



BSI Standards Publication

## Medical electrical equipment

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Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment

## National foreword

This British Standard is the UK implementation of EN ISO 80601-2-79:2019. It is identical to ISO 80601-2-79:2018. It supersedes BS ISO 80601-2-79:2018, which is withdrawn. Together with BS EN ISO 80601-2-80:2019, it supersedes BS EN ISO 10651-6:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Published by BSI Standards Limited 2019

ISBN 978 0 539 12082 0

ICS 11.040.10

**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2019.

### Amendments/corrigenda issued since publication

| Date              | Text affected                                                                                              |
|-------------------|------------------------------------------------------------------------------------------------------------|
| 30 September 2019 | This corrigendum renumbers BS ISO 80601-2-79:2018 as BS EN ISO 80601-2-79:2019                             |
| 30 November 2019  | Implementation of CEN correction notice 30 October 2019: Supersession added in CEN title page and foreword |
| 30 November 2019  | Supersession details updated                                                                               |

English Version

**Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment (ISO 80601-2-79:2018)**

Appareils électromédicaux - Partie 2-79: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'assistance ventilatoire en cas de trouble ventilatoire (ISO 80601-2-79:2018)

Medizinische elektrische Geräte - Teil 2-79: Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten zur Atemunterstützung von Patienten mit Atmungsbeeinträchtigungen (ISO 80601-2-79:2018)

This European Standard was approved by CEN on 28 July 2019.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 30 October 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

## European foreword

The text of ISO 80601-2-79:2018 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 80601-2-79:2019 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2020, and conflicting national standards shall be withdrawn at the latest by March 2020.

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

This document supersedes l'EN ISO 10651-6:2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 80601-2-79:2018 has been approved by CEN as EN ISO 80601-2-79:2019 without any modification.

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## Foreword

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

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

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

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

ISO 80601-2-79 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-79, in combination with ISO 80601-2-80<sup>[1]</sup>, cancels and replaces ISO 10651-6:2004<sup>[2]</sup>. This edition of ISO 80601-2-79 constitutes a major technical revision of ISO 10651-6:2004 and includes an alignment with the third edition of IEC 60601-1, the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, the second edition of IEC 60601-1-8 and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

- splitting the scope of ISO 10651-6:2004<sup>[2]</sup> into two parts:
  - one for VENTILATORY IMPAIRMENT, also known as RESPIRATORY IMPAIRMENT, (this document) and
  - one for VENTILATORY INSUFFICIENCY, also known as RESPIRATORY INSUFFICIENCY (ISO 80601-2-80);
- extending the scope to include the VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT, and thus not the VENTILATORY SUPPORT EQUIPMENT itself;
- identification of ESSENTIAL PERFORMANCE for VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES;

and the following additions:

- tests for ventilation performance;

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<sup>1</sup> Numbers in square brackets refer to the Bibliography.

- tests for mechanical strength (via IEC 60601-1-11);
- new symbols;
- requirements for VENTILATORY SUPPORT EQUIPMENT as a component of an ME SYSTEM;
- tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11);
- tests for CLEANING and DISINFECTION PROCEDURES (via IEC 60601-1-11);
- consideration of contamination of the breathing gas delivered to the PATIENT from the GAS PATHWAYS.

## Introduction

This document specifies requirements for VENTILATORY SUPPORT EQUIPMENT that is intended for use in the HOME HEALTHCARE ENVIRONMENT for PATIENTS who are not dependent on ventilation for their life support. VENTILATORY SUPPORT EQUIPMENT is frequently used in locations where SUPPLY MAINS is not reliable. VENTILATORY SUPPORT EQUIPMENT is often supervised by non-healthcare personnel (LAY OPERATORS) with varying levels of training. VENTILATORY SUPPORT EQUIPMENT complying with this document can be used elsewhere (i.e. in healthcare facilities).

Ventilatory support is often needed for PATIENTS who have stable ventilatory needs. This document addresses PATIENTS who have significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the PATIENT. This is best characterized by lung functions not worse than<sup>[3]</sup>:

- $FEV_1/FVC^2 < 70 \%$ ; or
- $50 \% \leq FEV_1 < 80 \%$  predicted

where

$FEV_1$  is the forced expiratory volume in 1 s, and

$FVC$  is the forced vital capacity.

Examples of diseases that require ventilation support are

- mild to moderate Chronic Obstructive Pulmonary Disease (COPD);
- neuromuscular/ amyotrophic lateral sclerosis (ALS);
- obese PATIENTS Obese Hypoventilation Syndrome (OHS);
- Cheyne–Stokes respiration (CSR/CSA).

CSR/CSA is an abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decrease that results in a temporary stop in breathing called an apnoea. The pattern repeats, with each cycle usually taking 30 s to 2 min.

Cardiac PATIENTS with CSR/CSA might be breathless without having significant reduction in  $FEV_1$ . Reducing the work of breathing can help normalize their breathing.

This VENTILATORY SUPPORT EQUIPMENT is intended for PATIENTS who are spontaneously breathing and do not require ventilation for life support or intermittent periods of ventilation to maintain vital signs. VENTILATORY SUPPORT EQUIPMENT intended for this group of PATIENTS typically does not require PHYSIOLOGICAL ALARM CONDITIONS as no ESSENTIAL PERFORMANCE exists. These PATIENTS can gain adequate relief from fatigue related to the work of breathing by using VENTILATORY SUPPORT EQUIPMENT during the night and while taking breaks during the day. This can enable a PATIENT with VENTILATORY IMPAIRMENT to continue to move about and participate in the activities of daily living. Non-TRANSIT-OPERABLE VENTILATORY SUPPORT EQUIPMENT that provides ventilatory support at the bedside and beside a chair or other resting place should be adequate in this application.

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

In this document, the following print types are used:

- Requirements and definitions: roman type;

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<sup>2</sup> This is also known as the Tiffeneau-Pinelli index.

- *Test specifications: italic type;*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type; normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD<sup>3</sup>, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- “clause” means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8);
- “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

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

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

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- “may” is used to describe permission (e.g. a permissible way to achieve compliance with a requirement or test);
- “can” is used to describe a possibility or capability; and
- “must” is used express an external constraint.

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

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

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<sup>3</sup> The general standard is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

## Medical electrical equipment

Part 2-79:

### Particular requirements for the basic safety and essential performance of ventilatory support equipment for ventilatory impairment

#### 201.1 Scope, object and related standards

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

##### 201.1.1 \* Scope

*Replacement:*

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of VENTILATORY SUPPORT EQUIPMENT, as defined in 201.3.205, for VENTILATORY IMPAIRMENT, as defined in 201.3.202, hereafter also referred to as ME EQUIPMENT, in combination with its ACCESSORIES:

- intended for use in the HOME HEALTHCARE ENVIRONMENT;
- intended for use by a LAY OPERATOR; and
- intended for use with PATIENTS who have VENTILATORY IMPAIRMENT, the most fragile of these PATIENTS, would not likely experience injury with the loss of this artificial ventilation; and
- not intended for PATIENTS who are dependent on artificial ventilation for their immediate life support.

EXAMPLE 1 PATIENTS with mild to moderate chronic obstructive pulmonary disease (COPD).

NOTE 1 In the HOME HEALTHCARE ENVIRONMENT, the SUPPLY MAINS is often not reliable.

NOTE 2 Such VENTILATORY SUPPORT EQUIPMENT can also be used in non-critical care applications of professional health care facilities.

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to the BREATHING SYSTEM of VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT.

EXAMPLE 2 Breathing sets, connectors, water traps, expiratory valve, HUMIDIFIER, BREATHING SYSTEM FILTER, external electrical power source, DISTRIBUTED ALARM SYSTEM.

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

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

NOTE 3 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for:

- VENTILATORS or ACCESSORIES for VENTILATOR-DEPENDENT PATIENTS intended for critical care applications, which are given in ISO 80601-2-12;
- VENTILATORS or ACCESSORIES intended for anaesthetic applications, which are given in ISO 80601-2-13<sup>[4]</sup>;
- VENTILATORS or ACCESSORIES intended for the emergency medical services environment, which are given in ISO 80601-2-84 <sup>[5]</sup> 4, the future replacement for ISO 10651-3<sup>[6]</sup>;
- VENTILATORS or ACCESSORIES intended for VENTILATOR-DEPENDENT PATIENTS in the HOME HEALTHCARE ENVIRONMENT, which are given in ISO 80601-2-72;
- VENTILATORY SUPPORT EQUIPMENT or ACCESSORIES intended for VENTILATORY INSUFFICIENCY, which are given in ISO 80601-2-80<sup>[1]</sup>;
- sleep apnoea therapy ME EQUIPMENT, which are given in ISO 80601-2-70<sup>[7]</sup>;
- continuous positive airway pressure (CPAP) ME EQUIPMENT;
- high-frequency jet VENTILATORS (HFJVs);
- high-frequency oscillatory VENTILATORS (HFOVs)<sup>[8]</sup>;
- oxygen therapy constant flow ME EQUIPMENT;
- cuirass or “iron-lung” ventilation equipment.

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

## 201.1.2 Object

### *Replacement:*

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for VENTILATORY SUPPORT EQUIPMENT, as defined in 201.3.205, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the VENTILATORY SUPPORT EQUIPMENT and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT.

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<sup>4</sup> Under preparation. Stage at the time of publication: ISO/DIS 80601-2-84:2017.

### 201.1.3 Collateral standards

*Addition:*

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

IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013, and IEC 60601-1-11:2015 apply as modified in Clauses 202, 206 and 211 respectively. IEC 60601-1-3<sup>[26]</sup> 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 may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

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

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx”, where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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

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

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

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

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

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

## 201.2 Normative references

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

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

NOTE 2 Informative references are listed in the Bibliography.

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

*Replacement:*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010<sup>5</sup>, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability +Amendment 1:2013+Amendment 1:2013*

IEC 60601-1-8:2006<sup>6</sup>, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems+Amendment 1:2012*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

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 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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

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

ISO 8836:2014, *Suction catheters for use in the respiratory tract*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

<sup>5</sup> There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

<sup>6</sup> There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and its Amendment 1:2012.

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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 17510:2015, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

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

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

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 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-7:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80601-2-12:—<sup>7</sup>, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

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*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005<sup>8</sup>, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance +Amendment 1:2012*

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

EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

<sup>7</sup> To be published. Stage at time of publication ISO/FDIS 80601-2-12:2018.

<sup>8</sup> There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1:2012.

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, ISO 7396-1:2016, ISO 8836:2014, ISO 9000:2015, ISO 9360-1:2000, ISO 16142-1:2016, ISO 17510:2015, ISO 17664:2017, ISO 18562-1:2017, ISO 23328-2:2002, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-11:2015, IEC 62366-1:2015, ISO 80601-2-12:—, ISO 80601-2-72:2015, ISO 80601-2-74:2017 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 DD.

### 201.3.201

#### HEALTHCARE PROFESSIONAL

term referring to an individual with relevant specialized 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 VENTILATORY SUPPORT EQUIPMENT.

[SOURCE: ISO 80601-2-12:—, definition 201.3.210, modified — added note.]

### 201.3.202

#### VENTILATORY IMPAIRMENT

#### RESPIRATORY IMPAIRMENT

clinically significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the PATIENT

Note 1 to entry: PATIENTS with VENTILATORY IMPAIRMENT exhibit a minimal level of illness acuity, fragility, or instability. Their dependence on the VENTILATORY SUPPORT EQUIPMENT to maintain adequate gas exchange is minimal. Without such support as needed, these PATIENTS would likely experience some difficulty with activities that they might normally pursue and this might interfere with daily living. Without ventilatory support as needed, these PATIENTS are likely to experience short periods of abnormal lung gas exchange which can result in them becoming more sedentary.

EXAMPLE PATIENTS with mild to moderate chronic obstructive pulmonary disease (COPD).

Note 2 to entry: VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT is suitable for use where PHYSIOLOGICAL ALARM CONDITION monitoring is usually not required because the absence or degradation of the ventilatory support is not likely to cause injury to the PATIENT (i.e. VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT has no ESSENTIAL PERFORMANCE).

### 201.3.203

#### VENTILATORY INSUFFICIENCY

#### RESPIRATORY INSUFFICIENCY

degradation in respiratory function severe enough to prohibit certain activities that the PATIENT might normally pursue, and to interfere with daily living; occurring in association with measurements of respiratory mechanics or gas exchange that are markedly abnormal

Note 1 to entry: PATIENTS with VENTILATORY INSUFFICIENCY exhibit an illness acuity, fragility or instability level up to and including a moderate to severe degradation in respiratory function. Their dependence on the VENTILATORY SUPPORT EQUIPMENT to maintain adequate gas exchange can range from minimal to moderate dependence. Without such support, the most fragile of these PATIENTS would likely be prohibited from certain activities that they might normally pursue and this would likely interfere with their daily living. The most fragile of these PATIENTS would likely experience injury with the loss of this artificial ventilation.

EXAMPLES PATIENTS with moderate to severe chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia and muscular dystrophy.

Note 2 to entry: VENTILATORY SUPPORT EQUIPMENT for RESPIRATORY INSUFFICIENCY is suitable for use where some PHYSIOLOGICAL ALARM CONDITION monitoring is required to prevent the absence or degradation of the ventilatory support, which in turn could cause the compromise of the health of the PATIENT.

[SOURCE: ISO 80601-2-80:2018<sup>[1]</sup>, definition 201.3.204]

### **201.3.204**

#### **VENTILATOR**

##### **VENTILATOR FOR VENTILATOR-DEPENDENT PATIENT**

ME EQUIPMENT intended to augment or provide ventilation of the lungs of a PATIENT who is dependent on this ventilation in the HOME HEALTHCARE ENVIRONMENT

Note 1 to entry: For the purposes of this part of ISO 80601, dependent means needed for the majority of the day (e.g. an average need of more than 16 h of ventilation per day).

Note 2 to entry: A VENTILATOR FOR VENTILATOR-DEPENDENT PATIENT is typically used without continuous HEALTHCARE PROFESSIONAL supervision.

Note 3 to entry: As this VENTILATOR is intended to be applied to PATIENTS who are VENTILATOR-DEPENDENT, the VENTILATOR is considered to be a life-sustaining ME EQUIPMENT or ME SYSTEM.

[SOURCE: ISO 80601-2-72:2015, definition 201.3.217, modified, replaced 'supporting' with 'sustaining'.]

### **201.3.205**

#### **VENTILATORY SUPPORT EQUIPMENT**

ME EQUIPMENT, suitable for domiciliary use without continuous professional supervision, intended to augment or provide ventilation of the lungs of a PATIENT who is not VENTILATOR-DEPENDENT

Note 1 to entry: VENTILATORY SUPPORT EQUIPMENT is a type of VENTILATOR, but is not a VENTILATOR for VENTILATOR-DEPENDENT PATIENT.

Note 2 to entry: A PATIENT suitable for VENTILATORY SUPPORT EQUIPMENT requires a narrow spectrum of ventilation modalities and monitoring for appropriate management.

[SOURCE: ISO 80601-2-80:2018<sup>[1]</sup>, definition 201.3.205]

## **201.4 General requirements**

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

### **201.4.3 ESSENTIAL PERFORMANCE**

*Additional subclause:*

**201.4.3.101 \* Additional requirements for ESSENTIAL PERFORMANCE**

- a) For the purposes of this document, VENTILATORY SUPPORT EQUIPMENT FOR VENTILATORY IMPAIRMENT is considered not to have ESSENTIAL PERFORMANCE. Notwithstanding this fact, when this document refers to ESSENTIAL PERFORMANCE as acceptance criteria, the continuous pressure shall be evaluated.
- b) The method of subclause 202.8.1.101 may be used to evaluate continuous pressure as an acceptance criterion following specific tests required by this document.

NOTE A continuous pressure mode is often referred to as a continuous positive airway pressure (CPAP) mode.

**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 VBS 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.

*Additional subclauses:*

**201.4.11.101 \* Additional requirements for pressurized gas input**

**201.4.11.101.1 Overpressure requirement**

- a) If the VENTILATORY SUPPORT EQUIPMENT is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1, then it:
  - 1) shall operate and meet the requirements of this part of ISO 80601 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 necessary 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 VBS. Under this condition, the flowrate from the VENTILATORY SUPPORT EQUIPMENT is likely to be outside of its specification.

- b) If the VENTILATORY SUPPORT EQUIPMENT has a maximum RATED input pressure in excess of 600 kPa, the VENTILATORY SUPPORT EQUIPMENT shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of twice the maximum RATED input pressure.

*Check compliance 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 VENTILATORY SUPPORT EQUIPMENT is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1, then

- a) the RATED range of input pressure shall cover the range specified in ISO 7396-1, and
- b) under NORMAL CONDITION,
  - 1) the maximum 10 s average input flowrate required by the VENTILATORY SUPPORT EQUIPMENT for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas input 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 VENTILATORY SUPPORT EQUIPMENT for each gas at a pressure of 280 kPa, measured at the gas input port;
  - ii) the maximum transient input flowrate averaged for 3 s required by the VENTILATORY SUPPORT EQUIPMENT for each gas at a pressure of 280 kPa, measured at the gas input port; and
  - iii) a warning to the effect that this ventilator 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 flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of adjacent equipment.

*Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings and by inspection of the ACCOMPANYING DOCUMENTS.*

EXAMPLE The highest driving gas consumption, the highest FRESH GAS delivery, and, if provided, the highest RATED gas consumption at any gas power supply output can be the most adverse conditions.

## 201.5 General requirements for testing of ME EQUIPMENT

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

*Additional subclauses:*

### 201.5.101 \* Additional requirements for the general requirements for testing of ME EQUIPMENT

#### 201.5.101.1 VENTILATORY SUPPORT EQUIPMENT test conditions

- a) For testing, the VENTILATORY SUPPORT 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 VENTILATORY SUPPORT EQUIPMENT intended to be connected to a gas supply in NORMAL USE (e.g. MEDICAL GAS PIPELINE SYSTEM or medical gas cylinder).

#### 201.5.101.2 \* Gas flowrate and leakage specifications

In this document, requirements for the flowrate, volume and leakage are expressed at STANDARD TEMPERATURE AND PRESSURE, DRY (STPD), except for those associated with the VBS, which are expressed at BODY TEMPERATURE AND PRESSURE, SATURATED (BTPS).

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

#### 201.5.101.3 \* VENTILATORY SUPPORT EQUIPMENT testing errors

- a) For the purposes of this document, declared tolerances shall include the measurement uncertainty.

- b) The MANUFACTURER shall disclose the measurement uncertainty of each disclosed tolerance in the technical description.

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

## **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

IEC 60601-1:2005+AMD1:2012, Clause 6, applies.

## **201.7 ME EQUIPMENT identification, marking and documents**

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

*Additional subclauses:*

### **201.7.2.4.101 Additional requirements for ACCESSORIES**

- a) ACCESSORIES supplied separately shall
- 1) fulfil the requirements of 201.7.2.13.101, 201.7.2.17.101 and 201.7.2.101, and
  - 2) be marked with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT, if applicable.

- b) 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 VENTILATORY SUPPORT EQUIPMENT MANUFACTURER or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to ensure compliance with this requirement. Additional requirements are found in 201.102.

*Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any limitations or adverse effects of the ACCESSORY.*

### **201.7.2.13.101 Additional requirements for physiological effects**

- a) Any natural rubber latex-containing components or ACCESSORIES in the GAS PATHWAYS shall be marked as containing latex.
- b) Such marking shall be CLEARLY LEGIBLE.
- c) Symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 4) may be used.
- d) The instructions for use shall disclose any natural rubber latex-containing components.

*Check compliance by inspection.*

### **201.7.2.17.101 Additional requirements for protective packaging**

- a) The marking on packages shall be CLEARLY LEGIBLE and shall include:
- 1) a description of the contents;
  - 2) an identification reference to the batch, type or serial number or symbols 5.1.5, 5.1.6 or 5.1.7 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 1, symbol 2 or symbol 3);
  - 3) for packages containing natural rubber latex, the word "LATEX", or symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 4);
- b) For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent for the MODEL OR TYPE REFERENCE.

*Check compliance by inspection.*

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

- a) The marking of ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:
  - 1) any particular warnings or precautions relevant to the immediate operation of the VENTILATORY SUPPORT EQUIPMENT.
- b) If applicable, marking of OPERATOR-detachable ME EQUIPMENT parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:
  - 1) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL;
  - 2) a warning not to obstruct the GAS INTAKE PORT.

EXAMPLE      WARNING: Gas Intake – Do not obstruct.

*Check compliance by inspection.*

#### **201.7.4.2 Control devices**

IEC 60601-1:2005+AMD1:2012, 7.4.2, applies, except as follows:

*Amendment (add after the second dash):*

- aa) The marking of the trigger sensitivity control, if provided, shall be such that the minimum (least PATIENT effort) and the maximum (greatest PATIENT effort) settings are self-evident to the OPERATOR.
- bb) The marking, if numeric, shall:
  - 1) use the lowest number to represent the setting for the least PATIENT effort; and
  - 2) not only be numeric.

#### **201.7.4.3 \* Units of measurement**

IEC 60601-1:2005+AMD1:2012, 7.4.3, applies, except as follows:

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

- aa) All gas volume, flowrate and leakage specifications:
  - 1) shall be expressed at STPD (STANDARD TEMPERATURE AND PRESSURE, DRY);
  - 2) except those associated with the VBS which shall be expressed at BTPS (BODY TEMPERATURE AND PRESSURE, SATURATED).
- bb) The unit of AIRWAY PRESSURE measurement shall be capable of being configured to be expressed in hPa.

#### **201.7.9.1 Additional general requirements**

IEC 60601-1:2005+AMD1:2012, 7.9.1, applies, except as follows:

*Amendment (replace the first dash with):*

- name or trade name and address of the MANUFACTURER; and
- where the manufacturer does not have an address within the locale, an authorized representative within the locale to which the responsible organization can refer.

### 201.7.9.2 Instructions for use

IEC 60601-1:2005+AMD1:2012, 7.9.2, applies, except as follows:

*Additional subclauses:*

#### 201.7.9.2.1.101 Additional general requirements

- a) 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 compliance by inspection of the instructions for use, the RISK MANAGEMENT FILE and the USABILITY ENGINEERING FILE.*

#### 201.7.9.2.1.102 Additional general requirements

The instructions for use shall:

- a) if the VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES are intended for single use, information on characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES were reused;
- b) if the VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES are intended for single use, information regarding
  - 1) the intended duration of use; and
  - 2) the consequences for the PATIENT if use is beyond the specified duration of use.

*Check compliance by inspection.*

#### 201.7.9.2.2.101 \* Additional requirements for warnings and safety notices

The instructions for use shall include:

- a) a warning statement to the effect that "WARNING: Do not cover the ventilator 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 ventilator to overheat.

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

EXAMPLE 3      WARNING: When using the ventilator in a carrying case, only use a carrying case that is listed in the instructions for use, to prevent the ventilator from overheating or interfering with patient ventilation.

- b) \* a warning statement to the effect that "WARNING: Do not add any attachments or accessories to the ventilator that are not intended for use in combination with the ventilator, as stated in the instructions for use of the ventilator or accessory as the ventilator might not function correctly leading to the risk of degradation or loss of ventilatory support."

- c) \* if the instructions for use include a VBS configuration with a BSF exposed to the humidity from nebulisation or humidification, a warning statement to the effect that “WARNING: When using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage.”
- d) a warning statement to the effect that “WARNING: This ventilator is not suitable for a ventilator-dependent patient.”

*Check compliance 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 VENTILATORY SUPPORT EQUIPMENT is ready for use.

- a) 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 provided, 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 all functions and settings necessary for NORMAL USE can be functionally 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) Portions of this test method may be performed automatically by the VENTILATORY SUPPORT EQUIPMENT or may require OPERATOR action.
    - ii) This test method should be as automated as practicable.

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

#### **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
  - 1) the conditions under which the VENTILATORY SUPPORT 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.
  - 2) a statement to the effect that “Do not use the ventilator at an altitude above [insert maximum RATED altitude] or outside a temperature of [insert RATED temperature range]. Using the ventilator outside of this temperature range or above this altitude can compromise the ventilator performance”;

- 3) a statement to the effect that “To reduce the likelihood of disconnection and to prevent adverse ventilator performance use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories”;
  - 4) if applicable, a statement to the effect that “The ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser.”
- b) The instructions for use intended for the LAY OPERATOR shall include
- 1) a description of a means to determine the operation time of the INTERNAL ELECTRICAL POWER SOURCE, if provided,
  - 2) a description of how to connect and test the connection of a DISTRIBUTED ALARM SYSTEM, if provided.

*Check compliance 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 ventilation modes provided by the VENTILATORY SUPPORT EQUIPMENT including, but not limited to, the following items:
- 1) the working principle of each of the VENTILATORY SUPPORT EQUIPMENT’S ventilation modes, including waveforms;
  - 2) the methods for controlling the cycling;
  - 3) the parameter settings;
  - 4) the range of parameter settings; and
  - 5) any limitation of parameter settings.
- b) The instructions for use intended for the HEALTHCARE PROFESSIONAL OPERATOR shall include
- 1) the RATED range of the following characteristics of the assembled OPERATOR-detachable parts of the VBS, over which the accuracies of set and monitored volumes and pressures are maintained:
    - i) inspiratory GAS PATHWAY resistance;
    - ii) expiratory GAS PATHWAY resistance; and
    - iii) compliance.
  - 2) the intended range of DELIVERED VOLUME.
- c) These specifications may be presented in ranges.
- d) The accuracies of set and monitored volumes may be presented as a function of these characteristics.
- NOTE Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min, maximum flowrate or the maximum pressure).
- e) If applicable, instructions for use intended for the HEALTHCARE PROFESSIONAL OPERATOR shall disclose
- 1) the essential technical characteristics of each recommended BREATHING SYSTEM FILTER.

EXAMPLES      Dead space and resistance.

*Check compliance by inspection of the instructions for use.*

#### **201.7.9.2.12 CLEANING, DISINFECTION, and STERILIZATION**

IEC 60601-1:2005+AMD1:2012, 7.9.2.12, applies, except as follows:

*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 VENTILATORY SUPPORT EQUIPMENT that can become contaminated with body fluids or by microbial material conveyed by the expired breathing gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

*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 provided, the care and maintenance PROCEDURES for the INTERNAL ELECTRICAL POWER SOURCE, including instructions for recharging and, if applicable, replacement.

*Check compliance by inspection of the instructions for use.*

#### **201.7.9.2.14.101 \* Additional requirements for ACCESSORIES, supplementary equipment, used material**

If applicable, the instructions for use shall disclose

- a) any restrictions on the positioning of components within the VENTILATOR BREATHING SYSTEM,

EXAMPLE      Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.

- b) any adverse effect of any recommended ACCESSORY on the ESSENTIAL PERFORMANCE or BASIC SAFETY of the VENTILATORY SUPPORT EQUIPMENT.

*Check compliance 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) a summary description of the filtering or smoothing techniques for measured or computed variables that are displayed or used for control necessary for the OPERATOR to form a mental model of the operation of the VENTILATORY SUPPORT EQUIPMENT;
- b) the interdependence of control functions;
- c) a pneumatic diagram of the VENTILATORY SUPPORT EQUIPMENT, including a diagram for OPERATOR-detachable parts of the VENTILATOR BREATHING SYSTEM either supplied or recommended in the instructions for use;
- d) a summary description of the means of initiating and terminating the inspiratory phase while the VENTILATORY SUPPORT EQUIPMENT is operating in each of its ventilatory modes;

- e) a statement to the effect that prior to use the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories with which the ventilator is intended to be used.

*Check compliance by inspection of the technical description.*

## **201.8 Protection against electrical HAZARDS from ME EQUIPMENT**

IEC 60601-1:2005+AMD1:2012, Clause 8, applies.

## **201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**

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

*Additional subclause:*

### **201.9.4.3.101 Additional requirements for instability from unwanted lateral movement**

- a) TRANSIT-OPERABLE VENTILATORY SUPPORT EQUIPMENT shall include a means by which the VENTILATORY SUPPORT EQUIPMENT can be secured without the use of a TOOL to prevent unwanted movement during transport while in use.
- b) The means shall secure the VENTILATORY SUPPORT EQUIPMENT to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 5 s each.

**EXAMPLES** Means to restrain physically the VENTILATORY SUPPORT EQUIPMENT during transport in a personal vehicle, in an ambulance or on a wheelchair.

*Check compliance by functional testing.*

### **201.9.4.4 Grips and other handling devices**

*Amendment (replace list item b) with):*

- b) TRANSIT-OPERABLE VENTILATORY SUPPORT EQUIPMENT shall be designed either:
- 1) with a handle that does not require more than one hand; or
  - 2) to be used with a carrying case or in-use bag.

*Check compliance by carrying with one hand.*

*Additional subclauses:*

### **201.9.6.2.1.101 Additional requirements for audible acoustic energy**

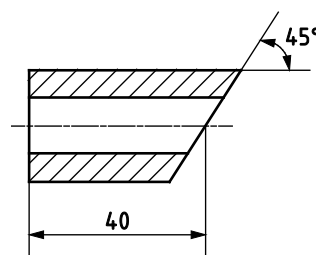
- a) The A-weighted sound pressure level emitted by the VENTILATORY SUPPORT EQUIPMENT shall be measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2 and disclosed in the instructions for use.
- b) The A-weighted sound power level shall be calculated according to 8.1 of ISO 3744:2010 and disclosed in the instructions for use.

*Check compliance with the following test.*

- c) Place the VENTILATORY SUPPORT EQUIPMENT on a sound-reflecting plane and attach the least favourable VBS from those indicated in the instructions for use.

**NOTE** The least favourable VBS configuration can vary by mode, breath type and flow pattern, as applicable.

- d) If a HUMIDIFIER is provided with or specified in the ACCOMPANYING DOCUMENTS of the VENTILATORY SUPPORT EQUIPMENT, include the HUMIDIFIER in the test and fill to the least favourable level.
- e) Connect the standard resistance, 40 mm length and outlet angle of 45° (as indicated in Figure 201.101) to the PATIENT-CONNECTION PORT.
- f) Acoustically isolate the BREATHING TUBES and the standard resistance out of the testing area such that the noise of the gas flowing through the BREATHING TUBES and exiting the standard resistance does not interfere with the sound measurement of the VENTILATORY SUPPORT EQUIPMENT.
- g) Set the VENTILATORY SUPPORT EQUIPMENT to a mode that generates a continuous pressure of 10 hPa (10 cmH<sub>2</sub>O) at the PATIENT-CONNECTION PORT.
- h) Using a microphone of a sound level meter, complying with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the sound pressure levels at 10 positions in a hemisphere with a radius from the geometric centre of the VENTILATORY SUPPORT EQUIPMENT as specified in 7.2 of ISO 3744:2010.
- i) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.1 of ISO 3744:2010.
- j) Calculate the A-weighted sound power level according to 8.6 of ISO 3744:2010.
- k) Confirm that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.
- l) Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter in a free field over a reflecting plane as specified in ISO 3744:2010. Average the values in accordance with 8.1 of ISO 3744:2010.
- m) Repeat d) to l) for each HUMIDIFIER provided with or specified in the ACCOMPANYING DOCUMENTS.
- n) Ensure that the measured sound pressure level is less than that disclosed in the instructions for use.



NOTE The internal diameter is 4 mm.

Figure 201.101 — Standard resistance

## 201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+AMD1:2012, Clause 10, applies.

## 201.11 Protection against excessive temperatures and other HAZARDS

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

### 201.11.1.2.2 \* APPLIED PARTS not intended to supply heat to a PATIENT