INTERNATIONAL STANDARD

ISO 80601-2-90

First edition
2021-08

Medical electrical equipment —

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

Appareils électromédicaux —

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

Reference number
ISO 80601-2-90:2021(E)

COPYRIGHT PROTECTED DOCUMENT

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

Published in Switzerland

Contents

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 *patient-connection port* within the disclosed accuracy or	[a]
generation of an *alarm condition*	
flowrate, if equipped	201.12.4.103
gas supply failure	201.13.2.103
internal electrical power source nears depletion, if equipped	201.11.8.101.1
obstruction	201.12.4.104
oxygen level, if equipped	201.12.4.101
internal electrical power source 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 ~ 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 ±(0,5 l/min +10 % of set flowrate) then the uncertainty of the measurement cannot exceed ±(0,16 l/min +3 % 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.

Additional subclauses:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

a) The A-weighted sound pressure level emitted by the *respiratory high-flow therapy equipment* shall be measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2 and disclosed in the *instructions for use*.

b) The A-weighted sound power level shall be calculated according to 8.1 of ISO 3744:2010 and disclosed in the *instructions for use*.

Check conformance with the following test:

c) Place the respiratory high-flow therapy equipment on the sound-reflecting plane and attach the least favourable breathing system and airway device rated as capable of delivering the maximum rated flowrate from those indicated in the instructions for use.

NOTE The least favourable *airway device i*s typically the one with the highest resistance to flow.

d) Include the humidifier, provided with the respiratory high-flow therapy equipment or specified in the accompanying documents of the respiratory high-flow therapy equipment, in the test and fill to the least favourable level.

e) Acoustically isolate the breathing tube, airway device and gas leaving the breathing system by a suitable means outside the test area such that noise caused by these does not interfere with the sound measurement of the respiratory high-flow equipment.

f) Set the respiratory high-flow therapy equipment to its maximum flowrate.

g) Using a microphone of the sound level meter, conforming with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the maximum time-weighted sound pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{AFmax}) at 10 positions in a hemisphere with a radius from the geometric centre of the respiratory high-flow therapy equipment in a free field over a reflecting plane as specified in 8.1.1 of ISO 3744:2010. Average the values in conformance with 8.2.2 of ISO 3744:2010.

h) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.1 of ISO 3744:2010.

i) Calculate the A-weighted sound power level according to 8.6 of ISO 3744:2010.

j) Confirm that the criteria for background noise specified in 4.2 of ISO 3744:2010 are fulfilled.

k) Ensure that the measured sound pressure level is less than that disclosed in the instructions for use.

201.10 Protection against unwanted and excessive radiation *hazards*

Clause 10 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

201.11 Protection against excessive temperatures and other *hazards*

Clause 11 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.11.1.2.2 * *Applied parts* not intended to supply heat to a *patient*

Amendment (add between second and third paragraphs):

In *normal use* and *single fault conditions* and over the *rated* flowrate range and at the maximum *rated* operating temperature, the temperature of the gas delivered by the *respiratory high-flow therapy equipment* at the *patient-connection port,* both with and without each *humidifier* specified for use in the instruction for use, when averaged over 120 s, shall not exceed:

aa) 70 °C; and

bb) an energy equivalent to 43 °C and 100 % relative humidity (a specific enthalpy not to exceed 197 kJ/m^3 dry air).

Table 201.102 contains examples of combinations of temperature and relative humidity with such a specific enthalpy.

Table 201.102 — Examples of permissible combinations of temperature and relative humidity

Temperature (°C)	**Relative humidity** (%)
43	100
44	95
45	90
48	76
50	69
55	52
60	40
65	30
70	23

Amendment (add at the end of the subclause):

Conformance is checked by application of the tests of ISO 80601-2-74:2021, 201.12.4.101.

201.11.2.2.1 *Risk* of fire in an *oxygen rich environment*

Amendment (add to the end of note 1):

It is reasonably foreseeable that the ambient room air where *respiratory high-flow therapy equipment* is in use has an oxygen concentration exceeding 25%.

201.11.6.6 * *Cleaning* and *disinfection* of *ME equipment* or *ME system*

Amendment (add additional requirement as new first paragraph):

aa) *Gas pathways* through the *respiratory high-flow therapy equipment* and its *accessories* not intended for *single use* that can become contaminated with body fluids or by microbial material conveyed by the expired gases during *normal condition* or *single fault condition* shall be designed to allow for:

1) *cleaning* and *disinfection*, or

2) *cleaning* and *sterilization*.

NOTE Additional requirements are found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 11.6.7 and IEC 60601-1-11:2015, 8.1 and 8.2.

3) Dismantling or parts replacement may be performed.

Amendment (add additional requirement and replace the compliance test):

bb) *Respiratory high-flow therapy equipment enclosures* shall be designed to allow for surface *cleaning* and *disinfection* to reduce to acceptable levels the *risk* of infection of *operators*, bystanders, or the *patient*.

cc) *Processing* instructions for the *respiratory high-flow therapy equipment* and its *accessories* shall:

1) conform with ISO 17664:2017; and

2) be disclosed in the *instructions for use*.

NOTE 1 ISO 14159[10] provides guidance for the design of *enclosures*.

Check conformance by inspection of the risk management file. When conformance with this document could be affected by the cleaning or the disinfection of the respiratory high-flow therapy equipment or its parts or accessories, clean and disinfect them for the number of cycles determined by the expected service life in accordance with the methods indicated in the instructions for use, including any cooling or drying period. After these procedures, ensure that basic safety and essential performance are maintained. Confirm that the manufacturer has evaluated the effects of multiple processing cycles and the effectiveness of those cycles.

NOTE 2 For *respiratory high-flow therapy equipment* intended for *home healthcare environment*, additional information regarding the order of test is found in 211.10.1.1.

201.11.6.7 *Sterilization* of *ME equipment* or *ME system*

Amendment (add note before compliance test):

NOTE Additional requirements are found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 11.6.6 and IEC 60601-1-11:2015, 8.1 and 8.2.

201.11.7 *Biocompatibility* of *ME equipment* and *ME systems*

Amendment (add after existing text prior to the compliance statement):

aa) The *manufacturers* of the *respiratory high-flow therapy equipment*, the *breathing system*, their parts and *accessories* shall address in the *risk management process* the *risks* associated with the *biocompatibility* and potential contamination of the gas stream arising from the *gas pathway*.

bb) The *gas pathways* shall be evaluated for *biocompatibility* according to ISO 18562-1:2017.

Check conformance by confirming conformity to ISO 18562-1:2017.

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

Additional subclauses:

201.11.8.101 * Additional requirements for interruption of the power supply/*supply mains* to *ME equipment alarm condition*

201.11.8.101.1 *Alarm conditions*

a) *Transit-operable respiratory high-flow therapy equipment* shall be equipped with an *internal electrical power source*.

b) If equipped with an *internal electrical power source, respiratory high-flow therapy equipment* shall be

   1) equipped with an automatic switchover to the *internal electrical power source* when the *supply mains* falls outside the values necessary to maintain normal operation.

   2) capable of powering the *respiratory high-flow therapy equipment* for at least 30 min from a fully charged *internal electrical power source*.

   3) provided with a means for determining the remaining capacity or operation time provided by the *internal electrical power source.*

   4) provided with a means to indicate that the *respiratory high-flow therapy equipment* is being powered from the *internal electrical power source.*

c) The *respiratory high-flow therapy equipment* with an *internal electrical power source* shall either:

   1) be equipped with an *alarm system* that:

      i) detects an *alarm condition* of at least a *low priority* to indicate the switchover to the *internal electrical power source*;

      ii) detects an *alarm condition* of at least a *low priority* to indicate there is at least 10 min of remaining power available in the *internal electrical power source;*

      iii) detects an *alarm condition* of at least a *medium priority* to indicate there is at least 5 min of remaining power available in the *internal electrical power source;*

      iv) provides at least 5 min between the start of these two *internal electrical power source* failure *alarm conditions;*

   2) or be equipped with an *intelligent alarm system*, based on additional information, determines that the impending *internal electrical power source* failure *alarm condition*:

      i) is suppressed; or

      ii) its priority is changed.

   NOTE The *operator* needs sufficient time "prior to the loss of all power" to take action to ensure that alternative arrangements can be made to continue the therapy.

d) If equipped with an *internal electrical power source,* the *instructions for use* shall disclose

   1) the operational time of the *respiratory high-flow therapy equipment* when powered from each power source under the following conditions:

      i) a fully charged power source; and

ii) the conditions of Table 201.104.

2) the behaviour of the *respiratory high-flow therapy equipment* after a switchover to

i) the *internal electrical power source*, and

ii) an alternative *supply mains*.

3) the behaviour of the *respiratory high-flow therapy equipment* during the recharging of

i) the *internal electrical power source*, and

ii) an alternative *supply mains*.

4) the minimum time between complete loss of *internal electrical power source* and

i) the start of the *low priority* impending *internal electrical power source* failure *alarm condition*, and

ii) the *medium priority* impending *internal electrical power source* failure *alarm condition*.

5) the maximum time required to fully charge the *internal electrical power source.*

e) *Respiratory high-flow therapy equipment* without an *internal electrical power source* shall be equipped with an *alarm system* that:

1) detects an *alarm condition* of at least a *medium priority* to indicate loss of power; or

2) utilizes an *intelligent alarm system*, based on additional information, determines that the loss of power *alarm condition* is suppressed or its priority is changed.

Check conformance by functional testing and inspection of the instructions for use.

201.11.8.101.2 Alternative power supply/*supply mains*

a) *Transit-operable respiratory high-flow therapy equipment* intended for the *home healthcare environment* shall have a means of connection to an alternative *supply mains*.

EXAMPLE 1 A 12 V d.c., 100 W connector for connection to an automotive vehicle power source.

EXAMPLE 2 A connection to alternative d.c. power source.

b) The *instructions for use* shall include:

1) a description of the means of connection;

2) the *rated* voltage range;

3) the *nominal* voltage range;

4) the maximum current required; and

5) instructions to consult the *instructions for use* of the alternative power supply with regards to charging and maintenance, if appropriate.

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

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.12.1 * Accuracy of controls and instruments

Amendment (add after existing sentence):

aa) The *respiratory high-flow therapy equipment* may provide means to reduce the visibility of its controls and indicators either automatically or by the *operator* action.

bb) If a means to reduce the visibility is provided, the *respiratory high-flow therapy equipment* shall automatically resume normal visibility during an *alarm condition*.

cc) The controls and indicators related to the *essential performance* of *respiratory high-flow therapy equipment* shall be *clearly legible* under the conditions specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2, but:

1) for a *transit-operable respiratory high-flow therapy equipment* with the light level extended from the range of '100 lx to 1 500 lx' to the range of '100 lx to 10 000 lx'; and

2) * with the intended position of the *operator* for the purpose evaluating the legibility of *markings* shall be at least 2 m from the *respiratory high-flow therapy equipment*.

Check conformance by functional testing and application of the tests of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2. See also 7.9.2.1.

Additional subclauses:

201.12.1.101 Continuous flow *breathing-therapy mode*

201.12.1.101.1 Flowrate accuracy

a) With a *breathing-therapy mode* of continuous flow selected and the *respiratory high-flow therapy equipment* operating in *normal condition*, the delivered flowrate accuracy, as determined for the test settings and conditions specified in this document, shall be disclosed in the *instructions for use*.

b) This disclosure shall include at least the maximum error of the delivered flowrate in relation to the set flowrate.

c) The errors may be reported separately for the following ranges of intended flowrate, Q:

1) $Q \geq 30$ l/min;

2) 30 l/min $\geq Q \geq 15$ l/min; and

3) $Q \leq 15$ l/min.

d) The accuracy of the performance of the *respiratory high-flow therapy equipment* shall either be:

1) determined for each *breathing system* and *airway device* configuration indicated in the *instructions for use*; or

2) determined for the worst-case *breathing system* and *airway device* configurations indicated in the *instructions for use*.

NOTE 1 The worst-case *breathing system* configuration and *airway device* can be different for each error or *nominal* flowrate.

e) If worst-case *breathing system* and *airway device* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformance by inspection of the risk management file for the rationale, if applicable, and with the following tests for flowrate errors.

f) Assemble the respiratory high flow therapy equipment as indicated in the instructions for use.

g) For the purposes of this test, the humidifier may be disabled and not contain any water.

NOTE 2 Condensate from a *humidifier* can damage reference mass flow measurement sensors.

h) Connect a reference flow measurement sensor to the patient-connection port.

NOTE 3 The gas at the *patient-connection port* can be heated. Care is needed to ensure that the reference flow measurement sensor is suitable for use under these conditions.

i) Record the pressure, P_{ref}, and temperature, T_{ref}, conditions that the reference flow measurement sensor normalizes to.

j) Record the ambient pressure, P_{amb}, of the test environment.

k) Using dry air or room air as the gas source, set the respiratory high flow therapy equipment to its minimum specified flowrate and allow the system to stabilize for 2 min.

NOTE 4 *If required, an additional air-path restriction can be needed to be introduced after the reference flow measurement sensor to achieve lower flowrates.*

l) Record the displayed flowrate on the respiratory high flow therapy equipment, Q_{disp}, and the measured flowrate from the reference flow measurement sensor, Q_{ref}, averaged over 10 s ±1 s.

m) Repeat steps k) to l) for the mean and the maximum flowrate settings available on the respiratory high flow therapy equipment.

n) Normalize the reference flow sensor measurements to gas conditions indicated in the instructions for use.

o) Confirm that the difference between the displayed flowrate and the measured flowrate is within the claimed accuracy specification in the instructions for use for each tested set flowrate.

NOTE 5 For converting *STPD* measurements to *BTPS* conditions, Q_{btps}, use Formula (1).

Calculate the normalized reference flow sensor measurements to *BTPS* conditions, Q_{btps}, using Formula (1).

$$Q_{\text{btps}} = Q_{\text{ref}} \times \frac{P_{\text{ref}}}{P_{\text{amb}} - P_{\text{sat}}(T_{\text{btps}})} \times \frac{T_{\text{btps}}}{T_{\text{ref}}} \quad (1)$$

where

Q_{ref} = the measured flowrate, in l/min;

P_{ref} is the reference pressure of the flow sensor, in Pa (*STPD* is 101,325 kPa);

T_{ref} is the reference temperature of the flow sensor, in K (*STPD* is 293,15 K);

P_{amb} is the measured ambient pressure, in Pa;

T_{btps} is 310,15 K; and

$P_{\text{sat}}(T_{\text{btps}})$ is nominally 6 281,8 Pa, the saturation pressure of *BTPS* gas, in Pa (see ISO 80601-2-74:2021, Annex GG, for the full calculation).

Formula (1) has been calculated over a range of altitudes for conversion between *STPD* and *BTPS* in Table 201.103. To apply the conversion, multiply the appropriate conversion factor with the measured *STPD* flowrate.

Table 201.103 — *STPD* and *BTPS* conversion factor for altitude

Altitude m	**Pressure** Pa	***STPD* to *BTPS* conversion factor**
0	101 325	1,1279
500	95 653	1,1995
1 000	90 241	1,2768
1 500	85 080	1,3605
2 000	80 160	1,4511
2 500	75 473	1,5493
3 000	71 011	1,6562

201.12.1.101.2 Accuracy of delivered oxygen concentration

For *respiratory high-flow therapy equipment* incorporating an oxygen concentration control,

a) with the *respiratory high-flow therapy equipment* operating in *normal condition*, the delivered oxygen concentration accuracy, as determined for the test settings and conditions specified in this document, shall be disclosed in the *instructions for use*.

b) this disclosure shall include:

   1) the maximum error of the delivered oxygen concentration in relation to the set oxygen concentration; and

   2) the effects of the *rated* range of input oxygen concentration.

c) the errors may be reported separately for the following ranges of intended flowrate, Q:

   1) $Q \geq 30$ l/min;

   2) 30 l/min $\geq Q \geq$ 15 l/min; and

3) $Q \leq 15$ l/min.

d) the accuracy of the performance of the *respiratory high-flow therapy equipment* shall either be:

1) determined for each *breathing system* configuration indicated in the *instructions for use*; or

2) determined for the worst-case *breathing system* configurations indicated in the *instructions for use*.

NOTE 1 The worst-case *breathing system* configuration can be different for each flowrate range.

e) if worst-case *breathing system* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformance by inspection of the risk management file for the rationale, if applicable, and with the following test for oxygen concentration delivery.

f) Assemble the respiratory high flow therapy equipment as indicated in the instructions for use.

g) For the purposes of this test, the humidifier may be disabled and not contain any water.

NOTE 2 Condensate from a *humidifier* can damage reference oxygen measurement sensors.

h) Connect a reference oxygen measurement sensor to the patient-connection port.

NOTE 3 The gas at the *patient-connection port* can be heated. Care is needed to ensure that the reference oxygen measurement sensor is suitable for use under these conditions.

i) Connect an oxygen supply to the respiratory high flow therapy equipment. Set the respiratory high flow therapy equipment to a flowrate of the first applicable column (selected by intended flowrate range) of Table 201.104 and allow the system to stabilize for 2 min.

NOTE 4 If required, an additional air-path restriction can be needed to be introduced after the reference oxygen measurement sensor to achieve lower flowrates.

j) Set the delivered oxygen concentration on the respiratory high flow therapy equipment to the oxygen concentration setting nearest to 30% for this flowrate and allow the system to stabilize for 2 min.

k) Record the measured oxygen concentration from the reference oxygen measurement sensor.

l) The error in the oxygen measurement can be calculated as the difference between the set delivered oxygen concentration and the measurement on the reference oxygen measurement sensor.

m) Confirm that error is less than the accuracy specification indicated in the instructions for use.

n) Repeat i) to m) for the oxygen concentration setting nearest to 60% and the maximum setting.

o) Repeat i) to n) for each applicable column (selected by intended flowrate range) of Table 201.104.

Table 201.104 — Test conditions for oxygen concentration tests

Adjustable parameter	Test condition		
	For *respiratory high-flow therapy equipment* intended to provide flowrates, Q		
	$Q \geq 30$ l/min	30 l/min $\geq Q \geq 15$	$Q \leq 15$ l/min
Flowrate, Q	30 l/min and the maximum settable flowrate	15 l/min	8,0 l/min or the minimum settable flowrate if greater than 8,0 l/min

201.12.2.101 *Usability* of *ME equipment*

a) Any flowrate setting change and its relation to any other flowrate settings shall be displayed while the setting change is being performed.

b) Any setting that affects the delivered oxygen concentration shall be displayed while the setting change is being performed.

c) *Respiratory high-flow therapy equipment* intended for the *home healthcare environment* shall provide the *responsible organization*:

1) with a means to allow the *healthcare professional operator* to have direct access to the therapy settings and *alarm limits* (see 201.106); and

2) the *healthcare professional operator* with a means to restrict the *lay operator* from adjusting the therapy settings and *alarm settings* (see 201.106).

EXAMPLE Settings needing protection include flowrate and oxygen concentration.

Check conformance by functional testing.

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 Oxygen monitor

a) For *respiratory high-flow therapy equipment* incorporating an oxygen concentration control, the *respiratory high-flow therapy equipment*:

1) shall be equipped with oxygen *monitoring equipment* for the measurement of the delivered oxygen concentration (e.g. in the breathing tube or at the *patient-connection port*) that is integral to the *respiratory high-flow therapy equipment;* or

2) the *instructions for use* shall contain a statement to the effect that the *respiratory high-flow therapy* is to be equipped with oxygen *monitoring equipment* that conforms with ISO 80601-2-55:2018 for measurement of the delivered oxygen concentration (e.g. in the breathing tube or at the *patient-connection port*) before being put into service.

b) Integrated oxygen *monitoring equipment* shall conform with the following subclauses of ISO 80601-2-55:2018:

1) 201.7.4.3;

2) 201.7.9.2.9.101 k);

3) 201.12.1.101;

4) 201.12.1.102;

5) 201.12.1.103; and

6) 208.6.1.2.

c) Where the oxygen *monitoring equipment* is not an integral part of the *respiratory high-flow therapy equipment*, the *instructions for use* shall include information on where to connect the oxygen *monitoring equipment*.

d) The oxygen *monitoring equipment* shall, in addition, be equipped with an *alarm system* that includes a high oxygen level *alarm condition*.

e) The high oxygen level *alarm condition:*

1) shall be at least *medium priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that the high oxygen level *alarm condition*:

i) is suppressed; or

ii) its priority is changed.

NOTE A low oxygen level *alarm condition* is required by ISO 80601-2-55.

Check conformity by inspection of the instructions for use or application of the tests of ISO 80601-2-55:2018.

201.12.4.102 * *Maximum limited pressure protection device*

a) A *protection device* shall be provided to prevent the *airway pressure* from exceeding the *maximum limited pressure* under both:

1) *normal condition*; and

2) *single fault condition*.

b) The *maximum limited pressure* shall not exceed for more than 200 ms 60 hPa (60 cmH_2O).

c) The *protection device* need not be a pressure relief valve but may be inherent in the design of the equipment.

EXAMPLE A speed limited centrifugal blower.

Check conformance by functional testing.

201.12.4.103 Flowrate monitoring

a) *Respiratory high-flow therapy equipment* should be equipped with *monitoring equipment* to measure the delivered flowrate.

EXAMPLE 1 Flow-metering devices for connection to terminal units of *medical gas pipeline systems* according to ISO 15002.

EXAMPLE 2 Integrated flowrate monitoring of critical care *ventilators*.

b) If equipped with flowrate *monitoring equipment*,

1) the accuracy of the flowrate *monitoring equipment* shall be disclosed in the *instructions for use*.

EXAMPLE 3± [2 +(8 % of the set flowrate)] l/min

2) under steady-state conditions, the indicated delivered flowrate shall be accurate within the tolerances specified in the *instructions for use*.

3) the flowrate *monitoring equipment* may be equipped with an *alarm system* to indicate when the delivered flowrate is outside the flowrate *alarm limits*.

NOTE Reduced flowrates can be caused by increased resistance in the *breathing system*.

c) If the flowrate *monitoring equipment* is equipped with an *alarm system*,

1) the delivered flowrate *alarm limits* may be:

i) pre-adjusted;

EXAMPLE 4 20% deviation from set flowrate.

ii) *responsible organization*-adjustable;

iii) *healthcare professional operator*-adjustable;

iv) *respiratory high-flow therapy equipment*-adjustable; or

v) a combination of *healthcare professional operator*-adjustable and *respiratory high-flow therapy equipment* -adjustable.

2) and if the *alarm limits* are adjustable by the *respiratory high-flow therapy equipment*, a summary description of the algorithm that determines the *alarm limit* values shall be disclosed in the *instructions for use*.

Check conformity by inspection of the instructions for use and functional testing.

201.12.4.104 Obstruction *alarm condition*

a) The *respiratory high-flow therapy equipment* shall be equipped with *monitoring equipment* with an *alarm system* that detects a *technical alarm condition* to indicate when the *alarm limit* for obstruction is reached.

EXAMPLE An *alarm condition* to warn of an obstructed inspiratory breathing tube.

b) The obstruction *technical alarm condition*:

1) shall be at least *medium priority*, unless

2) an *intelligent alarm system*, based on additional information, determines that the obstruction *technical alarm condition*:

i) is suppressed; or

ii) its priority is changed.

Additional subclause:

201.12.101 * Protection against accidental adjustments

a) Means of protection against accidental adjustment of controls that can create a *hazardous situation* shall be provided, including at least the following.

   1) Turning off the flow shall require a very deliberate action.
   2) Changing the oxygen level shall require a very deliberate action.
   3) Turning the *respiratory high-flow therapy equipment* off.

b) These means may be accomplished by

   1) utilizing hardware or software or a combination of both, or
   2) two or more interactions with at least one dedicated confirmation action.

c) The *usability* of these means of protection shall be evaluated in the *usability engineering process*.

   NOTE The requirements for the *usability engineering process* are found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 12.2 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020.

Check conformance by functional testing and inspection of usability engineering file.

201.13 *Hazardous situations* and fault conditions for *ME equipment*

Clause 13 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Additional subclauses:

201.13.2.101 * Additional specific *single fault conditions*

Respiratory high-flow therapy equipment shall be so constructed that the following *single fault conditions* do not cause an unacceptable *risk*:

a) misconnection of a *breathing system* control *functional connection*, monitoring *functional connection* or *accessory functional connection*;

b) a disruption of the gas delivery to the *respiratory high-flow therapy equipment*; and

c) failure to install, removal of or failure of an *operator*-detachable *breathing system filter*.

Check conformance by functional testing and inspection of risk management file.

201.13.2.102 * Independence of delivery control function and related *risk control* measures

a) A *single fault condition* shall not cause the simultaneous failure of:

   1) the delivery-control function; and
   2) the corresponding *protection device*.

b) A *single fault condition* shall not cause failure in such a way that a failure of:

1) the delivery-control function and the corresponding *monitoring equipment* is not detected, or
2) the delivery-control function and the corresponding *alarm system* is not detected.

Check conformance by inspection and functional testing.

201.13.2.103 * Failure of one gas supply to *respiratory high-flow therapy equipment*

a) Following the failure of one gas supply connected to a *high-pressure inlet*, the *respiratory high-flow therapy equipment* shall automatically use the remaining gas supply, and otherwise maintain normal operation other than delivered oxygen concentration.

b) The *respiratory high-flow therapy equipment* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate this gas supply failure.

c) The gas supply failure *technical alarm condition*:

1) shall be at least *low priority*; unless
2) an *intelligent alarm system*, based on additional information, determines that the gas supply failure *technical alarm condition* is suppressed.

Check conformance by functional testing.

201.14 *Programmable electrical medical systems* (*PEMS*)

Clause 14 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows.

201.14.1 General

Amendment (extend the last paragraph prior to the compliance check with):

aa) The flowrate control *PESS* of the *respiratory high-flow therapy equipment PEMS* shall be considered as software safety Class C as defined in IEC 62304:2006+AMD1:2015 unless there is an independent *risk control* measure implemented external to the *PESS*.

201.15 Construction of *ME equipment*

Clause 15 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Additional subclauses:

201.15.101 Mode of operation

Respiratory high-flow therapy equipment shall be suitable for *continuous operation*.

Check conformance by inspection.

201.15.102 Pre-use check

a) If the *respiratory high-flow therapy equipment* is intended for use in the *home healthcare environment*, the *respiratory high-flow therapy equipment* shall be provided with means that allow the following to be functionally tested by the *lay operator* to determine if they are operating correctly and ready for use:

   1) the assembled breathing tubes and related *accessories;*
   2) switchover to and operation from the *internal electrical power source*, if provided; and
   3) all *alarm signals*, including the *alarm signals* from a *distributed alarm system.*

b) This test method

   1) shall be performed automatically by the *respiratory high-flow therapy equipment*, but
   2) may require *operator* action.

   EXAMPLE Combination of the power-on self-test routines and *operator* actions that functionally check the *alarm signals*.

   NOTE Additional requirements are also found in 201.7.9.2.8.101.

c) The *model or type reference* of any required *accessories* or test equipment needed to perform these tests shall be disclosed in the *instructions for use* for the *lay operator*.

d) The *instructions for use* for the *lay operator* shall disclose the *procedure* by which tests are performed.

Check conformance by inspection of the instructions for use and functional testing.

201.15.103 Delivered oxygen concentration

a) *Respiratory high-flow therapy equipment* operating in *normal condition* shall supply gas at the *patient-connection port* with the oxygen concentration accuracy indicated in the *instructions for use*.

b) The disclosed oxygen concentration accuracy shall include the effects of:

   1) the range of the *rated* input oxygen concentration;
   2) the available flow from the oxygen source; and
   3) the delivered flowrate to the *airway device*.

Check conformity by functional testing.

201.16 *ME systems*

Clause 16 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Additional subclause:

201.16.1.101 Additional general requirements for *ME systems*

Accessories connected to the *breathing system* shall be considered to

a) be part of the *respiratory high-flow therapy equipment*, or

b) form an *ME system* with the *respiratory high-flow therapy equipment*.

Check conformance by application of the relevant tests of this document and the general standard.

201.16.2 * *Accompanying documents* of an *ME system*

Amendment (add after list element c)):

– If applicable, a description of the *use scenarios* and ranges of flowrates over which elevated temperature of the gas at the *gas output port* can lead to the failure of a respiratory gas *humidifier* to function to specification.

EXAMPLE When a blower/turbine-based *respiratory high-flow therapy equipment* is operating with settings that result in the delivered breathing gas temperature exceeding 27 °C, which is beyond the *rated* input temperature of the *humidifier*, cause the *humidifier* to reduce *humidification output* below the lower limit allowed by ISO 80601-2-74.

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems*

Clause 17 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Additional clauses:

201.101 Gas connections

201.101.1 *Breathing system* connectors

201.101.1.1 * General

a) *Operator*-detachable *breathing system* connections through which the main flow of gas to the *patient* passes in *normal condition*, excluding the *patient-connection port* shall be:

1) a 15 mm connector conforming with ISO 5356-1:2015;

2) a 22 mm connector conforming with ISO 5356-1:2015;

3) a 11,5 mm; connector conforming with ISO 5356-1:2015 for a neonatal or paediatric use; or

4) a connector that does not engage with a conical connector conforming with ISO 5356-1:2015 unless it conforms with the engagement, disengagement and leakage requirements of that standard.

b) The *breathing system*, its parts or *accessories* shall not be equipped with connectors that permit a *functional connection* to the *gas pathway* with a connector conforming with ISO 80369-7:2021.

Check conformance by application of the tests of ISO 5356-1:2015 and functional testing.

201.101.1.2 Other named ports

201.101.1.2.1 General

The following *operator*-detachable connectors shall be non-interchangeable if used within the *breathing system* for:

a) control functions;

b) monitoring functions; and

c) other *accessory* functions.

EXAMPLE Temperature sensor cable and heating wire connectors.

Check conformance by functional testing.

201.101.1.2.2 *Patient-connection port*

The *patient-connection port* shall be one of the following:

a) a female 15 mm conical connector conforming with ISO 5356-1:2015;

b) a female 22 mm conical connector conforming with ISO 5356-1:2015;

c) a coaxial 15 mm/22 mm conical connector conforming with ISO 5356-1:2015; or

d) a connector that does not engage with a conical connector conforming with ISO 5356-1:2015 unless it conforms with the engagement, disengagement and leakage requirements of that standard.

Check conformance by application of the tests of ISO 5356-1:2015.

201.101.1.2.3 *Accessory* port

If provided, each *accessory* port shall:

a) conform with ISO 80369-1:2018;

NOTE 1 It is expected that the R1 connector of ISO 80369-2[13] will meet this criterion as it is limited to connections to pressures not exceeding 150 hPa.

b) be provided with a means to secure the *accessory* in position; and

c) be provided with a means to secure closure after removal of the *accessory*.

NOTE 2 This port connects to the *gas pathway* and is generally used for measuring pressure, sampling of gases or for introduction of therapeutic aerosols.

Check conformance by inspection and application of the tests of ISO 80369-1:2018.

201.101.1.2.4 Monitoring probe port

If a port is provided for introduction of a monitoring probe, it shall:

a) not be compatible with connectors specified in ISO 5356-1:2015;

b) be provided with a means to secure the probe in position; and

c) be provided with a means to secure closure after removal of the probe.

Check conformance by inspection and application of the tests of ISO 5356-1:2015.

201.101.1.2.5 Low-pressure oxygen *inlet*

a) A low-pressure oxygen *inlet* connector of the *breathing system*, its parts and *accessories* that is *operator*-accessible without the use of a *tool* shall conform with ISO 80369-1:2018.

b) A *respiratory high-flow therapy equipment* with this *inlet* connector shall maintain *basic safety* and *essential performance* with oxygen supply systems up to 150 hPa, in *normal condition*.

NOTE It is expected that the R1 connector of ISO 80369-2[13] will meet this criterion as it is limited to connections to pressures not exceeding 150 hPa.

Check conformance by functional testing and application of the tests of ISO 80369-1:2018.

201.101.1.2.6 *Flow-direction-sensitive components*

If the *respiratory high-flow therapy equipment* incorporates any *flow-direction-sensitive components,* the *respiratory high-flow therapy equipment* shall be so designed that incorrect connection does not present an unacceptable *risk* to the *patient*.

Check conformance by inspection and inspection of the risk management file.

201.101.1.2.7 Nebulization port

If provided, a nebulization port shall:

a) conform with ISO 80369-1:2018;

b) be provided with a means to secure the nebulizer in position; and

c) be provided with a means to secure closure after removal of the nebulizer.

Check conformance by functional testing and application of the tests of ISO 80369-1:2018.

201.101.2 High-pressure oxygen *inlet connector*

a) A high-pressure oxygen *inlet connector* of the *respiratory high-flow therapy equipment*, which is *operator*-detachable without the use of a *tool,* shall conform with:

1) ISO 80369-1:2018; or

NOTE It is expected that the R2 connector of ISO 80369-2[13] will meet this criterion.

2) female 9/16-18 UNF-2A-RH fitting; or

3) for connection to either a *medical gas pipeline system* or a pressure regulator, a hose assembly conforming with ISO 5359:2014+AMD1:2017.

b) *Respiratory high-flow therapy equipment* with this *inlet connector* shall maintain *basic safety* and *essential performance* with oxygen supply systems up to 600 kPa, in *normal condition*.

Check conformance by functional testing and application of the tests of ISO 80369-1:2018 or ISO 5359:2014+AMD1:2017, as applicable.

201.101.3 *Gas intake port*

Respiratory high-flow therapy equipment that incorporates a *gas intake port* shall be designed such that the *gas intake port* cannot be blocked by a flat surface.

EXAMPLE A *gas intake port* incorporating a protective cage, or with multiple intake orifices arranged in a non-planar geometry.

Check conformance by functional testing.

201.102 Requirements for the *breathing system* and *accessories*

201.102.1 * General

All *breathing systems*, their parts and *accessories* that can affect the *basic safety* or *essential performance* of a *humidifier* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *respiratory high-flow therapy equipment* or by another entity ("third-party manufacturer").

Check conformance by the tests of this standard.

201.102.2 Labelling

a) The *accompanying document* provided with each *breathing system,* its parts or *accessories*, conforming with 201.102.1, shall include at least one *model or type reference* of compatible *respiratory high-flow therapy equipment*.

b) Statements shall be included in the *accompanying document* of each *breathing system*, its parts or *accessories* to the effect that:

   1) breathing systems, their parts and accessories are validated for use with specific equipment,

   2) incompatible parts can result in degraded performance, and

   3) the responsible organization is accountable for the compatibility of the equipment and all of the parts and accessories used to connect to the patient before use.

Check conformance by inspection of the accompanying document.

201.102.3 Breathing sets

a) Breathing sets, other than heated breathing sets, intended for use in the *breathing system* shall conform with ISO 5367:2014.

b) Heated breathing sets shall conform with ISO 80601-2-74:2021, 201.102.3.2.

Check conformance by application of the tests of ISO 5367:2014 or ISO 80601-2-74:2021, as appropriate.

201.102.4 * Humidification system

The *respiratory high-flow therapy equipment*:

a) shall be equipped with a *humidifier* conforming to ISO 80601-2-74:2021*;* or

b) the *instructions for use* shall contain a statement to the effect that the *respiratory high-flow therapy* is to be equipped with a *humidifier* that conforms with ISO 80601-2-74:2021 before being put into service.

Check conformance by inspection of the instructions for use or application of the tests of ISO 80601-2-74:2021.

201.102.5 *Breathing system filter* (*BSF*)

Any *BSF*, either incorporated into the *respiratory high-flow therapy equipment* or recommended for use with the *respiratory high-flow therapy equipment*, shall conform with the relevant requirements of ISO 23328-1:2003 and ISO 23328-2:2002.

Check conformance by application of the tests of ISO 23328-1:2003 and ISO 23328-2:2002.

201.102.6 *Airway devices*

Airway devices recommended for use with the *respiratory high-flow therapy equipment*, shall conform with ISO 18190:2016 and ISO 18562-1:2017.

NOTE *Airway devices* used with *respiratory high-flow therapy equipment* are non-sealing and typically include *high-flow nasal cannula*, tracheal tube, tracheostomy tube with *mask* or face *mask* or helmet with large *exhaust ports*.

Check conformance by application of tests of ISO 18190:2016 and ISO 18562-1:2017.

201.103 * Indication of duration of operation

a) *Respiratory high-flow therapy equipment* should have means to indicate visually the cumulative hours of operation of the *respiratory high-flow therapy equipment*, either

   1) automatically, or

   2) by *operator* action.

b) The *respiratory high-flow therapy equipment* may also have means to indicate visually

   1) the time since the last preventive maintenance, or

   2) the time until the next recommended preventive maintenance.

Check conformance by inspection.

201.104 *Functional connection*

201.104.1 General

Basic safety and *essential performance* shall be maintained if connections to the *functional connection* of *respiratory high-flow therapy equipment*:

a) are disrupted; or

b) if the equipment connected to those parts fails.

Check conformance by functional testing.

201.104.2 * Connection to an electronic health record

Respiratory high-flow therapy equipment should be equipped with a *functional connection* that permits data transmission from the *respiratory high-flow therapy equipment* to an electronic health record.

201.104.3 * Connection to a *distributed alarm system*

Respiratory high-flow therapy equipment should be equipped with a *functional connection* that permits connection to a *distributed alarm system*.

201.104.4 Connection for remote control

a) *Respiratory High-flow therapy equipment* may be equipped with a *functional connection* for connection for remote control of the *respiratory high-flow therapy equipment*.

b) If the *respiratory High-flow therapy equipment* is equipped with a *functional connection* for connection for remote control, it shall be equipped with a *functional connection* that permits connection to a *distributed alarm system.*

201.105 *Power supply cords*

Any *detachable power supply cord* or detachable d.c. power cord of an electrically powered *respiratory high-flow therapy equipment* shall be protected against accidental disconnection from the *respiratory high-flow therapy equipment* under a force of 30 N.

Check conformance by inspection and, for respiratory high-flow therapy equipment when provided with an appliance coupler or detachable d.c. power cord, by the following test.

a) Subject the detachable power supply cord for 1 min to an axial pull of force of 30 N.

b) During the test, the mains connector becoming disconnected from the appliance inlet or the detachable d.c. power cord becoming disconnected from the d.c. input connector of the respiratory high-flow therapy equipment is considered a failure.

201.106 *Respiratory high-flow therapy equipment* security

Means of restricting access to changing or to the storage of changes shall be described in the *technical description* [see 201.12.2.101 c) and 208.6.12.2].

EXAMPLE 1 Access controlled by a *tool*.

EXAMPLE 2 Access controlled by *responsible organization* password and a *technical description* that is separate from the *instructions for use*.

EXAMPLE 3 Access controlled by individual *operator* password.

NOTE 1 For a password to be considered secure, the owner of the password needs to be capable of changing the password.

EXAMPLE 4 Access controlled by voice recognition.

EXAMPLE 5 Access controlled by fingerprints.

NOTE 2 Multiple means of restriction can be needed (e.g. one for the *responsible organization* and one for each *operator*).

Check conformance by inspection of the technical description.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014+AMD1:2020 applies except as follows:

202.4.3.1 * Compliance criteria

Amendment (replace the second dash of 4.3.1 with):

— the *respiratory high-flow therapy equipment* operated using the conditions and test configuration of 201.12.1.101.1.

202.5.2.2.1 Requirements applicable to all *ME equipment* and *ME systems*

Amendment (add note to list element b)):

NOTE The requirements of this document are not considered deviations or allowances.

Additional subclause:

202.8.1.101 * Additional general requirements

a) *Respiratory high-flow therapy equipment* intended for the *home healthcare environment* shall be tested according to the requirements for the *home healthcare environment*.

b) The following degradations, if associated with *basic safety* or *essential performance*, shall not be allowed:

   1) component failures;

   2) changes in programmable parameters or settings;

   3) reset to default settings;

4) change of operating mode, if applicable;

EXAMPLE Change of therapy mode.

5) initiation of an unintended operation; and

6) during the testing, the error of the delivered flowrate shall not deviate by more than 35 %;

c) The *respiratory high-flow therapy equipment* may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the *instructions for use* during *immunity* testing) that does not adversely affect *basic safety* or *essential performance*.

206 Usability

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 applies except as follows:

Additional subclauses:

206.101 *Primary operating functions*

In the application of the requirements in 5.2 of IEC 62366-1:2015+AMD1:2020, the following shall be considered *primary operating functions*:

a) observing monitored therapy parameters from the intended *operator's* position;

EXAMPLE 1 Delivered flowrate

EXAMPLE 2 Delivered oxygen concentration

b) configuring the *breathing system* including connection of the detachable parts of the *breathing system* to the *respiratory high-flow therapy equipment*;

EXAMPLE *Humidifier*, nebulizer, water-trap, tubing, *breathing system filter*, *monitoring equipment*.

c) connecting or disconnecting the *patient-connection port* of the *breathing system* to the *patient*-interface;

d) selecting the appropriate size *airway device*.

e) attaching the *airway device* to the *patient*.

f) *processing* the *breathing system* components;

g) starting the *respiratory high-flow therapy equipment* from power off including

1) performing the start-up *procedure, and*

2) checking the correct function of the system (*patient* interface, hose, leakage and settings such as the temperature and water-level of the *humidifier*);

h) connecting or disconnecting the oxygen source;

i) turning off the *respiratory high-flow therapy equipment*; and

j) for *transit-operable respiratory high-flow therapy equipment*, transporting the *respiratory high-flow therapy equipment*, if applicable:

1) either directly, or

2) by use of specified *accessories*.

The following functions, if available, also shall be considered *primary operating functions*:

k) for *transit-operable respiratory high-flow therapy equipment*, attaching and disconnecting the *respiratory high-flow therapy equipment* to prevent unwanted movement during transport while in use.

l) performing a basic pre-use functional check of the *respiratory high-flow therapy equipment* including the *alarm system*;

m) setting and inadvertent change of settings of the *operator*-adjustable controls:

1) setting *alarm limits*;

2) inactivating *alarm signals*; and

3) setting therapy control parameters;

n) switching between power sources;

o) connecting and disconnecting the *distributed alarm system*;

p) testing power sources;

q) starting therapy from standby; and

r) activating standby.

The following actions associated with therapy also shall be considered *primary operating functions*:

NOTE For the purposes of this document the following functions are considered *primary operating functions* even though they might not be performed on the *respiratory high-flow therapy equipment's operator interface*.

s) humidifying/conditioning gases delivered through the *breathing system*; and

t) for *transit-operable respiratory high-flow therapy equipment*, connecting the *respiratory high-flow therapy equipment* on a trolley or wheelchair.

206.102 * Training

In the application of the requirements in 5.6 and 5.8 of IEC 62366-1:2015+AMD1:2020, training shall be considered necessary for both:

bb) the *healthcare professional operator;* and

cc) the designee of the *responsible organization* (e.g. *service personnel* or *processing* personnel).

Check conformity by inspection of the accompanying document.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 applies except as follows:

Replacement:

208.6.5.4.2 Selection of *default alarm preset*

aa) Whenever the *respiratory high-flow therapy equipment* is in *healthcare professional operator*-mode and the *healthcare professional operator* indicates to the *respiratory high-flow therapy equipment*, preferably through a function, that a different *patient* has been connected to the *respiratory high-flow therapy equipment*, then:

1) the default *respiratory high-flow therapy* settings, including the *default alarm preset,* shall be automatically selected, or

2) means shall be provided for the *healthcare professional operator* to select the *respiratory high-flow therapy equipment* settings, including the *alarm settings.*

bb) Whenever the *respiratory high-flow therapy equipment* is in *lay operator* mode and the *operator* switches the *respiratory high-flow therapy equipment* on, then:

1) the *respiratory high-flow therapy equipment* shall assume the retained *respiratory high-flow therapy equipment* settings from previous use, or

2) means shall be provided for the *operator* to select *respiratory high-flow therapy equipment* preset, including the *alarm settings*.

cc) The *manufacturer* shall disclose in the *instructions for use* an estimate of the duration of the power interruption after which the *respiratory high-flow therapy equipment* is unable to restore the preset and the subsequent behaviour of the *respiratory high-flow therapy equipment*.

Check conformance by functional testing and inspection.

Additional subclauses:

208.6.12.2 * *Operator alarm system* logging

Replacement:

If an *alarm system* is provided with an *operator alarm system* log:

a) the *alarm system* shall log:

1) every *alarm condition*;

2) the date and time of beginning of the *alarm condition*;

3) the date and time of end of the *alarm condition;*

4) the associated *alarm limits* for that *alarm condition*, if *operator*-adjustable; and

5) where feasible, the data that caused the *alarm condition*;

EXAMPLE 1 The low flowrate *alarm condition* is logged with start time and date, end time and date, flowrate *alarm limit* and the flowrate value.

b) the *alarm system* shall log for each *alarm signal* inactivation state:

1) its identity;

2) the date and time of the occurrence; and

3) for a *CDAS*, *operator* response (i.e., *responsibility accepted or responsibility rejected*);

c) the *operator alarm system* log shall include at least the following events:

1) initial state of the *respiratory high-flow therapy equipment*;

2) change of *operator*-adjustable *alarm settings*;

3) change of *operator*-adjustable therapy settings;

4) power supply source change;

5) access mode (*lay operator* or *healthcare professional operator*);

6) result of the last pre-use check;

d) the *alarm system* shall have a capacity of at least 1 000 events;

e) if a means is provided for the *operator* to indicate to the *alarm system* that a different *patient* has been connected, then that event should be logged in the *operator alarm system* log;

f) the *operator alarm system* log shall not lose the contents of the *alarm system* log during a loss of power for less than 365 d unless deleted by *responsible organization* action;

g) means may be provided for the *operator* to add explanatory notes or comments to the *operator alarm system* log and, if provided:

1) means should be provided to record the identity of the annotator and the date and time of the annotation;

h) means shall not be provided for the *operator* to edit or delete entries in the *operator alarm system* log, unless a new *patient* is admitted or a *responsible organization alarm system* log is provided;

i) the log may be provided either within the equipment or remotely through a communications interface;

j) the log may consist of multiple individual logs; and

k) the *instructions for use* shall indicate:

1) the means for the *operator* to access the *operator alarm system* log;

2) whether the log is maintained when the *alarm system* is powered down and whether or not the time of powering down is captured in the log;

3) what happens to the contents of the log after the *alarm system* has experienced a total loss of power (*supply mains* and/or *internal electrical power source*) for a finite duration;

4) the capacity of the log; and

5) what happens to the contents of the log as it reaches capacity.

EXAMPLE The *alarm system* discards the oldest data when the log becomes full.

Check conformance by inspection and functional testing.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015+AMD1:2020 applies except as follows:

211.7.4.7 Additional requirements for *cleaning*, *disinfection* and *sterilization*

Amendment (add after 'intended use, ' in the first paragraph):

in either *normal condition* or *single fault condition*,

Additional subclause:

211.10.1.1 General requirements for mechanical strength

Amendment (add before the first paragraph):

aa) The tests of IEC 60601-1-11:2015, Clause 10 and IEC 60601-1:2005+AMD1:2012+AMD2:2020, 15.3 shall be performed on the same test *respiratory high-flow therapy equipment* after the tests of 201.11.6.6 of this document are performed.

bb) If more than one *procedure* is specified in the *instructions for use*, each *procedure* shall be so tested. A separate *respiratory high-flow therapy equipment* may be used for each specified *procedure*.

Annexes

The annexes of IEC 60601-1:2005+AMD1:2012+AMD2:2020 apply, except as follows:

Annex C
(informative)

Guide to *marking* and labelling requirements for *ME equipment* and *ME systems*

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

Addition:

201.C.1 *Marking* on the outside of *ME equipment*, *ME systems* or their parts

Additional requirements for *marking* on the outside of *respiratory high-flow therapy equipment*, its parts and *accessories* are found in Table 201.C.101.

Table 201.C.101 — *Marking* on the outside of *respiratory high-flow therapy equipment*, its parts or *accessories*

Description of *marking*	Subclause
Arrow indicating the direction of the flow for *flow-direction-sensitive components*, if applicable	201.7.2.101 a) 2)
For *accessories* supplied separately, 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	201.7.2.4.101 b)
For *accessories* supplied separately, the requirements of 201.7.2.101	201.7.2.4.101 a)
For oxygen gas inputs, the *rated* range of oxygen concentration	201.7.2.18 cc)
Gas name or chemical *symbol*	201.7.2.18 aa)
Gas-specific colour coding	201.7.2.18 dd)
Intended for use in the magnetic resonance (MR) environment, if applicable	201.7.2.101 c)
Rated range of gas pressure	201.7.2.18 bb)
Warning not to obstruct the *gas intake port*, if applicable	201.7.2.101 b)

201.C.2 *Accompanying documents*, general

Additional requirements for general information to be included in the *accompanying documents* of *respiratory high-flow therapy equipment* or its parts are found in Table 201.C.102.

Table 201.C.102 — *Accompanying documents*, general

Description of requirement	Subclause
For each *breathing system* and *accessory*, the *model* or *type reference* of at least one compatible *respiratory high-flow therapy equipment*	201.102.2 a)
For each *breathing system*, its parts and *accessories*, a statement to the effect that the responsible organization is accountable for the compatibility of the equipment and all of the parts and accessories used to connect to the patient before use	201.102.2 b) 3)

Description of requirement	Subclause
For each *breathing system*, its parts and *accessory*, a statement to the effect that breathing systems, their parts and accessories are validated for use with specific equipment	201.102.2 b) 1)
For each *breathing system*, its parts and *accessory*, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b) 2)
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 3) i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 3) ii)
Respiratory high-flow therapy equipment is a high-flow device warning, if applicable	201.4.11.101.2 3) iii)
Units of measure for volumes, flows and leakages expressed as *STPD*	201.7.4.3 aa)
Units of measure for volumes, flows and leakages expressed for the *breathing system* as *STPD* or *BTPS*	201.7.4.3 bb)

201.C.3 *Accompanying documents, instructions for use*

Additional requirements for information to be included in the *instructions for use* of *respiratory high-flow therapy equipment* or its parts are found in Table 201.C.103.

Table 201.C.103 — *Instructions for use*

Description of requirement	Subclause
Accuracy of flowrate *monitoring equipment*, if equipped	201.12.4.103 b) 1)
Alternative *supply mains*, *instructions for use*	201.11.8.101.2 b) 5)
Alternative *supply mains*, maximum current required	201.11.8.101.2 b) 4)
Alternative *supply mains*, means of connection	201.11.8.101.2 b) 1)
Alternative *supply mains*, *nominal* voltage range	201.11.8.101.2 b) 3)
Alternative *supply mains*, *rated* voltage range	201.11.8.101.2 b) 2)
Any adverse effect of any recommended *accessory* on the *basic safety* or *essential performance* of the *respiratory high-flow therapy equipment*, if applicable	201.7.9.2.14.101 d)
A-weighted sound power level emitted by the *respiratory high-flow therapy equipment*	201.9.6.2.1.101 b)
A-weighted sound pressure level emitted by the *respiratory high-flow therapy equipment*	201.9.6.2.1.101 a)
Behaviour of the *respiratory high-flow therapy equipment* after a switchover to the *internal electrical power source* and alternative *supply mains*	201.11.8.101.1 d) 2)
Behaviour of the *respiratory high-flow therapy equipment* while the *internal electrical power source* and external reserve electrical power source is recharging	201.11.8.101.1 d) 3)
Capacity of the log	208.6.12 k) 4)
Declared tolerances include the measurement uncertainty	201.5.101.3 a)
Delivered oxygen concentration including the effects of *rated* range of input concentration and flowrate	201.15.103 b)

Description of requirement	Subclause
Description of the *internal electrical power source* care and maintenance *procedures*, including instructions for recharging or replacement, if applicable	201.7.9.2.13.101 b)
Description of the periodic visual safety inspections that should be performed by the *operator*	201.7.9.2.13.101 a)
Description of the *use scenarios* and ranges of flowrates over which elevated temperature of the gas at the *gas output port* can lead to the failure of a respiratory gas *humidifier* to function to specification, if applicable	201.16.2 100)
Disclosure of any restrictions on the placing of components within the *breathing system*, if applicable	201.7.9.2.14.101 c)
Disclosure of at least one set of *accessories*	201.7.9.2.14.101 a)
Disclosure of *ME equipment* necessary for the *respiratory high-flow therapy equipment's intended use*, if applicable	201.7.9.2.14.101 b)
For *accessories* supplied separately where *marking* the *accessory* is not practicable, the requirements 201.7.2.101	201.7.2.4.101 b) 1)
For the *healthcare professional operator instructions for use*, the information contained in *instructions for use* for the *lay operator*	201.7.9.2.1.101 c)
For the *healthcare professional operator instructions for use*, a description of how the listed *alarm conditions* can be tested	201.7.9.2.9.101.2 b)
For the *healthcare professional operator instructions for use*, any limitation of parameter settings	201.7.9.2.9.101.2 a) 4)
For the *healthcare professional operator instructions for use*, how to change *breathing system* configurations when necessary for a specific *ventilation-mode*	201.7.9.2.9.101.2 a) 5)
For the *healthcare professional operator instructions for use*, method by which all functions necessary for *normal use* can be tested to determine if they are operating correctly	201.7.9.2.8.101 b) 1)
For the *healthcare professional operator instructions for use*, method which can determine whether or not the assembled breathing tubes and related *accessories* are suitable for use	201.7.9.2.8.101 b) 2)
For the *healthcare professional operator instructions for use*, the parameter settings	201.7.9.2.9.101.2 a) 2)
For the *healthcare professional operator instructions for use*, the range of parameter settings	201.7.9.2.9.101.2 a) 3)
For the *healthcare professional operator instructions for use*, the working principle of each of the *respiratory high-flow therapy equipment's* therapy modes	201.7.9.2.9.101.2 a) 1)
For the *healthcare professional operator instructions for use*, whether or not the equipment is intended for use with nebulized medications and if so, any constraints	201.7.9.2.9.101.2 c)
For the *lay operator instructions for use*, a description of a means to determine the operation time of the *internal electrical power source*, if provided	201.7.9.2.9.101.1 b) 2)
For the *lay operator instructions for use*, a description of how to connect a *distributed alarm system*, if provided	201.7.9.2.9.101.1 b) 1)

Description of requirement	Subclause
For the *lay operator instructions for use*, conditions under which the *respiratory high-flow therapy equipment* maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101.1 a)
For the *lay operator instructions for use*, method by which the assembled breathing tubes and related accessories can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 1)
For the *lay operator instructions for use*, method by which the switchover to and operation from the *internal electrical power source* can be functionally tested to determine if it is operating correctly, if equipped	201.7.9.2.8.101 a) 2)
For the *lay operator instructions for use*, the *model or type reference* needed to perform the pre-use check can be performed	201.15.102 c)
For the *lay operator instructions for use*, the *procedure* by which the pre-use check can be performed	201.15.102 d)
Gas conditions of *instructions for use*	201.5.1.1.2
Intended position of the *operator*	201.7.9.2.1
Maximum error of the delivered oxygen concentration in relation to the set value in *normal condition*	201.12.1.101.2 b)
Maximum error of the flowrate in relation to the set value in *normal condition*	201.12.1.101.1 b)
Means for the *operator* to access the *operator alarm system* log	208.6.12 k) 1)
Measurement conditions for gas measurements	201.7.4.3 bb)
Minimum time between complete loss of the *internal electrical power source* and the start of the *low priority* impending *internal electrical power source* failure *alarm condition*	201.11.8.101.1 d) 4) i)
Minimum time between complete loss of the *internal electrical power source* and the *medium priority* impending *internal electrical power source* failure *alarm condition*	201.11.8.101.1 d) 4) ii)
Operational time of the power source	201.11.8.101.1 d) 1)
Processing instructions for the *respiratory high-flow therapy equipment* and its *accessories*	201.11.6.6 cc) 2)
Separate *instructions for use* for *healthcare professional operator*, if applicable	201.7.9.2.1.101 a) 2)
Separate *instructions for use* for *lay operator*, if applicable	201.7.9.2.1.101 a) 1)
To be equipped with *humidifier* before being put into service, if not equipped	201.102.4 b)
To be equipped with oxygen *monitoring equipment* for measurement of the delivered oxygen concentration before being put into service, if not equipped	201.12.4.101 a) 2)
To be equipped with oxygen *monitoring equipment* for measurement of the delivered oxygen concentration that complies with ISO 80601-2-55 before being put into service and how to connect the *monitoring equipment*, if not equipped	201.12.4.101 c)
Warning statement to the effect that do not lubricate fittings, connections, tubing, or other accessories of the equipment to avoid the risk of fire and burns	201.7.9.2.2.101 m)
Warning statement to the effect that do not use sealed patient interfaces with this equipment, to avoid the risk of suffocation or barotrauma	201.7.9.2.2.101 j)

Description of requirement	Subclause
Warning statement to the effect that ensure a sufficient intended leakage between the breathing system and the patient to allow the patient to exhale	201.7.9.2.2.101 r)
Warning statement to the effect that 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	201.7.9.2.2.101 h)
Warning statement to the effect that open flames during oxygen therapy are dangerous and is likely to result in fire or death. Do not allow open flames within 2 m of the equipment or any oxygen-carrying accessories	201.7.9.2.2.101 q)
Warning statement to the effect that 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,	201.7.9.2.2.101 o)
Warning statement to the effect that 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.	201.7.9.2.2.101 p)
Warning statement to the effect that the therapy supplied to the patient can be adversely affected by the gas added by the use of a pneumatic nebuliser, if applicable	201.7.9.2.2.101 g)
Warning statement to the effect that 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	201.7.9.2.2.101 k)
Warning statement to the effect that this equipment is only suitable for a spontaneously breathing patient	201.7.9.2.2.101 f)
Warning statement to the effect that to not connect the equipment to the battery of a wheelchair battery-powered wheelchair unless the connection is listed in the instructions for use of the equipment or wheelchair as this can affect the equipment performance which consequently can result in degradation of health of the patient, if applicable	201.7.9.2.2.101 d)
Warning statement to the effect that to not cover the equipment or place in a position that affects proper operation", including applicable examples	201.7.9.2.2.101 a)
Warning statement to the effect that to 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 affect the equipment performance which consequently can result in degradation of health of the patient	201.7.9.2.2.101 c)
Warning statement to the effect that 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	201.7.9.2.2.101 i)

Description of requirement	Subclause
Warning statement to the effect that 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	201.7.9.2.2.101 e)
Warning statement to the effect that use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns	201.7.9.2.2.101 n)
Warning statement to the effect that 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	201.7.9.2.2.101 l)
Warning statement to the effect to 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	201.7.9.2.2.101 b)
What happens to the contents of the log after the *alarm system* has experienced a total loss of power (*supply mains* or *internal electrical power source*) for a finite duration	208.6.12 k) 3)
What happens to the contents of the log as it reaches capacity	208.6.12 k) 5)
Whether the log is maintained when the *alarm system* is powered down and whether or not the time of powering down is captured in the log	208.6.12 k) 2)
Which portions of the *gas pathways* through the *respiratory high-flow therapy equipment* can become contaminated with body fluids or expired gases during both *normal condition* and *single fault condition*	201.7.9.2.12 aa)

201.C.4 *Accompanying documents, technical description*

Additional requirements for information to be included in the *technical description* of *respiratory high-flow therapy equipment* or its parts are found in Table 201.C.104.

Table 201.C.104 — *Technical description*

Description of requirement	Subclause
Description of a method for checking the function of *alarm system* for *alarm condition*s of this document, if not performed automatically at start-up	201.7.9.3.101 a)
Disclosure of the interdependence of control functions	201.7.9.3.1.101 a)
Disclosure of the uncertainty for each disclosed tolerance	201.5.101.3 b)
Listing of which *alarm condition*s that are checked automatically at start-up	201.7.9.3.101 b)
Means of restricting access	201.106
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*	201.7.9.3.1.101 b)
Statement to the effect that the responsible organization needs to ensure the compatibility of the equipment and all of the parts and accessories intended to be used to connect to the patient prior to use	201.7.9.3.1.101 c)

Annex D
(informative)

Symbols on *marking*

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

Addition:

Table 201.D.2.101 — Additional *symbols* on *marking*

No	*Symbol*	Reference	Title and description
1		IEC/TR 60878:2015[23] *Symbol* 7.3.1-1 of IEC 62570:2014	MR Safe To identify an item which poses no unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. Note – When color reproduction is not practical, the *symbol* may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.
2		IEC/TR 60878:2015[23] *Symbol* 7.3.1-2 of IEC 62570:2014	MR Safe Alternative graphical *symbol* representation. Same meaning as IEC 62570-7.3.1-1.
3		IEC/TR 60878:2015[23] *Symbol* 7.3.2 of IEC 62570:2014	MR Conditional To identify an item which poses no unacceptable *risks* within defined conditions to the *patient*, medical staff or other persons within the MR environment. Note 1 – When color reproduction is not practical, the *symbol* may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. Note 2 – The MR Conditional *symbol* may be supplemented by supplementary *marking* that describes the conditions for which the item has been demonstrated to be MR Conditional.

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document.

Subclause 201.1.1 — Scope

There are key contextual differences between *respiratory high-flow therapy equipment* and a *ventilator* intended for *ventilator-dependent patients*. One difference is the ability of the *patient* to maintain appropriate spontaneous ventilation of the lungs. Another is the balance between mechanical ventilation and other important lifestyle functions, such as eating, speaking, psychosocial aspects and general physical activity. When choosing and configuring modes, circuits, and *alarm conditions*, the supervising clinician and *patient* need to balance the knowledge and certainty of mechanical ventilation against the *patient's* clinical needs, autonomy and lifestyle.

There has been growing interest in an alternative to conventional oxygen therapy – heated, humidified high-flow oxygen therapy. This form of respiratory support can be delivered through a variety of *airway devices*. It typically comprises provision of air and oxygen mixture to a *patient* at rates of flow higher than that delivered traditionally in oxygen therapy, and with the intent to minimize entrainment of room air. This is commonly referred to by clinicians as "High Flow Nasal Cannula Therapy", "Nasal High Flow", "High Flow Oxygen Therapy" or "Humidified High Flow Therapy".

Several physiological effects have been described with the use of *respiratory high-flow therapy equipment*:

— pharyngeal dead space washout,

— reduction of nasopharyngeal resistance,

— a positive expiratory pressure effect,

— an alveolar recruitment,

— greater humidification, more comfort and better tolerance by the *patient*,

— better control of the oxygen concentration in the lung, and

— mucociliary clearance.

Additional information is contained in ISO/TR 21954[12].

Respiratory high-flow therapy equipment conforming to ISO 80601-2-90 is used by *patients* who require a wide range of support to provide adequate gas exchange. This can include *patients* with pulmonary vascular dysfunction, such as those *patients* with the oxygen-dependent phenotype of COVID-19.

Provision of high flow through nasal cannulas has been observed to create positive pharyngeal pressure, typically of up to approximately 1 hPa for each 10 l/min of flow during expiration. The resulting pressure is dependent not only on the flow, but also on the ratio of cross-sectional area of the prongs and the nares, and whether or not the mouth is closed.

Respiratory high-flow therapy equipment is typically composed of five parts:

1) a connection to gas sources,
   - air, and
   - oxygen;

   NOTE 1 Gas sources include *medical gas pipeline systems*, gas cylinders, oxygen concentrators and ambient air.

2) a flow controller, which is used to select and deliver the desired flow.

   NOTE 2 The flow controller can be at a fixed rate.

   NOTE 3 The flowrate range is dependent upon the intended *patient* population (e.g., neonatal, paediatric and adult *patients* can require different flowrates).

3) a *humidifier*;

   NOTE 4 When dry gas is utilized, a *humidifier* is typically needed.

4) a breathing tube; and

5) a non-sealed *airway device*, which is used to deliver gas to the *patient*.

These parts can be combined (e.g., the gas source, flow controller and *humidifier* can be combined). *Respiratory high-flow therapy equipment* interfaces with the *patient* whose upper airway is intact via a non-sealing *high-flow nasal cannula*[38] [42] or, less commonly, a non-sealing *mask*[28] or helmet as well as a *patient* whose upper airway is bypassed via a non-sealing connection to a tracheal tube, or tracheostomy.

Subclause 201.4.3.101 — Additional requirements for *essential performance*

Essential performance is "delivery of a continuous flow of gas and oxygen concentration within the *disclosed accuracy* or generation of an *alarm condition*". The general standard requires that the *risk* associated with loss or degradation of *essential performance* be reduced to acceptable levels in both *normal condition* and *single fault condition*. This includes any failure e.g. of any component or power source. This document identifies some specific *risk control* measures that address this issue, but in general it is the responsibility of the *manufacturer* to ensure adequate *risk control* measures in *single fault condition*. The most common *risk control* measure for the *risk* associated with loss or degradation of *essential performance* is to generate an *alarm condition*, which also includes *alarm conditions* not specified by this document, to notify the *operator* that the expected *essential performance* might not be maintained. See 4.3 and 4.7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020.

The distributed *essential performance* criteria captured within Table 201.101 have been identified by the committees as the minimum clinical performance necessary to reduce the possibility of exposing the *patient* to unacceptable *risk*. Those *risks* include:

— hypoxaemia from lack flow of oxygen or mixed gas;

— hyperoxia from high concentration of inhaled oxygen; and

— suffocation due to airway blockage by dried secretions from lack of humidification.

Compliance criteria for some of the clauses within IEC 60601-1, ISO 80601-2-90 and the other applicable collateral standards includes "maintain *essential performance*". The committees have recognized the difficulty in confirming that all aspects of *essential performance* are maintained when completing longer duration testing.

Footnote a to Table 201.101 indicates methods of evaluating delivery of therapy as acceptance criteria following specific tests required by this document. It is intended to provide criteria which can be used to easily verify that *essential performance* has been maintained. Although the degradations detailed within 202.8.1.101 are associated with *immunity* testing, the same criteria are intended to be used when the compliance criteria from any other clause or subclause requires confirmation that *essential performance* is or has been maintained.

Those aspects of *essential performance* that cannot be reasonably linked to the compliance criteria within 202.8.1.101 need to be confirmed via other means. But one need only confirm that the specific requirements indicated in 202.8.1.101 that are likely to have an impact on specific clinical performance are maintained after testing.

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

Since much of the *breathing system* is likely to be draped over or around the *patient*, it is likely to come into direct contact with the *patient* during *normal use*. Also of concern are electrical *hazards* should any circuitry be incorporated into the *breathing system*. By ensuring that those items are subject to the requirements for *applied parts*, these issues are addressed by the requirements already in the general standard.

Subclause 201.4.11.101 — Additional requirements for pressurized gas input

Respiratory high-flow therapy equipment designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its *rated* range of supply pressures; and these pressures can only be maintained if the *respiratory high-flow therapy equipment* in *normal condition* does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that *respiratory high-flow therapy equipment* should be designed to prevent an unacceptable *risk* under possible *single fault conditions* of the pressurized gas supply.

Pressurized medical gas supplies, including *medical gas pipeline systems* and cylinder pressure regulators conforming to current relevant standards, supply gas-specific terminal outlets at a pressure that is within an internationally agreed-upon pressure range of 280 kPa to 600 kPa under *normal condition*. It is expected that *respiratory high-flow therapy equipment* operates to its declared specification at any supply pressure within this range.

In the case of a pressure regulator failure, the gas supply pressure could rise to the pressure regulator's supply pressure, which can be cylinder (tank) pressure. To safeguard against this or similar eventualities, gas-specific medical gas supply systems are required to be provided with a means to limit their output pressure to not more than 1 000 kPa. All gas-powered *ME equipment* should be designed so as not to present an unacceptable *risk* if its supply pressure rises up to this value. There is a specific requirement that *respiratory high-flow therapy equipment* should continue operation with acceptable performance such that *patients* can continue to be ventilated until such time as normal operation can be restored or that alternative arrangements can be made.

Respiratory equipment with maximum *rated* input pressures exceeding 600 kPa are required to fulfil these conditions at up to twice their maximum *rated* input pressure.

Under the *single fault condition* that the supply pressure of any one gas drops below 280 kPa, under steady-state conditions, it is understood that *respiratory high-flow therapy equipment* cannot be expected to continue to operate on this gas. However, it is required that in this case, the *respiratory high-flow therapy equipment* should detect the unacceptable low pressure, produce an *alarm signal* and also, in the case of two pressurized gas supplies, automatically switch to use the other gas source (oxygen or air) to supply the *respiratory high-flow therapy equipment*. This requirement is stated in 201.13.2.101.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, *medical gas pipeline systems,* supplying compressed medical gases through gas-specific terminal outlets, are designed so that they can maintain this pressure at the input of gas-powered devices while supplying steady-state flowrates up to 60 l/min at a single outlet connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, at 60 l/min, across the terminal unit and the hose assembly connecting the device to the pipeline.

The *medical gas pipeline system* is also required to be capable of supplying sufficient gas that this flowrate can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the *medical gas pipeline system* by the application of a 'diversity factor'; a factor agreed upon between the supplier and *responsible organization* to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the *medical gas pipeline system* is capable of supplying an average flowrate of 60 l/min to the required proportion of terminal outlets. However, if the flowrate demand from many adjacent equipment exceeds 60 l/min, there is an increased possibility that the *respiratory high-flow therapy equipment* input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the terminal unit and input hose assembly (also because of the flow-drop characteristic in the case of pressure regulator supplying a single terminal outlet).

In addition to steady-state flowrates of 60 l/min, the switching of the internal pneumatic subsystem and the operation of a *patient* demand subsystem can result in *respiratory high-flow therapy equipment* requiring transient input flowrates far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimize the pressure drop, such transient demands can generally be accommodated from the gas contained locally within the pipe work of the *medical gas pipeline system*. There can be temporary pressure drops of the input pressure at the *inlet connector* of the *respiratory high-flow therapy equipment* to below 280 kPa due to transient flowrates in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the *manufacturer*. *Manufacturers* need to evaluate their own designs to establish whether any consequent transient pressure drop adversely affects the performance of their *respiratory high-flow therapy equipment* when used with recommended supply hose configurations and when connected to alternative gas-specific terminal outlets such as those fitted to cylinder pressure regulator conforming to ISO 10524-1[8].

Equipment that can draw greater average or transient flowrates during *intended use* are permitted, but their *accompanying documents* are required to disclose those flowrates and warn of the need for a different diversity factor.

The average flowrate of 60 l/min is greater than the test flowrate used during the commissioning of *medical gas pipeline systems*. In itself, this should be of no concern because the conditions specified for the test do not allow a direct comparison between the two values. The subcommittee responsible for pipeline standards, ISO/TC 121/SC 6, in consultation with ISO/TC 121/SC 1 and ISO/TC 121/SC 3, agreed to the 60 l/min average flowrate value, and also the 200 l/min for up to 3 s transient flowrates, during the preparation of the first edition of the current series of standards for *medical gas pipeline systems* and were aware of the need to satisfy that specification when finalizing the *medical gas pipeline system* test requirements.

Manufacturers should be aware that other medical gas supply system standards permit the fitting of gas-specific terminal outlets to supply systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 201.5.101 — Additional requirements for general requirements for testing of *ME equipment*

After due consideration, the committees decided that where this document specifies adjoining ranges for variables as the basis for testing and the declaration of performance, the end values of both ranges should be applicable to both ranges. This means that a *manufacturer* is free to use a round-number end value (e.g. 300 ml) in specifications and is not forced to truncate artificially the declared range in order to avoid having to also satisfy the test requirements of the adjacent range. This permits, for example, one *respiratory high-flow therapy equipment* to have a declared flowrate range of 30 l/min to 60 l/min and another 2 l/min to 30 l/min, with each *respiratory high-flow therapy equipment* only being required to be tested for the conditions specified for ≥30 l/min or ≤30 l/min respectively.

Subclause 201.5.101.2 — Gas flowrate specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally, one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (~ 37 °C) irrespective of the temperature of the gas delivered by *respiratory high-flow therapy equipment*. The volume of a given amount of gas increases by about 13,5 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurised gas to medical equipment, including *respiratory high-flow therapy equipment*, follow engineering conventions and specify gas quantities and flowrates at *STPD* conditions. This practice is followed in this document for all requirements concerning gas input.

However, *respiratory high-flow therapy equipment* conforming with this document is intended to deliver flow to the *patient's* lungs and the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered from the *respiratory high-flow therapy equipment*. With a standard temperature of 0 °C, 1 l of gas referenced to *STPD* (*standard temperature pressure dry*) can expand the lungs by 1,8 l at a pressure of 70 kPa.

In *respiratory high-flow therapy equipment* a variety of flow transducers are used. Whereas a heated-wire anemometer measures the rate of mass flow of the gas independent of pressure, a pneumotachograph measures the flow of gas at the actual pressure. Therefore, the necessary corrections depend on the type of flow transducer. When a pressure correction is required, this can be adequately estimated.

With a blower-based *respiratory high-flow therapy equipment* that uses ambient air, the humidity of the drawn-in air can be unknown to the *respiratory high-flow therapy equipment*. All these effects together inevitably introduce some errors in the conversion of the measured flow signal to *BTPS* reference conditions. However, these errors are only in the range of several percent. However, it remains the responsibility of the *manufacturer* to verify that the accuracy requirements of 201.12.4.101, 201.12.4.102 and 201.12.4.103 are met.

Subclause 201.5.101.3 — *Respiratory high-flow therapy equipment* testing errors

When testing *respiratory high-flow therapy equipment* performance several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flowrates.

Because of the relative significance of these uncertainties, it is important that *manufacturers* allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester to recognise the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a *manufacturer* determines that a parameter has an intended tolerance of ±10 %, but the measurement uncertainty is ±3 %, then the test results are acceptable if, given the uncertainty band for the measured value, the probability of the measured values being within the

limit is at least 50 %. In almost all cases, measurement uncertainty has a symmetrical distribution, and the 50 % likelihood criterion is met if the measured value is within the disclosed limit, in this example, within ±10 % of the setting. The third-party testing organization needs to control measurement uncertainty to the same as that disclosed for type testing, in this example ±3 %.

Note that a third party testing organization obtaining a measured value outside the limit does not necessarily invalidate the claim – the deviation from the limit is required to be compared to the uncertainty of the measurement to establish the probability of the data representing a true deviation from specification.

See IEC Guide 115 for more information regarding measurement uncertainty.

Furthermore, the *manufacturer* is required to disclose the measurement uncertainty for each declared value in order to provide both information to the *responsible organization* and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

Subclause 201.7.9.2.2.101 — Additional requirements for warnings and safety notices

b)

The *operator* should be aware that only the parts or *accessories* listed in the *instructions for use* have been *validated* by the *manufacturer*. The use of non-*validated* parts can represent an unacceptable *risk*.

For example:

— a power supply unit other than the one recommended by the *manufacturer* can be designed and manufactured with poor quality (bad reliability), can adversely affect the electromagnetic compatibility of the *respiratory high-flow therapy equipment*, etc.;

— the connection of parts to the *breathing system* that are not listed in the *instructions for use* can increase the resistance of the *breathing system* and can increase the unintentional leakage of the *breathing system*, etc. to a level that adversely affects the *basic safety* and *essential performance*.

d)

Wheelchair batteries, even though they mostly convey the appearance that they supply standard voltages for auxiliary battery-powered equipment, often provide neither the appropriate connector nor an adequate voltage range to safely supply the *respiratory high-flow therapy equipment* for normal operation. Depending on the battery load condition required for the movement of the wheelchair, the voltages supplied at the auxiliary connector often show major voltage drops and simultaneous current limitations. It is reasonably foreseeable that these variations are often outside the external *supply mains* ratings of the *respiratory high-flow therapy equipment*. These might adversely affect the performance of the *respiratory high-flow therapy equipment* or in the extreme these voltage fluctuations might lead to a stoppage of therapy. In addition, these *supply mains* variations can also adversely affect the electromagnetic compatibility of the *respiratory high-flow therapy equipment*.

The *operator* needs to be aware that only wheelchairs listed in the *instructions for use* have been *validated* by the *manufacturer*. The use of non-*validated* wheelchairs can represent an unacceptable *risk* for the *patient*.

h)

Respiratory high-flow therapy equipment needs for its proper function a specific range of pressure, flowrate and gas concentration at the *high-pressure inlets*. Deviations of the inlet gas concentration for oxygen can influence the calibration of the oxygen sensor. Significant inaccuracies of the measurement of delivered oxygen concentration can occur.

In case the pressure or the deliverable flow of the central gas supply is too low, the *respiratory high-flow therapy equipment* would switch over to the remaining gas, e.g. from oxygen to air, with impact on the delivered oxygen concentration.

Subclause 201.7.9.2.8.101 — Additional requirements for start-up *procedure*

In some designs, adequate checking of the *alarm system* can be performed with a combination of *operator*-action and the power-on self-test routines that verify the integrity of the software and the integrity of the computer controlling the *respiratory high-flow therapy equipment*, as well as the measuring sensors and the *alarm signal* generation.

Subclause 201.7.9.3.1.101 — Additional general requirements

The *manufacturer* is expected to express the description of the *respiratory high-flow therapy equipment* in general terms so the reader can understand the important behaviour of the *respiratory high-flow therapy equipment* (e.g. mean values, etc.). Some items that one would find in the *instructions for use* for the *healthcare professional operator* are placed in the *technical description* for home use *respiratory high-flow therapy equipment* as that information is not expected to be meaningful to the *lay operator*, but is necessary for the *healthcare professional operator*.

Subclause 201.11.1.2.2 — *Applied parts* not intended to supply heat to a *patient*

The human airway has a very significant ability to absorb or deliver heat and moisture. Reference the common practice of sitting in a sauna without *harm* to the respiratory tract[35]. Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract[34]. A more recent study reported tolerance of inspired gas temperatures of 46,9 °C to 49,3 °C and 100 % RH (265,6 kJ/kg) for 45 min[35].

When considering gas mixtures other than oxygen/air, the following should be observed. Given that most of the energy is contained in the water vapour, the equivalent of air at 43 °C, 100 % RH is the maximum enthalpy that should be allowed. This has a specific volume of 0,978 6 m^3/kg of dry air and an enthalpy content of 197 kJ/m^3 of dry air. Assuming the volume breathed by the *patient* is the same, whatever gas mixture is used, then the safe enthalpy limit is 197 kJ/m^3 of dry gas. This enthalpy per unit volume gives a more relevant measure of the energy delivered to the *patient*.

Taking into account the enthalpy of inspired gas that has been shown to be tolerated without causing thermal injury to the human airways and the very short exposure times of thermal overshoot from a heated *humidifier* in clinical practice, the delivered gas energy limit of 197 kJ/m^3 of dry gas when averaged over 120 s can be used.

Studies to measure the relative importance of exposure time and temperature in causing cutaneous burns determined that a surface temperatures of at least 44 °C and 6 h exposure were required to cause irreversible damage to epidermal cells[41]. This is confirmed by studies conducted by the U.S. Navy Medical Research and Development Command[45], which concluded that fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.

Gas at body temperature and fully saturated (37 °C and 100 % RH) does not transfer thermal energy to or from the *patient* with a normal body temperature of 37 °C. Dry gas at body temperature (37 °C and 0 % RH) draws heat away through evaporation. Gas at 41 °C and fully saturated has the capacity to deliver less than 130 kJ/kg of dry gas breathed by the *patient*.

The enthalpy content of 197 kJ/m^3 has for a long time been in use to limit the energy transfer of humidified breathing air to the respiratory tract of a *patient* with bypassed upper airways and no negative feedback with regard to this limitation was known at the time of the consideration of this document. Even in the vulnerable neonatal *patient* population, the committees are aware of no reports of injury resulting from excessive thermal output from a respiratory gas *humidifier* when operating to specification. The committees asked for clinical advice as to whether in addition to the enthalpy limitation, the temperature needed also to be limited. A German group of clinicians, after considering the issue and the literature available, came to the following conclusion:

The literature shows[32][35][45]:

— thermal inhalational traumas with temperatures above 100 °C but with unknown humidity content;

- the very low RH of about 5 % only at 100 °C with an enthalpy content of 197 kJ/m^3;
- the good experience with the limit of enthalpy content of 197 kJ/m^3 of dry air in humidified breathing gases;
- the physical facts that a blower/turbine type *ventilator* increases the temperature of the gas taken from the environment in the range of 15 °C to 25 °C;
- *ventilators* are used in environments up to 45 °C;
- an additional temperature limitation is intended to limit the temperature under worst-case condition; and
- a sufficient safety margin to protect the *patient* from thermal injuries of its airways.

The clinician group recommended to keep the thermal energy limitation of 197 kJ/m^3 and add a maximum temperature limitation of 70 °C, whichever is lower. The committees agreed and confirmed this proposal.

Subclause 201.11.6.6 — *Cleaning* and *disinfection* of *ME equipment* or *ME system*

The *essential principles* of ISO 16142-1 require that medical devices are "not [to] compromise the clinical condition or the safety of *patients*, or the safety and health of users or, where applicable, other persons, provided that any *risks* which may be associated with their use constitute acceptable *risks* when weighed against benefits to the *patient* and are compatible with a high level of protection of health and safety."

This means that *respiratory high-flow therapy equipment*, their *accessories* and parts should not be used if there is an unacceptable *risk* of the *patient*, *operator* or other person being infected as a result of contact with the *respiratory high-flow therapy equipment*, *accessories* or parts.

Therefore, after long-term use in the home, *respiratory high-flow therapy equipment*, their *accessories* and parts, if transferred to a new *patient,* require an appropriate level of *disinfection*, depending on their use, but rarely need to be *sterile*.

Recommendations for hygienic *processing* of *respiratory high-flow therapy equipment*, their *accessories* and parts are based on the general hygiene requirements for the *processing* of medical devices and need to take into consideration the special requirements and needs of *patient* care in the clinical environment. The requirements for hygienic *processing* of this document are intended to:

- make the *responsible organization* for *processing* the *respiratory high-flow therapy equipment* aware of how to implement these tasks in a responsible manner through appropriate delegation;
- help all parties involved in the *processing* of *respiratory high-flow therapy equipment*, their *accessories* and parts to comply with the *manufacturer's* instructions.

The *cleaning* and *disinfection procedures* of the *manufacturer* are also intended to provide practical support to all those involved in *patient* care in the clinical environment with regard to implementing the hygiene measures required for the *patient's* safety.

It should be noted that *respiratory high-flow therapy equipment*, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any *respiratory high-flow therapy equipment* that has already been used on another *patient* is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and *processing procedures* are essential to protect the next person handling the equipment or the next *patient* on whom the equipment is used. Hence, *respiratory high-flow therapy equipment*, their re-usable *accessories* and parts that have been used are required to undergo a *processing process*, following the *manufacturer's* instructions, prior to reuse by another *patient*.

The following basic considerations need to be addressed by the *manufacturer* when specifying the *processing* instructions of *respiratory high-flow therapy equipment*, its *accessories* or parts:

- protecting the *patient*, the *operator* and the *responsible organization* (including personnel involved in performing the *processing process*);

— the limits of the *procedures* used for *processing* (such as the number of *processing* cycles);

— the necessity to guarantee the proven standardised *procedures* are at a consistently high and verifiable quality, based on an established quality management system.

The recommended *processing process* should be determined by:

— the potential degree and type of contamination of the *respiratory high-flow therapy equipment*, *accessories* or parts;

— the *risk* of infecting another *patient* resulting from their reuse and the type of application of the *respiratory high-flow therapy equipment*.

Special consideration of the possible *risk* associated with the contamination of gas-conducting components due to the *patient's* re-breathing under *single fault condition* should be considered.

On the basis of the above, a *verified* and *validated* documented *processing procedure* needs to be specified in such detail so that the outcome is reproducible. An acceptable *residual risk* from the *hazard* of infection for the next *patient* can be assumed if the:

— documented *processing procedure's* effectiveness has been *verified* through appropriate scientific methods by the *manufacturer*;

— reliability of the documented *processing procedures* has been *verified* in practice through appropriate quality assurance measures by the *responsible organization* carrying out the *processing procedures*.

When selecting and evaluating the *processing procedures*, the *manufacturer* should consider:

— the amount and type of pathogenic microorganisms expected to contaminate the *respiratory high-flow therapy equipment*, *accessories* or parts;

— the *risk* for the pathogenic microorganisms to be transmitted to the *patient*, *operator* or other persons;

— the microorganism's resistance to the recommended *processing procedures*.

The *risks* posed by a processed *respiratory high-flow therapy equipment*, *accessories* or parts are determined by the following factors:

a) undesired effects, which can result from:

   1) the previous use;

   2) the previous *processing processes;*

   3) transportation and storage;

b) the *risks* from subsequent uses, such as the following:

   1) residues from the previous use (such as secretions, other body fluids, and drugs);

   2) residues from the previous *processing processes* (such as *cleaning* agents, disinfectants and other substances, including their reaction products);

   3) changes of physical, chemical or functional properties of the device;

   4) changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints);

c) the *risk* of transmission of any pathogenic microorganisms.

When considering the suitability of the *processing process* and the feasibility of the *processing process* for the *respiratory high-flow therapy equipment*, *accessories* or parts, the *manufacturer* should consider the following points:

1) the *risks* involved in the *processing process*;
2) the cost effectiveness of the *processing process*;
3) the practicability of the *processing process*;
4) the availability of the *cleaning* equipment and the *cleaning* agents specified in the *processing process*;
5) the efficiency of the *processing process*;
6) the reproducibility of the *processing process*;
7) quality management requirements of the *processing process*;
8) the environmental impact of the *processing process* and the disposal of the *respiratory high-flow therapy equipment*, *accessories* or parts.

The *manufacturer* should verify all *cleaning* agents and *processing procedures* used with regard to their suitability and repeatability with the *respiratory high-flow therapy equipment*, *accessories* or parts, depending on the type of use.

The *responsible organization* should verify that manual *cleaning* and *disinfection* of the *respiratory high-flow therapy equipment*, *accessories* or parts are always carried out in accordance with the *procedures* specified in the *accompanying document*.

The *manufacturer* should specify *validated* automated *cleaning* and *disinfection procedures*. If they are not followed, the effectiveness of the *cleaning* and *disinfection* cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of *cleaning* agents and disinfectants as well as residence time.

To ensure the reproducibility of automated *processing procedures*, tests should be carried out on a regular basis.

The *manufacturer* should ensure that the specified *disinfection procedures* are *verified* to be bactericidal, fungicidal and virucidal so that the cleaned and disinfected *respiratory high-flow therapy equipment*, *accessories* or parts do not pose an unacceptable *risk* of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually, comes in contact with the next *patient*, *operator* or person.

Effective *disinfection* requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Following any *processing procedure*, safety and functional testing of the *respiratory high-flow therapy equipment* (as specified by the *manufacturer's* instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the *respiratory high-flow therapy equipment*.

The extent and type of the tests depends on the *respiratory high-flow therapy equipment*, *accessory* or part and these need to be defined in the *accompanying document*.

Subclause 201.11.8.101 — Additional requirements for interruption of the power supply/*supply mains* to *ME equipment alarm condition*

One half hour was chosen as the minimum acceptable time necessary to ensure that alternative arrangements could be made to continue the function of *transit-operable respiratory high-flow therapy equip*. Climatic, traffic and other conditions require at least this period before restoration of power or arrangement for other supplies.

Subclause 201.12.1 — Accuracy of controls and instruments

cc) 2)

In situations where the *respiratory high-flow therapy equipment* is being used to treat highly infectious diseases (e.g., SARS, COVID-19), the *operators* are wearing a substantial amount of personal protective equipment (e.g., multiple layers of protective clothing and gloves as well as goggles that might be blurred due to aerosol). To ensure that the *operator* can both clearly see and adjust the *respiratory high-flow therapy equipment*, minimum intended position of the *operator* was extended to 2 m for the purpose of legibility testing.

Subclause 201.12.4.102 — *Maximum limited pressure protection device*

The value chosen for the *maximum limited pressure*[29][33] is a compromise between the need to avoid barotrauma in the case of misconnection (e.g. a direct connection to a tracheal tube) and the need to provide an adequate pressure to drive the required flow through the air*way device*.

Subclause 201.12.101 — Protection against accidental adjustments

Unacceptable *risks* to the *patient* can occur as a result of accidental adjustments of operating controls or turning off the *respiratory high-flow therapy equipment*. To control this *risk*, the *operator-equipment interface* should be designed to prevent accidental adjustments. The *usability engineering process* is used to ensure that these *risks* are reduced to acceptable levels. Example methods could include mechanical *risk control* techniques such as locks, shielding, friction-loading and detents; pressure-sensitive finger pads; capacitive finger switches; and microprocessor-oriented "soft" *risk controls*; and a specific sequence of key or switch operations.

Subclause 201.13.2.101 — Additional specific *single fault conditions*

Operation of *respiratory high-flow therapy equipment* without an *operator*-detachable *breathing system filter* in place is considered reasonably foreseeable when considering those parts of the *breathing system* that might become contaminated with body fluids or microbial material conveyed by the expired gases. If *respiratory high-flow therapy equipment* can operate without the *breathing system filter*, then one must assume that it has been operated without the *breathing system filter* and therefore those parts of the *breathing system* have been contaminated.

Subclause 201.13.2.102 — Independence of delivery control function and related *risk control* measures

This requirement prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

Subclause 201.13.2.103 — Failure of one gas supply to *respiratory high-flow therapy equipment*

This subclause addresses the *hazardous situation* created when an entire unit (e.g. the whole critical care unit or all of the operating theatres) experiences simultaneous failure of multiple *respiratory high-flow therapy equipment* caused by the loss of a single pressurized gas source where at least one gas source is provided by a pressurized *medical gas pipeline system*.

EXAMPLE 1 A *respiratory high-flow therapy equipment* is connected to both air and oxygen *medical gas pipeline systems* and one of the *medical gas pipeline systems* fails. The *respiratory high-flow therapy equipment* then uses the other *medical gas pipeline system* to supply gas.

EXAMPLE 2 A blower-based *respiratory high-flow therapy equipment* is connected is to an oxygen *medical gas pipeline system* and that *medical gas pipeline system* fails. The *respiratory high-flow therapy equipment* then uses the room air provided by its blower.

Subclause 201.16.2 —*Accompanying documents* of an *ME system*

Many respiratory gas *humidifiers* control their humidification output by servo controlling the temperature of a water bath to achieve a set gas temperature at the *humidifier* chamber outlet. This temperature is frequently defined to be a function of gas flowrate as measured by the *humidifier*, and is defined to target a desirable absolute humidity – the rate of evaporation of water and the rate of heat transfer from the water to the air are closely correlated. This works provided the input gas temperature is below a threshold. For example, for one leading *manufacturer* of *humidifiers*, the water vapour output starts to reduce when the input gas temperature exceeds 27 °C.

Respiratory high-flow therapy equipment that incorporates a blower to provide a source of breathing air drawn from an air intake inevitably increases the temperature of the air above the intake temperature. The extent of this rise in temperature will depend on the set oxygen concentration (and hence the proportion of the breathing gas that has been compressed), the blower outlet pressure (which can significantly exceed the *respiratory high-flow therapy equipment gas output port* pressure) and the efficiency of the blower technology used.

This has been confirmed in published bench study[37]. This study confirmed that with unfavourable conditions, specifically *humidifier* chamber inlet gas temperatures above 37 °C, *humidifier* output could fall well below recommended minimum levels of 20 mgH_2O/l.

For *respiratory high-flow therapy equipment* capable of generating an elevated gas temperature at the *gas output port*, the *responsible organization* needs to have information available to allow them to determine whether the *humidifier* is likely to remain effective.

Subclause 201.101.1.1 — General

Non-standard *breathing system* connectors can represent an unacceptable *risk* as attempts are made to fit a *breathing system* to *respiratory high-flow therapy equipment* in an emergency. Non-standard *breathing system* connectors can cause leaks if used with similar but not compatible connectors.

Whilst there are many anecdotal reports of misconnections, published evidence of serious incidents is scarce. Many clinicians openly admit that misconnections are commonplace but go unreported either because the mistake was rectified in time or because serious *harm* did not arise from the event. Discussions with *authorities having jurisdiction* reveal that commonplace but potentially serious events are not reported because users consider them as normal events.

In the *risk assessment* of the *breathing system* and its connectors, it can be summarised that there are fundamentally three main routes of delivery to the body: intravascular, enteral and respiratory. Some medical devices are intended to be connected to one of these routes depending upon their application or function. Misconnections, which result in the delivery of a substance inappropriately to the body, create *risks* to the *patient*.

The assessment of the *risk* associated with the inadvertent cross connection between these three systems identifies the application of respiratory gases to the delivery route intervascular as “immediate fatal risk to patient”.

Considering *usability*, a review of the role of *usability* in accident areas such as aviation, nuclear power and marine transportation exists[27]. The review makes the point that all human beings, without any exceptions whatsoever, make *use errors* and that such *use errors* are a completely normal and an expected part of human cognitive function. The review goes on to say that whilst many accidents are regarded as human error (which is synonymous with *use error*) the guilty party can often be someone else, for example the trainer, the equipment designer, the equipment purchaser etc. Well-designed equipment can prevent or at least ameliorate the effects of *use error*. The review states that one must expect users to misconnect devices which are provided with compatible connectors and recognise that the potential for misconnection rises as the number of devices with similar connectors increases.

Considering further that medical devices have for very many years followed the established principle of safety under *single fault condition*, which means that a *single fault condition* should not result in an unacceptable *risk*. This principle is also embodied in IEC 60601 family of standards. Extending this principle to the application of Luer connectors is a logical step (i.e., that misconnection should not result in an unacceptable *risk*).

Misconnection of medical devices with Luer connectors is a frequent event. The widespread use of Luer connectors on a multitude of medical devices can therefore result in connections which have serious, or even fatal, consequences for the *patient*. Fundamentally, the problem results from the application of a single connector design to several incompatible applications.

Claims of a lack of recorded misconnection occurrence indicate a lack of understanding *risk* and *usability*. It's known that most of the actual occurrences are recorded not as medical device failures and if anything, are seen as wrong route of delivery issues – not as misconnections. Human beings without exceptions make errors. We therefore expect *operators* to misconnect medical devices that are provided with compatible connectors. The safety concept of the ISO 80369 series is based on the principle that the different applications protect each other by an inherent design of the connectors dedicated to their field of application i.e., the safety concept of the ISO 80369 series is to prevent users from misconnecting medical devices of different applications.

This leads to the clear conclusion that Luer taper or Luer-lock connectors conforming with ISO 594-1[2], ISO 594-2[3] or ISO 80369-7 are unsafe and therefore are not permitted for use for connection the *gas pathways* of *respiratory high-flow therapy equipment*.

Subclause 201.102.1 — General

It is the responsibility of the *manufacturers* of a *breathing system*, its parts or *accessories* to verify that their product conforms with the requirements of this document by testing their product, in combination with the other items for which compatibility is claimed, to the requirements of this document.

Subclause 201.102.4 — Humidification system

As *respiratory high-flow therapy equipment* can deliver therapy to *patients* through a variety of non-sealed *airway devices*, the equipment can need to comply with the requirements of multiple categories within ISO 80601-2-74 (e.g. Category 1 for tracheostomy connections and Category 3 for *high-flow nasal cannulas* or face *masks* or helmets with large *exhaust ports*.

Subclause 201.103 — Indication of duration of operation

Respiratory high-flow therapy equipment require maintenance for continued safe use. A practicable means to ensure that this information is available to the *operator* or the *responsible organization* is to require that the *respiratory high-flow therapy equipment* keep track of how long it has been in operation since the last preventive maintenance or when the next recommended preventive maintenance is due.

Subclause 201.104.2 — Connection to electronic health record

Electronic documentation of *patient* care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual *patient* through accurate and complete documentation, and to improve the completeness and accuracy of aggregate data to facilitate continuous quality improvement. Providing remote supervisory capability is rapidly becoming the standard of care in the *home healthcare environment*.

Subclause 201.104.3 — Connection to *distributed alarm system*

Patients are not always located near enough to the *lay operator* to ensure that *alarm signals* coming from the *patient's* room can be heard. It is reasonably foreseeable that some rooms of a *patient's* home or limited care facility are out of earshot of other rooms. As a result, it is desirable for *respiratory high-flow therapy equipment* intended for use in the *home healthcare environment* to be equipped with a means to connect to a *distributed alarm system* that can provide additional *alarm signal* presentation points. A

distributed alarm system facilitates delivery of *alarm signals* to other rooms where the *operator* might be located, thereby permitting a timely response and intervention to support *patient* care.

Subclause 202.4.3.1 — Compliance criteria and

Subclause 202.8.1.101 — Additional general requirements

It is not the intent of the committees to require that the *immunity* tests be performed multiple times (e.g. at multiple flowrates and oxygen concentrations), but that the *manufacturer* should determine which flowrate and oxygen concentration represents the worst case for a given *immunity* test and use those conditions.

Given the typical use models for this equipment and relative stability of *patients* for which this equipment is intended, the committees considered flowrate accuracy and oxygen delivery accuracy as the appropriate parameters to monitor during *immunity* tests.

The committees recognized that during environmental stress (for example, shock, vibration, electromagnetic disturbances) *respiratory high-flow therapy equipment* performance can degrade. In such a situation, the duration of altered performance would be about minutes to, at most, few tens of minutes. Shock and drop disturbances can be even shorter (i.e. less than 100 ms). The question then became how to express the percent change in flowrate performance that would not cause *harm* to a *patient* during a brief interval of environmental stress.

The committees discussed the potential consequences of a 35% flow deviation delivered to neonatal *patients*. Clinical consensus statements[46][50] indicate that flow settings of 2 l/min to 8 l/min are safe and efficacious for term and most preterm infants. Although a transient 35% increase would raise an 8 l/min flow to 10,8 l/min, a recent physiological study[39] shows that resulting mean *airway pressures* would still be significantly below those targeted during bubble CPAP in common clinical practice

Subclause 206.102 — Training

The modern *respiratory high-flow therapy equipment* is complex equipment whose use requires specific training for each *manufacturer's* make and model. Different *manufacturers* often refer to similar modes of therapy by different names and, although in principle those modes are similar to those of another *manufacturer's respiratory high-flow therapy equipment*, their modes are unique in sometimes minor and sometimes complex ways. It is essential, therefore, that the *lay operator* and every person involved with the operation and setup of *respiratory high-flow therapy equipment* is fully trained in that *respiratory high-flow therapy equipment's* operational characteristics, in particular its controls, capabilities and limitations, prior to any use.

Subclause 208.6.12.2 — *Operator alarm system* logging

Optimal management of a *patient* requires the ability to review the history of important *alarm conditions*. This is a more reasonable means of *risk control* for equipment than *latching alarm signals*. Additional information is also found in IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, Annex A, for 6.12 – *alarm condition* logging.

Annex BB
(informative)

Data interface requirements

BB.1 Background and purpose

Heightened interest in the monitoring of *respiratory high-flow therapy equipment* in the *home healthcare environment* or intended for use in professional healthcare facilities, as well as accountability and responsiveness of the parties involved has become evident on an international scale. Consequently, *patients*, caregivers, clinicians, service providers, and payers have begun the systematic definition and collection of information with regard to monitoring the performance of this type of *respiratory high-flow therapy equipment*. This trend is also driven by an enhanced data infrastructure. In order to establish a common definition for monitoring the ventilatory performance of the *respiratory high-flow therapy equipment*, explicit criteria need be applied to choosing and defining parameters. This framework is intended to inform about a common definition of parameters for *respiratory high-flow therapy equipment* in the *home healthcare environment*. The selection is based on some agreement about what is to be monitored, and for what purpose.

It is important to note that any data collection needs to be carried out according to privacy and confidentiality legislation and ethical principles.

A harmonized effort to develop internationally accepted therapy indicators for *respiratory high-flow therapy equipment* in the *home healthcare environment* not only fosters increasingly robust cross-national analyses, but can also facilitate the development of comparable data that can be used as a basis for the setting of international benchmarks.

The standardization of data available from *respiratory high-flow therapy equipment* in the *home healthcare environment* is intended to help to eliminate the current shortcomings and contribute significantly to the improvement of the therapy. This approach seeks to provide a definition that can used across *respiratory high-flow therapy equipment* therapy equipment for providing therapy data independent of *respiratory high-flow therapy equipment manufacturer* or what mechanisms are used to transport the data, either locally or remotely to a *healthcare professional operator*. This approach ensures comparability between data regardless of the transport mechanism chosen to be most appropriate for a *patient* situation. It also provides for flexible and cost-effective integration into disparate equipment that *healthcare professional operators* can use for *patient* data management. This approach also maintains comparability between data while allowing advancement in data transport technology to provide solutions that better meet the needs of *patients*, caregivers, clinicians, service providers and payers. As such, the definition of specific equipment communication interface hardware or software considerations such as protocols or transport mediums is outside of the scope of this document.

A number of monitoring requirements exist for *respiratory high-flow therapy equipment* in the *home healthcare environment*, depending on the needs of the *patient*, caregiver, clinician, service provider, and payer, which require various levels of data. This document seeks to define the data that for *respiratory high-flow therapy equipment* in the *home healthcare environment* are required to meet the objectives of these users.

The following levels of data are defined.

— **Parameters and units of measurement:** Parameters and units of measurement used in the *respiratory high-flow therapy equipment*.

— **Equipment identification:** Information identifying the *respiratory high-flow therapy equipment*.

— **Usage monitoring:** Data providing monitoring of the therapy.

— **Equipment settings:** The different therapy modes provided by *respiratory high-flow therapy equipment* in the *home healthcare environment* that require different settings.

— **Therapy monitoring:** Settings relating to monitoring of *patient* therapy.

— ***Respiratory high-flow therapy equipment alarm limits*:** Settings relating to therapy-related *alarm limits*.

— **Event information:** Information provided about events related to the usage of the *respiratory high-flow therapy equipment*.

— **Service monitoring:** Indicators relating to preventative or corrective maintenance of the *respiratory high-flow therapy equipment* and its *accessories*.

All *respiratory high-flow therapy equipment* should provide the information to enable identification of the *respiratory high-flow therapy equipment*. Implementation of any further data levels is optional.

Information identifying pressure units used in the data set should also be provided.

BB.2 Data definition

Table BB.101 defines the pressure and flowrate units in the data set.

Table BB.101 — Parameters and units of measurement

Parameter	Description	Type
Pressure units	Specification of the units of measurement for pressure-related data	Value: (cmH_2O or hPa)
Flowrate units	Specification of the units of measurement for flowrate-related data	Value: (l/min or l/s)

Table BB.102 defines *respiratory high-flow therapy equipment* identification data.

Table BB.102 — Equipment Identification

Parameter	Description	Type
Equipment *manufacturer*	Identification of the *manufacturer* of the equipment	Text string
Equipment model	Identification of the product or model number of the equipment	Text string
Equipment serial number	Identification number of the equipment	Text string
Equipment software version	Identification of the software version(s) implemented in the equipment	Text string
NOTE More than one software version might need to be communicated from the equipment.		

Table BB.103 defines data required for usage monitoring.

A set of measured and calculated values should be provided for each therapy session, where a therapy session is any period of time the *respiratory high-flow therapy equipment* is providing therapy.

Table BB.103 — Usage monitoring

Parameter	Description	Type
Therapy start date/time	The current UTC (Coordinated Universal Time) date and time when the usage session was started	ISO 8601-1[6] Date Time (YYYY-MM-DDThh:mm:ss)
Therapy stop date/time	The current UTC date and time when the usage session was stopped	ISO 8601-1[6] Date Time (YYYY-MM-DDThh:mm:ss)
Hours of therapy	Number of hours the equipment is powered on and providing therapy	Value: (h)
Hours of *patient* use	Number of hours the equipment is providing therapy to the *patient* for the current usage session	Value: (h)

Table BB.104 defines applicable current settings of the *respiratory high-flow therapy equipment* for each mode of operation.

Table BB.104 — Equipment settings

Parameter	Description	Type
Mode of operation	Equipment *breathing-therapy mode* as defined within the document	Type selected
Patient category	*Patient* cohort classification (if applicable)	Type selected
Airway device	*Airway device* classification — invasive — non-invasive	Type selected
Breathing system	*Breathing system* classification (if applicable) — single limb with leak port — other	Type selected
Language	Identification of the user interface language setting according to ISO 639-1:2002[4]	Value: (2-letter alpha)
Display brightness	Setting of the luminous intensity as a percentage of the maximum setting	Decimal value (2-digit %)

Table BB.105 defines the indicators relating to monitoring of *patient* therapy.

Table BB.105 — Therapy monitoring

Parameter	Description	Type
Flowrate	Delivered flowrate	Decimal value: (l/min)
Oxygen concentration	Inspiratory oxygen concentration	Value: (% oxygen)

Table BB.106 defines the applicable current *alarm limits* of the *respiratory high-flow therapy equipment*.

Table BB.106 — *Respiratory high-flow therapy equipment alarm limits*

Parameter	Description	Type
High oxygen concentration *alarm condition*	Setting of the high oxygen concentration *alarm limit*	Value: (% oxygen)
Low oxygen concentration *alarm condition*	Setting of the low oxygen concentration *alarm limit*	Value: (% oxygen)
High flowrate *alarm condition*	Setting of the high flowrate *alarm limit*	Value: (l/min)
Low flowrate *alarm condition*	Setting of the low flowrate *alarm limit*	Value: (l/min)

Table BB.107 defines applicable *respiratory high-flow therapy equipment* usage information.

Table BB.107 — Event information

Parameter	Description	Type
Power supply source	Current source of electrical power — external AC *supply mains* — *internal electrical power source* — external DC *supply mains*	Type in use
Alarm signal inactive state present	List of text strings (*alarm off*, *alarm paused*, *audio off*, *audio paused*, *acknowledged*)	List of text strings
Active *alarm condition*	Currently active *alarm conditions*	List of text strings (*manufacturer*-defined)
Access mode	Current access mode of the *respiratory high-flow therapy equipment* — *lay operator* — *healthcare professional operator* — *responsible organization* — *service personnel*	Type in use

Table BB.108 defines applicable service and maintenance parameters.

Table BB.108 — Service monitoring

Parameter	Description	Type
Maintenance needed	A *manufacturer*-specific list of any items requiring maintenance, e.g. *mask*, tubing, filter	List of text strings (*manufacturer*-defined)
Respiratory high-flow therapy equipment service indicator	An indication that service is required	Text string: (*manufacturer*-defined)
Hours of therapy	Number of hours the equipment is powered on and providing therapy	Value: (h)
Hours until next scheduled maintenance	The next *manufacturer*-specified suggested maintenance interval	Value: (h)

Annex CC
(informative)

Reference to the IMDRF *essential principles* and labelling guidances

This document has been prepared to support the *essential principles* and labelling requirements of *respiratory high-flow therapy equipment* as a medical device according to the International Medical Device Regulators Forum (IMDRF).

Table CC.1 lists the clauses and subclauses of this document corresponding to the *essential principles* of IMDRF/GRRP WG/N47:2018[24]. Table CC.2 lists the clauses and subclauses of this document corresponding to the labelling principles of IMDRF/GRRP WG/N52:2019.

Table CC.1 — Correspondence between this document and theIMDRF *essential principles*

***Essential principle* of IMDRF/GRRP WG/N47:2018**[24]	**Corresponding clause(s)/sub-clause(s) of this document**	**Qualifying remarks/Notes**
5.1.1	All	The requirement for training is not addressed.
5.1.3	201.4, 201.4.3.101	
a)	201.4, 201.4.3.101	
b)	201.4, 201.4.3.101, 201.11.8.101, 201.12.4	
5.1.5	-	
a)	201.12.1, 206	
b)	206	
5.1.6	All	
5.1.7	201.4	
5.1.8	201.4	
5.1.9	201.4	
5.3.1		
a)	201.11.7	
b)	201.11.6.6	
e)	201.11.6.6 bb)	
f)	201.11.7, 201.12.1.101	
5.3.2	201.7.9.2.12 aa), 201.11.6.6, 201.11.7	
5.3.3	201.11.7	
5.3.5	201.11.6.6	
a)	201.11.6.6	
b)	201.11.7	

Essential principle of IMDRF/GRRP WG/N47:2018[24]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
c)	201.11.6.6	
5.4.1	201.11.6.6	
5.5.1	201.7.2.4.101, 201.7.9.2.14.101, 201.101, 201.102	
5.5.2	-	
a)	201.9, 201.12.1, 201.12.4, 206	
b)	201.12.1, 201.12.4, 206	
c)	202	
h)	202	
5.5.3	201.11	
5.5.5	201.7.2.4.101, 201.7.9.2.14.101, 201.12.4.101, 201.16.101, 201.101. 201.102	
5.5.6	201.12.101	
5.5.7	201.12.1, 206	
5.6.1	201.9.4.3.101, 211	
5.6.3	201.9.6.2.1.101	
5.6.4	201.101, 201.104	
5.6.5	201.11.1.2.2	
5.7.1	201.13	
5.7.2	201.11.8.101	
5.7.3	201.11.8.101	
5.7.5	202	
5.7.6	202	
5.7.7	201.8, 201.13	
5.8.1	201.14	
5.8.2	201.14	
5.9	-	
a)	201.12.1	
c)	201.7.2.101, 201.12.1, 206	
5.10.1	201.7.9.2.1.101, 211201	
5.12.1	201.12.1, 206	
5.12.2	201.12.1, 206	
5.12.3	201.7.9.2.8.101, 201.7.9.2.9.101.1, 206, 211	
6.1.1	201.11.7	

Essential principle of IMDRF/GRRP WG/N47:2018[24]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
6.1.2	201.11.7	
6.1.3	201.11.7	
6.4.1	201.12.1, 201.12.1.101	
6.4.2	201.12.4., 201.12.4.101, 201.12.4.102, 201.12.4.103, 201.12.4.104, 201.13	

Table CC.2 — Correspondence between this document and the IMDRF labelling principles

Labelling principles of IMDRF/GRRP WG/N52:2019[25]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
5.1.1	201.7.9.2.1.101, 201.7.9.2.2.101, 211	
5.1.4	201.7.2.101 b), 201.7.2.101 c)	
5.1.5	201.7	
5.2.1	201.7.2.101	
5.3.6	201.7.9.2.1.101, 201.7.9.2.2.101, 211	
5.3.10	201.7.9.2.1.101, 201.7.9.2.2.101, 211	
5.3.11	201.7.9.2.1.101, 201.7.9.2.2.101, 211	
5.3.12	201.12.1	
5.3.13	201.7.9.2.2.101	
5.3.14	201.7.9.2.8.101	
5.3.17	201.7	
5.3.18	201.7.9.2.8.101	
5.3.19	201.7.9.2.8.101	
5.3.20	201.7.9.2.12, 201.7.9.2.8.101, 201.7.9.2.13.101	
5.3.26	201.7.9.2.12 aa)	
5.3.27	201.7.9.2.8.101, 201.7.9.2.14.101, 201.16	
6.1.1	201.7.9.2.1.101, 201.7.9.2.2.101, 206, 211	
9.1	201.7.9.2.9.101.1, 211	
9.2	201.7.9.2.9.101.1, 211	
9.3	201.7.9.2.9.101.1, 211	
9.4	201.7.9.2.9.101.1, 211	
9.5	201.7.9.2.9.101.1, 211	
9.6	201.7.9.2.9.101.1, 211	
9.7	201.7.9.2.9.101.1, 211	

Annex DD
(informative)

Reference to the *essential principles*

This document has been prepared to support the *essential principles of safety and performance* of *respiratory high-flow therapy equipment*, its *accessories* or parts as medical devices according to ISO 16142-1:2016.

Conformance with this document provides one means of demonstrating conformance with the specific *essential principles* of ISO 16142-1:2016. Other means are possible. Table DD.1 maps the clauses and subclauses of this document with the *essential principles* of ISO 16142-1:2016.

Table DD.1 — Correspondence between this document and the *essential principles*

***Essential principle* of ISO 16142-1:2016, Annex B**	**Corresponding clause(s)/sub-clause(s) of this document**	**Qualifying remarks/Notes**
1	All	The part relating to manufacturing is not addressed.
a)	206	
b)	206	
2	201.4, 201.4.3.101	The part relating to manufacturing is not addressed.
a)	all	
b)	201.4, 201.4.3.101	The part relating to manufacturing is not addressed.
c)	201.4, 201.4.3.101, 201.11.8.101, 201.12.4	
d)	201.7	
3	all	The part relating to manufacturing is not addressed.
4	all	
5	201.4	
6	201.4	
8.1	201.11.7	
a)	201.11.7	
b)	201.11.7	
8.2	201.7.9.2.12 aa), 201.11.6.6, 201.11.7	
8.3	201.11.6.6, 201.11.7	
8.4	201.11.7	
9.1	—	
a)	201.11.6.6	

Essential principle of ISO 16142-1:2016, Annex B	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
b)	201.11.7	
c)	201.116.6	
12.1	201.7.2.4.101, 201.7.9.2.14.101, 201.101, 201.102	
12.2	—	
a)	201.9, 201.12.1, 201.12.4, 206	
b)	201.12.1, 201.12.4, 206	
c)	202	
g)	202	
12.4	201.11	
13.1	201.12.1	
13.2	201.12.1	
13.3	201.12.1, 206	
15.1	201.14	
15.2	201.14	
16.1	201.13	
16.2	201.11.8	
16.3	201.11.8.101	
16.4	201.11.8.101	
16.5	202	
16.6	202	
16.7	201.8, 201.13	
17.1	201.9.4.3.101, 211	
17.3	201.9.6.2.1.101	
17.4	201.101, 201.102	
17.5	201.101, 201.102	
17.6	201.11	
18.1	201.12.1, 201.12.1.101	
18.2	201.12.4, 201.12.4.101, 201.12.4.102, 201.12.4.103, 201.12.4.104, 201.13	
19.1	201.7.2.101, 201.12.1, 206	
19.2	201.7.2.101, 201.12.1, 206	
20.1	201.12.1, 206	The part relating to manufacturing is not addressed
20.2	201.12.1, 206	The part relating to manufacturing is not addressed

Essential principle of ISO 16142-1:2016, Annex B	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
21.1	201.7.9.2.1.101, 201.7.9.2.2.101, 211	
21.3	201.7.2.101	
21.4	201.7.2.101 b), 201.7.2.101 c)	
21.7	—	
f)	201.12.101	
k)	201.7.9.2.8.101, 201.7.9.2.14.101, 201.16	
l)	201.7.9.2.8.101	
n)	202	
21.9	—	
a)	201.7.9.2.2.101	
b)	202, 211	

Annex EE
(informative)

Reference to the general safety and performance requirements

Table EE.1 provides the clauses and subclauses of this document corresponding to the general safety and performance requirements given in regulation (EU) 2017/745[26].

NOTE When a general safety and performance requirement does not appear in Table EE.1, it means that it is not addressed by this document.

Table EE.1 — Correspondence between this document and the general safety and performance requirements

General safety and performance requirements of regulation (EU) 2017/745, Annex I[26]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
1	All	
2	206	
4	201.4, 201.4.3.101	
4 a)	201.4, 201.4.3.101	
4 b)	201.4, 201.4.3.101, 201.11.8.101, 201.12.4	
5 a)	201.12.1, 206	
6	All	
7	201.4	
8	201.4	
10.1 a)	201.11.7	Only the requirements related to toxicity are covered.
10.1 b)	201.11.7	This requirement is covered with respect to the *gas pathways*
10.1 d)	201.11.6.6	Covered for *normal use* including *cleaning*, *disinfection* and *sterilization*.
10.1 g)	201.11.6.6 bb)	Covered for *normal use* including *cleaning*, *disinfection* and *sterilization*.
10.1 h)	201.11.7, 201.12.1.101	Covered for *biocompatibility*, flowrate accuracy and concentration accuracy
10.2	201.7.9.2.12 aa), 201.11.6.6, 201.11.7	Only the part of GSPR 10.2 relating to design is addressed
10.3	201.11.6.6, 201.11.7	Only the part of GSPR 10.3 relating to design is addressed.
10.4.1	201.11.7	Only the part of GSPR 10.4 relating to design is addressed.

General safety and performance requirements of regulation (EU) 2017/745, Annex I[26]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
10.6	201.11.7	Only the part of GSPR 10.6 relating to design is addressed.
11.1	201.11.6	Only the part of GSPR 11.1 relating to design is addressed.
11.1 b)	201.11.6.6	Only the part of GSPR 11.1 relating to design is addressed.
11.1 c)	201.11.7	
11.1 d)	201.11.6.6	
11.2	201.11.6.6	
14.1	201.7.2.4.101, 201.7.9.2.14.101, 201.101, 201.102	
14.2 a)	201.9, 201.12.1, 201.12.4, 206	Only the part of GSPR 14.2 a) relating to design is addressed.
14.2 b)	202	Only the part of GSPR 14.2 b) relating to design is addressed.
14.2 f)	202	Only the part of GSPR 14.2 f) relating to design is addressed.
14.3	201.11	Only the part of GSPR 14.3 relating to design is addressed.
14.5	201.7.2.4.101, 201.7.9.2.14.101, 201.12.4.101, 201.16.101, 201.101. 201.102	Covered with respect to use with the listed *accessories*, connecting *accessories* and *operator*-detachable components and positioning of the *patient*-interface.
14.6	201.12.1, 206	
15.1	201.12.1	The part of GSPR 15.1 relating to stability is not addressed.
17.1	201.14	
17.2	201.14	
18.1	201.13	
18.2	201.11.8.101	
18.3	201.11.8.101	
18.5	202	
18.6	202	
18.7	201.8, 201.13	
18.8	201.12.101	
20.1	201.9.4.3.101, 211	
20.3	201.9.6.2.1.101	Only the part of GSPR 20.3 relating to design is addressed.
20.4	201.101, 201.102	
20.5	201.101, 201.104	Only the part of GSPR 20.5 relating to design is addressed.
20.6	201.11.1.2.2	

General safety and performance requirements of regulation (EU) 2017/745, Annex I[26]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
21.1	201.12.1, 201.12.1.101	Only the protection of the *patient* is covered.
21.2	201.12.4., 201.12.4.101, 201.12.4.102, 201.12.4.103, 201.12.4.104, 201.13	Only the first sentence of GSPR 21.2 is covered.
21.3	201.7.2.101, 201.12.1, 206	
22.1	201.12.1, 206	Only the requirements related to design are addressed.
22.2	201.12.1, 206	Only the requirements related to design are addressed.
22.3	201.7.9.2.8.101, 201.7.9.2.9.101.1, 206, 211	
23.1	211	
23.1 a)	201.7.9.2.1.101, 201.7.9.2.2.101, 206, 211	
23.1 b)	201.7.2.101	
23.1 g)	201.7.9.2.2.101	
23.1 h)	201.7.2.101 b), 201.7.2.101 c)	
23.4 e)	201.7.9.2.9.101	
23.4 f)	201.7.9.2.9.101, 201.7.9.2.14.101	
23.4 g)	201.7.9.2.2.101, 201.7.9.2.9.101	
23.4 h)	201.12.1	
23.4 k)	201.7.9.2.8.101	
23.4 n)	201.7.9.2.12 aa)	
23.4 q)	201.7.9.2.8.101, 201.7.9.2.14.101, 201.16	
23.4 s)	201.7.9.2.2.101, 202, 211	

Annex FF
(informative)

Terminology — Alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP) and the IEC Electropedia provide access to many of these terms and definitions.

Term	Source
accessory	IEC 60601-1:2005, 3.3
accompanying document	IEC 60601-1:2005, 3.4
accompanying information	ISO 20417:2021, 3.2
acknowledged	IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.37
airway device	201.3.201
airway pressure (P_{aw})	201.3.202
alarm condition	IEC 60601–1:2005+AMD1:2012 +AMD1:2020, 3.141
alarm limit	IEC 60601-1-8:2006, 3.3
alarm off	IEC 60601-1-8:2006, 3.4
alarm paused	IEC 60601-1-8:2006, 3.5
alarm settings	IEC 60601-1-8:2006, 3.8
alarm signal	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.142
alarm system	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.143
appliance coupler	IEC 60601-1:2005, 3.6
appliance inlet	IEC 60601-1:2005, 3.7
applied part	IEC 60601-1:2005, 3.8
audio off	IEC 60601-1-8:2006, 3.12
audio paused	IEC 60601-1-8:2006, 3.13
basic safety	IEC 60601-1:2005, 3.10
biocompatibility	ISO 18562-1:2017, 3.2
body temperature pressure, saturated	201.3.203
breathing system	201.3.204
breathing system filter	ISO 23328-2:2002, 3.1
breathing-therapy mode	ISO 19223:2019, 3.11.22
BSF	ISO 23328-2:2002, 3.1
BTPS	201.3.203
CDAS	IEC 60601-1-8:2006+AMD2:2020, 3.47
cleaning	ISO 17664:2017, 3.1

Term	Source
clearly legible	IEC 60601-1:2005+AMD1:2012, 3.15
continuous operation	IEC 60601-1:2005, 3.18
default alarm preset	IEC 60601-1-8:2006, 3.16
detachable power supply cord	IEC 60601-1:2005, 3.21
disinfection	ISO 17664:2017, 3.3
distributed alarm system	IEC 60601–1-8:2006+AMD1:2012+AMD2:2020, 3.17
emergency medical services environment	IEC 60601-1-12:2014, 3.1
enclosure	IEC 60601-1:2005, 3.26
essential performance	IEC 60601-1:2005+AMD1:2012, 3.27
essential principles	ISO 16142-1:2016, 3.3
essential principles of safety and performance	ISO 16142-1:2016, 3.3
exhaust port	201.3.205
expected service life	IEC 60601-1:2005+AMD1:2012, 3.28
false positive alarm condition	IEC 60601-1-8:2006, 3.21
flow-direction-sensitive component	201.3.206
fresh gas	201.3.207
functional connection	IEC 60601-1:2005, 3.33
gas intake port	201.3.208
gas output port	201.3.209
gas pathway	ISO 18562-1:2017, 3.5
harm	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.38
hazard	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.39
hazardous situation	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.40
healthcare professional	201.3.210
high-flow nasal cannula	201.3.211
high-pressure inlet	201.3.212
home healthcare environment	IEC 60601-1-11:2015, 3.2
humidifier	201.3.213
immunity	IEC 60601-1-2:2014, 3.8
information for safety	ISO 20417:2021, 3.9
information supplied by the manufacturer	ISO 20417:2021, 3.10
inlet connector	201.3.214
instructions for use	ISO 20417:2021, 3.11
intelligent alarm system	IEC 60601-1-8:2006, 3.24
intended use	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.44
internal electrical power source	IEC 60601-1:2005, 3.45

Term	Source
latching alarm signal	IEC 60601-1-8:2006, 3.26
lay	IEC 60601-1-11:2015, 3.3
low priority	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.151
mains connector	IEC 60601-1:2005, 3.48
manufacturer	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.55
marked	ISO 20417:2021, 3.17
marking	ISO 20417:2021, 3.17
mask	201.3.215
maximum limited pressure ($P_{lim,max}$)	201.3.216
ME equipment (medical electrical equipment)	IEC 60601-1:2005, 3.63
ME system (medical electrical system)	IEC 60601-1:2005, 3.64
mechanical hazard	IEC 60601-1:2005, 3.61
medical gas pipeline system	ISO 7396-1:2016, 3.36
medium priority	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.153
model or type reference	IEC 60601-1:2005, 3.66
monitoring equipment	201.3.217
nominal <value>	IEC 60601-1:2005, 3.69
normal condition	IEC 60601-1:2005, 3.70
normal use	IEC 60601-1:2005, 3.71
objective evidence	IEC 60601–1:2005+AMD1:2012+AMD 2:2020, 3.72
operator	IEC 60601-1:2005, 3.73
operator interface	IEC 60601-1-6:2010+A2:2020, 3.1
oxygen rich environment	IEC 60601-1:2005, 3.75
patient	IEC 60601-1:2005+AMD1:2012, 3.76
patient-connection port	201.3.218
PEMS (programmable electrical medical systems)	IEC 60601-1:2005, 3.90
portable	IEC 60601-1:2005+AMD1:2012, 3.85
power supply cord	IEC 60601-1:2005, 3.87
primary operating function	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.146
procedure	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.88
process	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.89
processing	ISO 17664:2017, 3.8
protection device	201.3.219
rated <value>	IEC 60601-1:2005, 3.97
residual risk	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.100
respiratory high-flow therapy equipment	201.3.220

Term	Source
responsibility accepted	IEC 60601-1-8:2006+AMD2:2020, 3.52
responsibility rejected	IEC 60601-1-8:2006+AMD2:2020, 3.53
responsible organization	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.101
risk	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.102
risk control	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.105
risk management	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.107
risk management file	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.108
service personnel	IEC 60601-1:2005, 3.113
single fault condition	IEC 60601-1:2005+AMD1:2012, 3.116
single use	ISO 20417:2021, 3.26
spontaneous breath rate	ISO 19223:20198, 3.5.1.3
standard temperature and pressure, dry	201.3.221
sterile	ISO 20417:2021, 3.28
sterilization	ISO 17664:2017, 3.17
STPD	201.3.221
supply mains	IEC 60601-1:2005, 3.120
symbol	ISO 20417:2021, 3.29
technical alarm condition	IEC 60601-1-8:2006, 3.36
technical description	ISO 20417:2021, 3.30
tool	IEC 60601-1:2005, 3.127
transit-operable	IEC 60601-1-11:2015, 3.6
usability	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.136
usability engineering	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.137
usability engineering file	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.147
use scenario	IEC 62366-1:2015, 3.22
validation (validated)	201.3.222
ventilation-mode	ISO 19223:2019, 3.11.2
ventilator	ISO 19223:2019, 3.1.1
ventilator-dependent	201.3.223
verification (verified)	IEC 60601-1:2005+AMD1:2012, 3.138

Bibliography

[1] ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

[2] ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

[3] ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

[4] ISO 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

[5] ISO 4135:2021, *Anaesthetic and respiratory equipment — Vocabulary and semantics*

[6] ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

[7] ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

[8] ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

[9] ISO 11195, *Gas mixers for medical use — Stand-alone gas mixers*

[10] ISO 14159, *Safety of machinery — Hygiene requirements for the design of machinery*

[11] ISO 15002, *Flow-metering devices for connection to terminal units of medical gas pipeline systems*

[12] ISO/TR 21954, *Guidance on the selection of the appropriate types of ventilatory equipment based on the intended patient population, use environment, and operator*

[13] ISO 80369-2:—[2], *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications*

[14] ISO 80601-2-12:2020, *Medical electrical equipment —Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

[15] ISO 80601-2-13:2011, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

[16] ISO 80601-2-70:2015, *Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*

[17] ISO 80601-2-72:2015, *Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

[18] ISO 80601-2-79:2018, *Medical Electrical Equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment*

[2] Under preparation. Stage at the time of publication: ISO/DIS 80369-2:2020.

[19] ISO 80601-2-80:2018, *Medical Electrical Equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency*

[20] ISO 80601-2-84:2020, *Medical Electrical Equipment — Part 2-84: Particular requirements for basic safety and essential performance of ventilators for the emergency medical services environment*

[21] ISO 80601-2-87:2021, *Medical electrical equipment — Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators*

[22] IEC 60601-1-3:2008, *Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment*

[23] IEC/TR 60878:2015, *Graphical symbols for electrical equipment in medical practice*

[24] IMDRF/GRRP WG/N47:2018 [3], *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*

[25] IMDRF/GRRP WG/N52:2019 [3], *Labeling Principles for Medical Devices and IVD Medical Devices*

[26] (EU) 2017/745, (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. *OJ L 117, Official Journal of the European Union,* pp. 1-175

[27] ALLNUTT, M.F. (1987) Human factors in accidents. *Br. J. Anaesth*. **59**, pp.856-864

[28] BAHAMMAM A.S., SINGH T.D., GUPTA R., PANDI-PERUMAL S.R., (2018) Choosing the proper interface for positive airway pressure therapy in subjects with acute respiratory failure. *Respir Care*. **63**(2), pp.227-237

[29] BROWER R.G., MATTHAY M.A., MORRIS A., SCHOENFELD D., THOMPSON B.T., WHEELER A., (2000) The Acute Respiratory Distress Syndrome Network, Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. *N Engl J Med*. **342**(18), pp.1301-1308

[30] DOLIDON, S., DUPUIS, J., MOLANO VALENCIA, L., SALAÜN, M., THIBERVILLE, L., MUIR, J-F, CUVELIER, A.,.PATOUT, M., Characteristics and outcome of patients set up on high-flow oxygen therapy at home. *Ther Adv Respir Dis*. Jan-Dec 2019;13:1753466619879794. doi: 10.1177/1753466619879794

[31] FROESE, A.B., High-Frequency Ventilation. In: *Principles and Practice of Mechanical Ventilation*, Second edition; (ed. *Tobin, M.J.*, MD), McGraw-Hill, New York. 2006, pp. 473-492. ISBN 0873894286

[32] GALLAGHER S., VERCRUYSSEN M., DENO N.*,* (1985) Hot air breathing: effects of elevated wet bulb temperatures on tissue temperatures of the mouth. *Am Ind Hyg Assoc J.* **46**(6). pp. 332-335

[33] HEDLEY-WHYTE J., PONTOPPIDAN H., MORRIS M.J. The response of patients with respiratory failure and cardiopulmonary disease to different levels of constant volume ventilation, *J Clin Invest*, **45**(10), 1966, pp. 1543-1554

[3] Available at http://www.imdrf.org/documents/documents.asp.

[34] KEILTY S.E., PONTE J., FLEMING T.A., et al (1994) Effect of inspiratory pressure support on exercise tolerance and breathlessness in patients with severe stable chronic obstructive pulmonary disease. *Thorax* **49**(10), pp.990-994

[35] KILLICK E., (1931) Physiological response to breathing hot air, Dept of Physiology, University of Leeds

[36] KUBICKA Z.J., LIMAURO J., DARNALL R.A. (2008) Heated, humidified high-flow nasal cannula therapy: yet another way to deliver continuous positive airway pressure? *Pediatrics*. **121**(1), pp. 82–88

[37] LELLOUCHE F, et al. (2004) Influence of ambient and ventilator output temperatures on performance of heated-wire humidifiers. *Am J Resp Crit Care* **170**(10), pp. 1073-1079

[38] MAURI T., TURRINI C., ERONIA N., GRASSELLI G., VOLTA C.A., BELLANI G., PESENTI A. (2017) Physiologic effects of high-flow nasal cannula in acute hypoxemic respiratory failure. *Am J Respir Crit Care Med*. **195**(9), pp.1207-1215

[39] MAZMANYAN et al. (2020) Mechanisms of nasal high flow therapy in newborns. *J Appl Physiol*. **128**(4) pp.822-829

[40] MECKLENBURGH, J.S., (1988) Construction of linear resistance units for a model lung. *Med and Biol Elect and Comp*, **26**, pp. 552-554

[41] MORITZ, A.R. AND HENRIQUES, F.C. JR., (1974). Studies of thermal injury I. The relative importance of time and surface temperature in the causation of cutaneous burns. *Am. J. Pathol*., **23**, pp. 695-720

[42] MOTOYASU A., MORIYAMA K., OKANO H., YOROZU T., (2019) High-flow nasal cannula therapy reduced the respiratory rate and respiratory distress in a standard model simulator and in patients with hypoxemic respiratory failure. *Chron Respir Dis*. 2019 Jan-Dec;16:1479973119880892

[43] NAGATA K, KIKUCHI T, HORIE T, SHIRAKI A, KITAJIMA T, KADOWAKI T, TOKIOKA F, CHOHNABAYASHI N, WATANABE A, SATO S, TOMII K. Domiciliary High-Flow Nasal Cannula Oxygen Therapy for Patients with Stable Hypercapnic Chronic Obstructive Pulmonary Disease. A Multicenter Randomized Crossover Trial. *Ann Am Thorac Soc*. 2018 **15**(4). pp.432-439

[44] REA H, MCAULEY S, JAYARAM L, GARRETT J, HOCKEY H, STOREY L, O'DONNELL G, HARU L, PAYTON M, O'DONNELL K. The clinical utility of long-term humidification therapy in chronic airway disease. *Respir Med*. 2010 **104**(4), pp.525-533

[45] Report of the Naval Medical Research and Development Command, Physiological Design Goals for Thermal Protection for Divers, Conference report of 5 September 1980

[46] ROHR et al. (2016) Evidence Support and Guidelines for Using Heated, Humidified, High-Flow Nasal Cannulae in Neonatology. *Clin Perinatol*. **43**(4) pp.693-705

[47] STORGAARD LH, HOCKEY HU, LAURSEN BS, WEINREICH UM. Long-term effects of oxygen-enriched high-flow nasal cannula treatment in COPD patients with chronic hypoxemic respiratory failure. *Int J Chron Obstruct Pulmon Dis*. 2018 **16**(13), pp.1195-1205

[48] STROTHER G.K., *Physics, with applications in life sciences*, Houghton Mifflin Co., USA, 1977, pp. 71-73

[49] WILKINSON D.J., ANDERSEN C.C., SMITH K., HOLBERTON J.. (2008) Pharyngeal pressure with high-flow nasal cannulae in premature infants. *J Perinatol*. **28**(1), pp. 42–47

[50] YODER et al. (2014) Consensus approach to nasal high-flow therapy in neonates. *J Perinatol*. **37**(7) pp.809-813

ICS 11.040.10

Price based on 89 pages