INTERNATIONAL STANDARD

ISO 80601-2-12

First edition
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Medical electrical equipment —

Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

Appareils électromédicaux —

Partie 2-12: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs pulmonaires pour utilisation en soins intensifs

Reference number
ISO 80601-2-12:2011(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 80601-2-12 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 80601-2-12 cancels and replaces the second edition of IEC 60601-2-12:2001. This edition of ISO 80601-2-12 constitutes a major technical revision of IEC 60601-2-12:2001 and includes an alignment with the third edition of IEC 60601-1.

The most significant changes are the following modifications:

— extending the scope to include the critical care VENTILATOR and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the VENTILATOR, and thus not only the critical care VENTILATOR itself;

— identification of ESSENTIAL PERFORMANCE for a critical care VENTILATOR and its ACCESSORIES;

— modification of the obstruction of the expiratory limb (continuing AIRWAY PRESSURE) ALARM CONDITION requirement;

and the following additions:

— tests for ventilation performance;

— tests for mechanical strength;

— new symbols;

— requirements for a critical care VENTILATOR as a component of an ME SYSTEM;

— tests for enclosure integrity (water ingress);

— tests for closed suction survivability of the VENTILATOR;

— tests for cleaning and disinfection procedures;

— consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

ISO 80601 consists of the following parts, under the general title *Medical electrical equipment*:

— *Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

— *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

— *Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

— *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

— *Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment for medical use*

IEC 80601 consists of the following parts, under the general title *Medical electrical equipment:*

— IEC 80601-2-30: *Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*

— IEC 80601-2-35: *Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*

— IEC 80601-2-58: *Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*

— IEC 80601-2-59: *Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*

— IEC 80601-2-60: *Particular requirements for basic safety and essential performance of dental equipment*

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

Introduction

In this International Standard, 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 IEC 60601-1:2005, CLAUSE 3, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

— "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this International Standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular International Standard are by number only.

In this International Standard, 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 International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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 attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this International Standard not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed, and not earlier than 5 years from the date of publication for equipment already in production.

Medical electrical equipment —

Part 2-12:
Particular requirements for basic safety and essential performance of critical care ventilators

201.1 Scope, object and related standards

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

201.1.1 Scope

Subclause 1.1 of IEC 60601-1:2005, Clause 1 is replaced by:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a VENTILATOR in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT:

— intended to be attended by a professional OPERATOR for those PATIENTS who are dependent on mechanical ventilation; and

NOTE 1 Such VENTILATORS are considered a LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM.

— intended for use in critical care environments in a professional healthcare facility or intended for use in transport within a professional healthcare facility.

NOTE 2 A critical care VENTILATOR intended for use in transport within a professional healthcare facility is not considered an emergency and transport ventilator.

This International Standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to a BREATHING SYSTEM, or to a VENTILATOR, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATOR.

This International Standard is not applicable to ME EQUIPMENT or an ME SYSTEM operating in ventilation modes intended for patients who are not dependent on mechanical ventilation.

NOTE 3 A critical care VENTILATOR, when operating in such a mode, is not considered LIFE-SUPPORTING ME EQUIPMENT OR ME 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 standard are not covered by specific requirements in this standard except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

NOTE 4 Additional information can be found in IEC 60601-1:2005, 4.2.

This International Standard is not applicable to continuous positive airway pressure (CPAP) ME EQUIPMENT, sleep apnoea therapy ME EQUIPMENT, HOME HEALTHCARE ENVIRONMENT VENTILATORS, ventilatory support ME EQUIPMENT, emergency and transport ventilators, anaesthetic ventilators, high-frequency jet ventilators (HFJVs) and high-frequency oscillatory ventilators (HFOVs).[26] This International Standard does not specify the requirements for ME EQUIPMENT that is intended solely to augment the ventilation of spontaneously breathing PATIENTS within a professional healthcare facility.

This International Standard does not specify the requirements for VENTILATORS or ACCESSORIES intended for anaesthetic applications which are given in ISO 80601-2-13.

This International Standard does not specify the requirements for VENTILATORS or ACCESSORIES intended for home care ventilators for ventilator-dependent PATIENTS which are given in ISO 10651-2[1)].

This International Standard does not specify the requirements for VENTILATORS or ACCESSORIES intended for emergency and transport which are given in ISO 10651-3[2)].

This International Standard does not specify the requirements for VENTILATORS or ACCESSORIES intended for home-care ventilatory support devices which are given in ISO 10651-6[3)].

201.1.2 Object

Subclause 1.2 of IEC 60601-1:2005 is replaced by:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a VENTILATOR, as defined in 201.3.222, and its ACCESSORIES.

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

201.1.3 Collateral standards

Subclause 1.3 of IEC 60601-1:2005 applies with the following addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005, Clause 2 as well as 201.2 of this particular standard.

IEC 60601-1-3:2008 and IEC 60601-1-11:2010 do not apply.

201.1.4 Particular standards

Subclause 1.4 of IEC 60601-1:2005 is replaced by:

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 IEC 60601-1:2005 or the collateral standards.

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1) In the future, this standard is expected to be harmonized with IEC 60601-1:2005 and IEC 60601-1-11:2010, at which time it will be replaced by ISO 80601-2-xx.

2) In the future, this standard is expected to be harmonized with IEC 60601-1:2005, at which time it will be replaced by ISO 80601-2-xx.

3) In the future, this standard is expected to be harmonized with IEC 60601-1:2005 and IEC 60601-1-11:2010, at which time it will be replaced by ISO 80601-2-xx.

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

The numbering of clauses and subclauses of this particular standard corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this standard 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-8 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 IEC 60601-1:2005 or the applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of IEC 60601-1:2005 or the applicable collateral standard.

“Amendment” means that the clause or subclause of IEC 60601-1:2005 or the applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that 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 standard” is used to make reference to IEC 60601-1:2005, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of IEC 60601-1:2005 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

The following referenced documents are indispensable for the application 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 Informative references are listed in the bibliography beginning on page 74.

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

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — 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*

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*

IEC 61672-1:2002, *Electroacoustics — Sound level meters — Part 1: Specifications*

Addition:

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

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

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

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 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7000:2004, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7010:—[4], *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 7010:2003, *Graphical symbols — Safety colours and safety signs — Safety signs used in workplaces and public areas* including (Amendment 1:2006)

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum* including (Amendment 1:2010)

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum* including (Amendment 2:2010)

ISO 8185:2007, *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

ISO 8836:2007, *Suction catheters for use in the respiratory tract*

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 10079-1:1999, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements*

ISO 10079-3:1999, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source*

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4) To be published. (Revision of ISO 7010:2003)

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 11195:1995, *Gas mixers for medical use — Stand-alone gas mixers*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.* Amendment 1:2008

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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 80601-2-13:—[5], *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

ISO 80601-2-55:—[5], *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60068-2-27:2008[6], *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

ISO 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-11:2010, *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 60601-2-2:2009, *Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 62304:2006, *Medical device software — Software life cycle processes*

IEC 62366:2007, *Medical devices — Application of usability engineering to medical devices*

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5) To be published.

6) Cancels and replaces ISO 60068-2-29:1987.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7396-1:2007, ISO 8185:2007, ISO 9360-1:2000, IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-8:2006, IEC 60601-2-2:2009, IEC 62304:2006, IEC 62366:2007, ISO 4135:2001 and the following apply.

NOTE An alphabetical index of defined terms is found beginning on page 77.

Addition:

201.3.201
AIRWAY PRESSURE
P_{aw}
pressure at the PATIENT-CONNECTION PORT

201.3.202
BSF
BREATHING SYSTEM FILTER
device intended to reduce transmission of particulates, including microorganisms, in breathing systems

[ISO 23328-2:2002, definition 3.1]

201.3.203
DELIVERED VOLUME
V_{del}
volume of gas delivered through a PATIENT-CONNECTION PORT during a breath

[ISO 4135:2001, definition 3.4.2 modified]

NOTE DELIVERED VOLUME is also referred to as tidal volume when all of the DELIVERED VOLUME enters the PATIENT'S respiratory tract. This is frequently not the case when there is significant tracheal tube leakage (as in neonates) or in non-invasive ventilation.

201.3.204
EMERGENCY INTAKE PORT
dedicated GAS INTAKE PORT through which gas is drawn when the supply of FRESH GAS is insufficient or absent

[ISO 4135:2001, definition 3.2.3 modified]

201.3.205
EXHAUST PORT
port through which waste gas is discharged to the atmosphere or to an ANAESTHETIC GAS SCAVENGING SYSTEM

[ISO 4135:2001, definition 4.2.1.6, modified]

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

[ISO 4135:2001, definition 3.1.7, modified]

201.3.207
FRESH GAS
respirable gas delivered to a VENTILATOR BREATHING SYSTEM

[ISO 4135:2001, definition 3.1.8, modified]

NOTE FRESH GAS does not include the following:

— air drawn through the EMERGENCY INTAKE PORT;

— air drawn through leaks in the VENTILATOR BREATHING SYSTEM; or

— gas exhaled by the PATIENT.

201.3.208
GAS INTAKE PORT
port through which gas is drawn for use by the PATIENT

[ISO 4135:2001, definition 3.2.11, modified]

201.3.209
GAS OUTPUT PORT
port through which gas is delivered at respiratory pressures via the inspiratory limb to the PATIENT-CONNECTION PORT

[ISO 4135:2001, definition 3.2.8, modified]

201.3.210
GAS RETURN PORT
port through which gas is returned at respiratory pressures via the expiratory limb from the PATIENT-CONNECTION PORT

[ISO 4135:2001, definition 3.2.9, modified]

201.3.211
HIGH-PRESSURE INPUT PORT
input port to which gas is supplied at a pressure exceeding 100 kPa

[ISO 4135:2001, definition 3.2.10.1, modified]

201.3.212
LOW-PRESSURE INPUT PORT
input port to which gas is supplied at a pressure $\leq$ 100 kPa

[ISO 4135:2001, definition 3.2.10.2, modified]

201.3.213
MANUAL VENTILATION PORT
port to which a manual inflating device is connected

[ISO 4135:2001, definition 3.2.12 modified]

201.3.214
MAXIMUM LIMITED PRESSURE
$P_{LIM\,max}$
highest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

[ISO 4135:2001, definitions 3.3.3 and 3.3.4 modified]