INTERNATIONAL STANDARD

ISO 80601-2-84

First edition
2020-07

Medical electrical equipment —

Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

Appareils électromédicaux —
Partie 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence

Reference number
ISO 80601-2-84:2020(E)

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Published in Switzerland

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

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee 62D, *Electromedical equipment*.

This first edition cancels and replaces ISO 10651-3:1997, which has been technically revised. The main changes compared to the previous edition are as follows:

— extension of the scope to include the *EMS ventilator* and its *accessories*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator for the emergency medical services environment*, and thus not only the *ventilator for the emergency medical services environment* itself;

— identification of *essential performance* for *ventilator for the emergency medical services environment* and its *accessories*;

— modification of the tests for environmental conditions (via IEC 60601-1-12);

— modification of the tests for *alarm conditions* (via IEC 60601-1-8);

— modification of the tests for electromagnetic disturbances (via IEC 60601-1-2);

— addition of the following:

  — tests for ventilation performance;

  — test for instability from unwanted lateral movement;

— test for audible acoustic energy;

— tests for mechanical strength (via IEC 60601-1-12);

— tests for environmental conditions (via IEC 60601-1-12);

— tests for *alarm conditions* (via IEC 60601-1-8);

— tests for electromagnetic disturbances (via IEC 60601-1-2);

— inclusion of the *usability engineering process* (via IEC 60601-1-6);

— new symbols;

— requirements for *ventilator for the emergency medical services environment* as a component of an *ME system*;

— tests for *enclosure* integrity (water ingress via IEC 60601-1-12);

— tests for *cleaning* and *disinfection*;

— determination of probability of component failure during the *expected service life*;

— delivered gas maximum enthalpy requirement;

— performance test and disclosure requirements for other *inflation-types*;

— enhanced inspired oxygen *monitoring equipment* requirements;

— consideration of input gas of Oxygen 93 %;

— use of the vocabulary and semantics of ISO 19223:2019;

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

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is a major update of the requirements for a *ventilator for the emergency medical services environment*. It includes harmonizing the requirements from ISO 10651-3, which it replaces, with the third edition of IEC 60601-1 including its first amendment, the fourth edition of IEC 60601-1-2, the second edition of IEC 60601-1-6 including its first amendment, the third edition of IEC 60601-1-8 including its first amendment and the first edition of IEC 60601-1-12.

In this document, the following print types are used:

— Requirements and definitions: roman type;

— *Instructions, test specifications and terms defined in clause 3 of the general standard, in this particular document or as noted: 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.

In referring to the structure of this document, the term

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

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

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

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

For the purposes of this document, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformance with this document;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

Annex C contains a guide to the marking and labelling requirements in this document.

Annex D contains a summary of the symbols referenced in this document.

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

Medical electrical equipment —

Part 2-84: Particular requirements for basic safety and essential performance of ventilators for the emergency medical services environment

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012.

201.1.1 * Scope

Replacement:

This document applies to the *basic safety* and *essential performance* of an *EMS ventilator* in combination with its *accessories*, hereafter also referred to as *ME equipment:*

— intended for *patients* who need differing levels of support from artificial ventilation including *ventilator-dependent patients*;

— intended to be operated by a *healthcare professional operator*;

— intended for use in the *EMS environment*; and

— intended for invasive or non-invasive ventilation.

NOTE 1 An *EMS ventilator* can also be used for transport within a *professional healthcare facility*.

* An *EMS ventilator* is not considered to utilize a *physiologic closed loop-control system* unless it uses a physiological *patient* variable to adjust the ventilation therapy settings.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the *ventilator breathing system*, or to an *EMS ventilator*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *EMS ventilator*.

NOTE 2 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, 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 the following:

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in critical care applications, which are given in ISO 80601-2-12.

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72[3].

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13[4].

— *ventilators* or *accessories* intended for ventilatory support equipment (intended only to augment the ventilation of spontaneously breathing *patients*), which are given in ISO 80601-2-79[5] and ISO 80601-2-80[6] [1].

— obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70[7].

— *operator*-powered resuscitators, which are given in ISO 10651-4[8].

— gas-powered emergency resuscitators, which are given in ISO 10651-5[9].

— *continuous positive airway pressure* (*CPAP*) *ME equipment*.

— high-frequency jet *ventilators* (HFJVs), which are given in ISO 80601-2-87[11].

— high-frequency oscillatory *ventilators* (HFOVs)[10], which are given in ISO 80601-2-87[11].

NOTE 4 An *EMS ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilation-modes*.

— cuirass or "iron-lung" *ventilators*.

201.1.2 Object

Replacement:

The object of this particular document is to establish *basic safety* and *essential performance* requirements for an *EMS ventilator,* as defined in 201.3.201, and its *accessories*.

Accessories are included because the combination of the *EMS ventilator* and the *accessories* needs to have acceptable *risk*. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of an *EMS ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745.

[1] ISO 80601-2-79 and ISO 80601-2-80 replace ISO 10651-6, which has been withdrawn.

201.1.3 Collateral standards

Amendment (add at the end of the subclause):

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

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 and IEC 60601-1-12 apply as modified in Clauses 202, 206, 208 and 212 respectively. IEC 60601-1-3[12] and IEC 60601-1-11 do 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 IEC 60601-1:2005+AMD1:2012 or the collateral standards.

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 particular document corresponds to those 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, 208.4 in this document 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+AMD1:2012 or the applicable collateral standard is replaced completely by the text of this particular document.

“Addition” means that the text of this document is additional to the requirements of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard.

“Amendment” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the 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 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, 208 for IEC 60601-1-8, 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 document, the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of

IEC 60601-1:2005+AMD1:2012 or the 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.

Clause 2 of the general standard applies, except as follows:

Replacement:

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 19054:2005+AMD1:2016, *Rail systems for supporting medical equipment*

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+AMD1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

IEC 60601-1-8:2006+AMD1:2012, *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 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*

Addition:

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

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

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

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8836:2019, *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*

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 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3:2018, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

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 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 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use: — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use: — Part 2: Non-filtration aspects*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

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

ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

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

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-10:2007+AMD1:2013, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

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 60601-1-12:2014, *Medical Electrical Equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

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

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7010:2019, ISO 7396-1:2016+AMD1:2017, ISO 8836:2019, 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, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-10:2007+AMD1:2013, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 62304:2006+AMD1:2015, IEC 62366-1:2015, ISO 80601-2-12:2020, ISO 80601-2-74:2017 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

NOTE An alphabetized index of defined terms is found in Annex DD.

201.3.201
EMS ventilator
ventilator for emergency medical services environment
ventilator intended for use in the *EMS environment*

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 *Essential performance*

Addition:

201.4.3.101* Additional requirements for *essential performance*

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

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of ventilation at the *patient-connection port* within the *alarm limits* set by the *operator*	
or generation of an *alarm condition*	
expired volume, if equipped	201.12.4.103
gas supply failure	201.13.102
high *airway pressure*	201.12.4.105
internal electrical power source depleted	212.8.2
inspiratory oxygen concentration, if equipped	201.12.4.101
Subclauses 202.4.3.1 and 202.8.1.101 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this document.	

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

In the *risk management file*, the *manufacturer* shall:

aa) state the probability of component failure that results in the *ventilator* needing to be taken out of service during the *expected service life*, assuming that the preventative inspection, preventive maintenance and calibration are performed according to the *accompanying documents*; and

bb) summarize the methodology used to determine this probability.

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

Amendment (add at end of subclause):

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.

Addition:

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

a) An *EMS ventilator* shall:

1) operate and meet the requirements of this document throughout its *rated* range of input pressure; and

2) not cause an unacceptable *risk* under the *single fault condition* of an input pressure of 1 000 kPa.

b) An *EMS ventilator* with a maximum *rated* input pressure in excess of 600 kPa shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

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