601-2-90:2021)

Appareils électromédicaux - Partie 2-90: Exigences particulières pour la sécurité de base et les performances essentielles des équipements de thérapie respiratoire à haut débit (ISO 80601-2-90:2021)

Medizinische elektrische Geräte - Teil 2-90: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Geräten für die Beatmungstherapie mit hohem Durchfluss (ISO 80601-2-90:2021)

This European Standard was approved by CEN on 26 July 2021.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 80601-2-90:2021) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2022, and conflicting national standards shall be withdrawn at the latest by April 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 80601-2-90:2021 has been approved by CEN as EN ISO 80601-2-90:2021 without any modification.

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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 or www.iec.ch/members_experts/refdocs).

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. In the IEC, see www.iec.ch/understanding-standards.

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, *Electromedical 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 and IEC websites.

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 and www.iec.ch/national-committees.

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 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 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 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.

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 201.3.220, 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 3.154, 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:

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 80601-2-74:2021, *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*

IEC Guide 115:2021, *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 ISO 7396-1:2016+AMD1:2017, 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 4135:2021^[5], 3.8.1.2]

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 4135:2021^[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 4135:2021^[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 4135:2021^[5], 3.6.1.1, modified —notes deleted.]

201.3.205

exhaust port

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

[SOURCE: ISO 4135:2021^[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 4135:2021^[5], 3.1.4.15]

201.3.207

fresh gas

respirable gas delivered to a *breathing system*

[SOURCE: ISO 4135:2021^[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 4135:2021^[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 4135:2021^[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 4135:2021^[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 4135:2021^[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 4135:2021^[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 4135:2021^[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 4135:2021^[5], 3.1.4.26.1]

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 4135:2021^[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 4135:2021^[5], 3.1.4.41.3]

201.3.217

monitoring equipment

equipment or part that measures and indicates the value of a variable to the *operator*

Note 1 to entry: *Monitoring equipment* includes devices that are not electrical in operation, such as a pressure gauge.

Note 2 to entry: The value can be displayed continually or intermittently.

Note 3 to entry: The *monitoring equipment* can be primarily intended for detection of an *alarm condition* or for external communication.

[SOURCE: ISO 4135:2021^[5], 3.11.1.3, modified —replaced 'user' with 'operator'.]

201.3.218

patient-connection port

port of a *breathing system* intended for connection to an *airway device*

EXAMPLE A *high-flow nasal cannula*, tracheal tube, tracheostomy tube, face *mask* and supralaryngeal airway are all *airway devices*.

Note 1 to entry: The *patient-connection port* is the end of the *breathing system* proximal to the *patient*.

Note 2 to entry: The *patient-connection port* is typically a connector suitable for connection to an *airway device* such as a tracheal tube, tracheostomy tube, face *mask* or supralaryngeal airway.

Note 3 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the form of specific standardized connectors, for example, a connector conforming to ISO 5356-1.

[SOURCE: ISO 4135:2021^[5], 3.1.4.41, modified —deleted note 4.]

201.3.219

protection device

part or function of medical device or *accessory* that, without intervention by the *operator*, protects the *patient*, other people or the environment from hazardous output due to incorrect delivery of energy or substances

[SOURCE: ISO 4135:2021^[5], 3.1.4.48, modified —replaced 'user' with 'operator'.]

201.3.220**respiratory high-flow therapy equipment**

ME equipment or *ME system* intended to provide a continuous flow of heated and humidified gas that exceeds the *patient's* inspiratory flow to a spontaneously breathing *patient*

Note 1 to entry: *Respiratory high-flow therapy equipment* is intended for a spontaneous breathing *patient* 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.

Note 2 to entry: *Respiratory high-flow therapy equipment* is intended to provide a sufficiently high flow to minimize the *patient's* entrainment of room air.

Note 3 to entry: *Respiratory high-flow therapy equipment* typically connects to a *patient* with a non-sealing, *high-flow nasal cannula*, a tracheostomy tube with mask or a face *mask* or helmet with large *exhaust ports*.

201.3.221**standard temperature and pressure, dry****STPD**

pressure of 101,325 kPa at an operating temperature of 20 °C, dry

[SOURCE: ISO 4135:2021^[5], 3.1.1.8]

201.3.222**validation**

confirmation, through the provision of *objective evidence*, that the requirements for a specific *intended use* or application have been fulfilled

Note 1 to entry: The *objective evidence* needed for a *validation* is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The term “*validated*” is used to designate the corresponding status.

Note 3 to entry: The use conditions for *validation* can be real or simulated.

[SOURCE: ISO 9000:2015^[7], 3.8.13]

201.3.223**ventilator-dependent**

dependent upon artificial ventilation in order to prevent serious deterioration of health or death

Note 1 to entry: A *ventilator-dependent patient* cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood.

EXAMPLE *Patients* with Duchennes Muscular Dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

[SOURCE: ISO 4135:2021^[5], 3.1.5.18]

201.4 General requirements

Clause 4 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.4.3 Essential performance

Additional subclause:

201.4.3.101 * Additional requirements for essential performance

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

NOTE The *essential performance* requirements of the *humidifier* used with *respiratory high flow-therapy equipment* are found in ISO 80601-2-74.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of a continuous flow of humidified gas and oxygen concentration at the <i>patient-connection port</i> within the disclosed accuracy or generation of an <i>alarm condition</i>	^a
flowrate, if equipped	201.12.4.103
gas supply failure	201.13.2.103
<i>internal electrical power source</i> nears depletion, if equipped	201.11.8.101.1
obstruction	201.12.4.104
oxygen level, if equipped	201.12.4.101
<i>internal electrical power source</i> failure, if equipped	201.11.8.101.1
^a Subclause 202.8.1.101 indicates methods of evaluating delivery of therapy as acceptance criteria following specific tests required by this document.	

201.4.6 * *ME equipment* or *ME system* parts that contact the *patient*

Amendment (add at end of 4.6 prior to the compliance check):

- aa) The *breathing system* or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause (i.e., 4.6 of IEC 60601-1:2005+AMD1:2012+AMD2:2020).

Additional subclauses:

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

a) If the *respiratory high-flow therapy equipment* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1, then it

- 1) shall operate and meet the requirements of this document throughout its *rated* range of input pressure, and
- 2) shall not cause an unacceptable *risk* under the *single fault condition* of 1 000 kPa.

NOTE 1 Internal pressure regulators can be needed to accommodate the *single fault condition* of maximum input pressure, as well as the *rated* range of input pressure.

NOTE 2 Under the *single fault condition* of overpressure, it is desirable for gas to continue to flow to the *breathing system*. Under this condition, the flowrate from the *respiratory high-flow therapy equipment* is likely to be outside of its specification.

b) If the *respiratory high-flow therapy equipment* has a maximum *rated* input pressure in excess of 600 kPa, the *respiratory high-flow therapy equipment* shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

Check conformance by functional testing in normal use and under normal condition with the most adverse operating settings, by functional testing in single fault condition and inspection of the risk management file.

201.4.11.101.2 Compatibility requirement

If the *respiratory high-flow therapy equipment* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1, then

a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1, and

NOTE Taking account of requirements for over-pressure and under-pressure, this corresponds to a range 280 kPa to 600 kPa.

b) under *normal condition*,

- 1) the maximum 10 s average input flowrate required by the *respiratory high-flow therapy equipment* for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the *gas intake port*, and
- 2) the transient input flowrate shall not exceed 200 l/min averaged for 3 s.

or

3) the *accompanying documents* shall disclose the following:

- i) the maximum 10 s average input flowrate required by the *respiratory high-flow therapy equipment* for each gas at a pressure of 280 kPa, measured at the *gas intake port*;
- ii) the maximum transient input flowrate averaged for 3 s required by the *respiratory high-flow therapy equipment* for each gas at a pressure of 280 kPa, measured at the *gas intake port*;

- iii) a warning to the effect that this equipment is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flowrate at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flowrate, thereby minimizing the risk that the equipment interferes with the operation of adjacent equipment.

Check conformance by functional testing in normal use and under normal condition with the most adverse operating settings and by inspection of the accompanying documents.

201.5 General requirements for testing of ME equipment

Clause 5 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Additional subclauses:

201.5.101 * Additional requirements for the general requirements for testing of ME equipment

201.5.101.1 Respiratory high-flow therapy equipment test conditions

- a) For testing, the *respiratory high-flow therapy equipment*:
 - 1) shall be connected to gas supplies as specified for *normal use*;
 - 2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.
- b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

NOTE This subclause is only applicable to *respiratory high-flow therapy equipment* intended to be connected to a gas supply (e.g. *medical gas pipeline system* or medical gas cylinder) in *normal use*.

201.5.101.2 * Gas flowrate specifications

In this document, requirements for the flowrate are expressed at *standard temperature and pressure, dry (STPD)*, except for those associated with the *breathing system*, which are expressed under the conditions disclosed in the *instructions for use*.

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

201.5.101.3 * Respiratory high-flow therapy equipment testing errors

- a) For the purposes of this document, acceptance criteria for testing declared tolerances shall use the type A evaluation method (statistical uncertainty) *procedure* from IEC Guide 115:2021, 4.4.2.

NOTE This is a change from previous respiratory documents, which required tolerances to be adjusted by subtracting measurement uncertainty from disclosed tolerance values to determine acceptance criteria.

- b) Test equipment and methods shall be selected and controlled to ensure that the uncertainty (with coverage factor $k = 2$, for confidence of $\sim 95\%$) is no more than 30% of the disclosed tolerance for the parameter being tested.

EXAMPLE If the *manufacturer* wishes to claim a tolerance for delivered flowrate of $\pm(0,5 \text{ l/min} + 10 \% \text{ of set flowrate})$ then the uncertainty of the measurement cannot exceed $\pm(0,16 \text{ l/min} + 3 \% \text{ of set flowrate})$.

- c) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty.
- d) The *manufacturer* shall disclose the measurement uncertainty of each disclosed tolerance in the *technical description*.

Check conformance by inspection of the instructions for use and the technical description.

201.6 Classification of *ME equipment* and *ME systems*

Clause 6 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

201.7 *ME equipment* identification, *marking* and documents

Clause 7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Additional subclauses:

201.7.1.101 Information to be supplied by the manufacturer

The *information supplied by the manufacturer of respiratory high-flow therapy equipment* and its *accessories* shall conform with ISO 20417:2021.

In applying ISO 20417:2021, the terms in this document and those in the general standard shall be used as follows.

- a) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.
- b) The term "*medical device*" shall assume the same meaning as *ME equipment*.
- c) The term "*user*" shall assume the same meaning as *operator*.
- d) The term "*patient*" shall include animals.

Check conformance by application of ISO 20417:2021.

201.7.2.4.101 Additional requirements for *accessories*

Accessories supplied separately shall fulfil the requirements of

- a) 201.7.2.101; and
- b) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *respiratory high-flow therapy equipment*, if applicable.
 - 1) If *marking* the *accessory* is not practicable, this information may be placed in the *instructions for use*.

NOTE The *manufacturer* of the *accessory* can be the *respiratory high-flow therapy equipment manufacturer* or another entity ("third-party manufacturer" or durable medical equipment provider) and all these entities are expected to ensure conformance with this requirement. Additional requirements are found in 201.102.

Check conformance by inspection and inspection of the risk management file for any limitations or adverse effects of the accessory.

201.7.2.18 External gas source

Amendment (add before the first dash):

- aa) the gas name or chemical *symbol* in accordance with ISO 5359:2014+AMD1:2017;
- bb) the *rated* range of gas pressure;
- cc) for oxygen gas inputs, the *rated* range of oxygen concentration;
- dd) gas-specific colour coding in accordance with ISO 32:1977^[1], if colour coding is used.

EXAMPLE Colour coding to match the colour of the flexible hose or a gas cylinder intended to be attached to the *inlet connector*.

NOTE In some countries, other colour coding is used.

201.7.2.101 Additional requirements for *marking* on the outside of *ME equipment* or *ME equipment parts*

- a) If applicable, *marking* of operator-detachable *ME equipment* parts or *accessories* shall
 - 1) be *clearly legible*; and
 - 2) include an arrow indicating the direction of the flow for *flow-direction-sensitive components* that are operator-removable without the use of a *tool*;
- b) If applicable, a *clearly legible marking* shall warn not to obstruct the *gas intake port*.

EXAMPLE WARNING: Gas Intake – Do not obstruct.

- 1) A *symbol* evaluated according to IEC 62366-1 as *information for safety* may be utilized.
- c) For *respiratory high-flow therapy equipment* intended to be used in the magnetic resonance (MR) environment, the *respiratory high-flow therapy equipment*, its parts and *accessories* shall have *clearly legible markings* conforming with:
 - 1) *symbol* 7.3.1-1 of IEC 62570 (Table 201.D.2.101, *symbol* 1) if ‘MR Safe’;
 - 2) *symbol* 7.3.1-2 of IEC 62570 (Table 201.D.2.101, *symbol* 2) if ‘MR Safe’, or
 - 3) *symbol* 7.3.2 of IEC 62570 (Table 201.D.2.101, *symbol* 3) if ‘MR Conditional’.

Check conformance by inspection.

201.7.4.3 Units of measurement

Amendment (add to the bottom as a new row in Table 1):

All gas volume, flowrate and leakage specifications:

- aa) shall be expressed at *STPD*;
- bb) except those associated with the *breathing system* which shall be expressed under the conditions disclosed in the *instructions for use* as either:

- 1) *STPD*; or
- 2) *BTPS*.

201.7.9.2.1 General

Amendment (add between the second and third bullet following the first paragraph):

— the intended position of the *operator*;

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

- a) If the *respiratory high-flow therapy equipment* is intended for use in the *home healthcare environment*, separate *instructions for use* shall be provided for:
 - 1) the *lay operator*; and
 - 2) the *healthcare professional operator*.
- b) The *manufacturer* may choose in which *instructions for use* to place the information required by this document unless otherwise indicated in this document based on *risk management* and *usability* considerations.
- c) The *healthcare professional operator instructions for use* shall include the information contained in the *lay operator instructions for use*.

Check conformance by inspection of the instructions for use, the risk management file and the usability engineering file.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The *instructions for use* shall include the following.

- a) A warning statement to the effect that “WARNING: Do not cover the equipment or place in a position that affects proper operation”, including applicable examples.

EXAMPLE 1 WARNING: Do not position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat.

EXAMPLE 2 WARNING: Do not block the gas intake port, thereby interfering with patient therapy.

EXAMPLE 3 WARNING: When using the equipment in a carrying case or in-use bag, only use a carrying case or in-use bag that is listed in the instructions for use, to prevent the equipment from overheating or interfering with *patient* therapy.
- b) * A warning statement to the effect that “WARNING: Do not add any attachments or accessories to the equipment that contravene the instructions for use of the equipment or accessory, as the equipment might not function correctly leading to the risk of degradation of health of the patient.”
- c) A warning statement to the effect that “WARNING: Do not use the equipment at an altitude above [insert maximum *rated* altitude] or outside a temperature of [insert *rated* temperature range]. Using the equipment outside of this temperature range or above this altitude can compromise the equipment performance which consequently can result in degradation of the health of the patient.”

- d) * If applicable, a warning statement to the effect that “WARNING: Do not connect the equipment to the battery of a battery-powered wheelchair unless the connection is listed in the instructions for use of the equipment or wheelchair as this can compromise the equipment performance which consequently can result in degradation of the health of the patient.”
- e) A warning statement to the effect that “WARNING: To reduce the likelihood of disconnection and to prevent adverse equipment performance use only accessories compatible with the equipment. Compatibility is determined by reviewing the instructions for use of either the equipment or the accessories”.
- f) A warning statement to the effect that “WARNING: The high-flow mode of this equipment is only suitable for a spontaneously breathing patient.”
- g) If applicable, a warning statement to the effect that “WARNING: The therapy supplied to the patient can be adversely affected by the gas added by the use of a pneumatic nebuliser.”
- h) * A warning statement to the effect that “WARNING: It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the equipment and indicated in the instructions for use as this can affect the performance of the equipment or pipeline system that can consequently result in serious deterioration of health.”
- i) A warning statement to the effect that “WARNING: To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only use tubes with a retention force in conformance with ISO 5367 or ISO 80601-2-74”.
- j) A warning statement to the effect that “WARNING: Do not use sealed patient interfaces with this equipment, to avoid the risk of suffocation or barotrauma”.

NOTE Full face *masks*, ET tubes and helmets are examples of sealed *patient* interfaces.

- k) A warning statement to the effect that “WARNING: There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the equipment or accessories near sparks or open flames.”
- l) A warning statement to the effect that “WARNING: Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns”.
- m) A warning statement to the effect that “WARNING: Do not lubricate fittings, connections, tubing, or other accessories of the equipment to avoid the risk of fire and burns.”
- n) A warning statement to the effect that “WARNING: Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.”
- o) A warning statement to the effect that “WARNING: Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask on bed coverings or chair cushions, if the equipment is turned on, but not in use; the oxygen will make the materials more flammable. Turn the equipment off when not in use to prevent oxygen enrichment.”

- p) A warning statement to the effect that "WARNING: Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking or open flames within the same room as the equipment or any oxygen-carrying accessories. If the patient intends to smoke, always turn the equipment off, remove the cannula and leave the room where the equipment is located. If unable to leave the room, wait 10 minutes after you have turned the equipment off."
- q) A warning statement to the effect that "WARNING: Open flames during oxygen therapy are dangerous and are likely to result in fire or death. Do not allow open flames within 2 m of the equipment or any oxygen-carrying accessories."
- r) A warning statement to the effect that "WARNING: Ensure a sufficient intended leakage between the breathing system and the patient to allow the patient to exhale."

Check conformance by inspection of the instructions for use.

201.7.9.2.8.101 * Additional requirements for start-up procedure

NOTE 1 For the purposes of this document, a start-up *procedure* is a pre-use functional test that is used for the initial setup for a *patient* to determine whether the *respiratory high-flow therapy equipment* is ready for use.

- a) For *respiratory high-flow therapy equipment* intended for use in the *home healthcare environment*, the *instructions for use* for the *lay operator* shall disclose a method by which
 - 1) the assembled breathing tubes and related *accessories* and
 - 2) if equipped with an *internal electrical power source*, the switchover to and operation from the *internal electrical power source*
 can be functionally tested to determine if they are operating correctly.

NOTE 2 Additional requirements are also found in 201.15.102.

- b) The *instructions for use* for the *healthcare professional operator* shall disclose a test method:
 - 1) by which functions necessary for *normal use* can be tested to determine if they are operating correctly; and
 - 2) which can determine whether or not the assembled breathing tubes and related *accessories* are suitable for use.
 - i) These test methods, or portions thereof, may be performed automatically by the *respiratory high-flow therapy equipment* or may require *operator* action.
 - ii) These test methods should be as automated as practicable.

Check conformance by inspection of the instructions for use.

201.7.9.2.9.101 Additional requirements for operating instructions

201.7.9.2.9.101.1 Lay operator operating instructions

- a) The *instructions for use* intended for the *lay operator* shall include the conditions under which the *respiratory high-flow therapy equipment* maintains the accuracy of controlled and displayed variables as disclosed in the *instructions for use*;

EXAMPLE 1 Acceptable range of water level in a *humidifier*.

EXAMPLE 2 Interval of calibration of a flow sensor.

- b) The *instructions for use* intended for the *lay operator* shall include:
- 1) a description of how to connect and test the connection of a *distributed alarm system*, if provided; and
 - 2) a description of a means to determine the operation time of the *internal electrical power source*, if provided.

NOTE See also IEC 60601-1-11:2015, 8.5.1.

Check conformance by inspection of the instructions for use.

201.7.9.2.9.101.2 Healthcare professional operator operating instructions

- a) The *instructions for use* intended for the *healthcare professional operator* shall include a detailed description of the function of all therapy modes provided by the *respiratory high-flow therapy equipment* including, but not limited to, the following items:
- 1) the working principle of each of the *respiratory high-flow therapy equipment's* therapy modes;
 - 2) the parameter settings;
 - 3) the range of parameter settings;
 - 4) any limitation of parameter settings; and
 - 5) how to change *breathing system* configurations when necessary for a specific therapy mode, if applicable.
- b) The *instructions for use* intended for the *healthcare professional operator* shall include a description of how at least the following *alarm conditions* can be functionally tested:
- 1) flowrate, if equipped; and
 - 2) obstruction.
- c) The *instructions for use* intended for the *healthcare professional operator* shall indicate whether or not the *respiratory high-flow therapy equipment*
- 1) is intended for use with nebulized medications, and if so,
 - 2) any constraints.

Check conformance by inspection of the instructions for use.

201.7.9.2.12 Cleaning, disinfection and sterilization

Amendment: (add after normal use)

and single fault condition

Amendment: (add after bulleted list)

- aa) The *instructions for use* shall identify any portions of the *gas pathways* through the *respiratory high-flow therapy equipment* that can become contaminated with body fluids or by microbial material conveyed by the expired breathing gases during both:
- 1) *normal condition*; and

2) *single fault condition*.

EXAMPLE A fault that causes loss of airflow.

Additional subclauses:

201.7.9.2.13.101 Additional requirements for maintenance

The *instructions for use* shall disclose:

- a) a description of periodic safety inspections that should be performed by the *operator*;
- b) if applicable, the care and maintenance *procedures* for the *internal electrical power source*, including instructions for recharging and replacement.

Check conformance by inspection of the instructions for use.

201.7.9.2.14.101 Additional requirements for accessories, supplementary equipment, used material

The *instructions for use* of a *respiratory high-flow therapy equipment* shall identify:

- a) at least one set of *accessories*; and
- b) if applicable, the *ME equipment* necessary for the *respiratory high-flow therapy equipment's intended use*.

If applicable, the *instructions for use* shall disclose

- c) any restrictions on the positioning of components within the *breathing system*.

EXAMPLE Where such components are *flow-direction-sensitive components*.

- d) any adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *respiratory high-flow therapy equipment*.

Check conformance by inspection of the instructions for use and inspection of the risk management file for any adverse effect of any recommended accessory.

201.7.9.3.1.101 * Additional general requirements

The *technical description* shall disclose:

- a) the interdependence of control functions;
- b) a pneumatic diagram of the *respiratory high-flow therapy equipment*, including a diagram for *operator-detachable parts* of the *breathing system* either supplied or recommended in the *instructions for use*; and
- c) a statement to the effect that prior to use the responsible organization needs to ensure the compatibility of the equipment and all of the parts and accessories with which the equipment is intended to be used.

Check conformance by inspection of the technical description.

201.7.9.3.101 Additional requirements for the *technical description*

- a) The *technical description* shall include a description of a method for checking the proper functioning of the *alarm system* for each of the *alarm conditions* specified in this document, if not performed automatically during the start-up *procedure*.
- b) The *technical description* shall disclose which checks are performed automatically.

Check conformance by inspection of the technical description.

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

Clause 8 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems*

Clause 9 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Additional subclause:

201.9.4.3.101 Additional requirements for instability from unwanted lateral movement

- a) *Transit-operable respiratory high-flow therapy equipment* shall include a means by which the *respiratory high-flow therapy equipment* can be secured without the use of a *tool* to prevent unwanted movement during transport while in use.

EXAMPLE 1 Means to restrain physically the *respiratory high-flow therapy equipment* during transport in a personal vehicle, in an ambulance or on a wheelchair.

- b) The means shall secure *transit-operable respiratory high-flow therapy equipment* so as to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 3 s in each orientation.

EXAMPLE 2 Attach the *respiratory high-flow therapy equipment* to an armature at a 1 m radius from an axis of horizontal rotation. When rotating through a circle every 2 s at constant speed, the lateral (centripetal) acceleration is approximately 1,0 g^[48].

Check conformance by functional testing.

201.9.4.4 Grips and other handling devices

Amendment (replace list item b) with):

- b) *Portable respiratory high-flow therapy equipment* shall be:
 - 1) equipped with a handle that does not require more than one hand; or
 - 2) equipped with a carrying strap.

Check conformance by carrying with one hand or by inspection of the carry case or in-use bag.