INTERNATIONAL STANDARD

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Medical electrical equipment —

Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

Appareils électromédicaux —
Partie 2-80: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'assistance ventilatoire en cas d'insuffisance ventilatoire

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Foreword

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

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

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

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

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

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

This first edition of ISO 80601-2-80, in combination with ISO 80601-2-79[1]1, cancels and replaces the second edition of ISO 10651-6:2004[2]. This edition of ISO 80601-2-80 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[2] into two parts:

  — one for ventilatory impairment, also known as respiratory impairment (ISO 80601-2-79);

  — one for ventilatory insufficiency, also known as respiratory insufficiency (this document);

— 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 only the VENTILATORY SUPPORT EQUIPMENT itself;

1 Numbers in square brackets refer to the Bibliography.

— identification of ESSENTIAL PERFORMANCE for VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES;

and the following additions:

— tests for ventilation performance;

— tests for mechanical strength (via IEC 60601-1-11);

— requiring capable of TRANSIT-OPERABLE use;

— 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 for 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).

Varying levels of ventilatory support are needed for PATIENTS who have stable ventilatory needs and in some cases, changing needs as their disease worsens. This document addresses PATIENTS who typically have severe enough respiratory function 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. This is best characterised by lung functions worse than[3]

— FEV_1/FVC[2] < 70 %, or

— FEV_1 < 50 % 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 severe Chronic Obstructive Pulmonary Disease (COPD), Amyotrophic Lateral Sclerosis (ALS)[4], severe bronchopulmonary dysplasia and muscular dystrophy. VENTILATORY SUPPORT EQUIPMENT intended for this group of PATIENTS typically can require TECHNICAL ALARM CONDITIONS in the event that ESSENTIAL PERFORMANCE is absent. The most fragile of these PATIENTS would likely experience injury, but not serious injury or death, with the loss of this artificial ventilation. For these PATIENTS, it is likely that ventilatory support is needed during waking hours while PATIENTS are moving inside or outside the home in order to facilitate mobility and functional independence in the activities of daily living.

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

In this document, the following print types are used:

— requirements and definitions: roman type;

— *test specifications: italic type*;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD[3], IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

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

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[2] This is also known as the Tiffeneau-Pinelli index.

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

— “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;

— "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.

Medical electrical equipment

Part 2-80:
Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

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 INSUFFICIENCY, as defined in 201.3.204, 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;

— intended for use with PATIENTS who have VENTILATORY INSUFFICIENCY or failure, the most fragile of which would likely experience injury with the loss of this artificial ventilation;

— intended for TRANSIT-OPERABLE use;

— not intended for PATIENTS who are dependent on artificial ventilation for their immediate life support.

EXAMPLE 1 PATIENTS with moderate to severe chronic obstructive pulmonary disease (COPD), moderate amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia or muscular dystrophy.

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 VENTILATOR BREATHING SYSTEM of VENTILATORY SUPPORT EQUIPMENT for VENTILATORY INSUFFICIENCY, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT for VENTILATORY INSUFFICIENCY.

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[5];

— VENTILATORS or ACCESSORIES intended for the emergency medical services environment, which are given in ISO 80601-2-84[6][4], the future replacement for ISO 10651-3[7];

— 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 IMPAIRMENT, which are given in ISO 80601-2-79[1];

— sleep apnoea therapy ME EQUIPMENT, which are given in ISO 80601-2-70[8];

— continuous positive airway pressure (CPAP) ME EQUIPMENT;

— high-frequency jet VENTILATORS (HFJVs);

— high-frequency oscillatory VENTILATORS (HFOVs)[9];

— oxygen therapy constant flow ME EQUIPMENT;

— cuirass or “iron-lung” ventilation equipment.

This document is a particular standard 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.

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.

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

IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013, IEC 60601-1-8:2006+AMD1:2012 and IEC 60601-1-11:2015 apply as modified in Clauses 202, 206, 208 and 211 respectively. IEC 60601-1-3:2008[10] 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 document taken together.

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

201.2 Normative references

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

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

NOTE 2 Informative references are listed in the Bibliography.

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, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability +Amendment 1:2013*[5]

IEC 60601-1-8:2006, *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*[6]

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 7000:2014, *Graphical symbols for use on equipment — Registered symbols*

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*

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*

[5] There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

[6] There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and its Amendment 1:2012.

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:—[7], *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 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*

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,

[7] To be published. Stage at time of publication ISO/DIS 80601-2-12:2017.