DRAFT INTERNATIONAL STANDARD

ISO/DIS 80601-2-84

ISO/TC **121**/SC **3**	Secretariat: **ANSI**
Voting begins on: **2018-03-07**	Voting terminates on: **2018-05-30**

Medical electrical equipment —

Part 2-84: Particular requirements for basic safety and essential performance of emergency and transport ventilators

Appareils électromédicaux —

Partie 2-84: Titre manque

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 80601-2-84:2018(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Published in Switzerland

Contents

Figures

Tables

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

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

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

Document ISO 80601-2-84 has been prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and IEC Technical Committee 62: *Electrical equipment in medical practice*, Subcommittee 62D: *Electric equipment*.

This first edition cancels and replaces the first edition of ISO 10651-3 (1997) [1][1]. This document constitutes a major technical revision and includes an alignment with the third edition of IEC 60601-1, the second edition of IEC 60601-1-8, IEC 60601-1-12 as well as the fourth edition of IEC 60601-1-2. This document is also intended to cancel and replace EN 794-3 [2].

This document includes the following significant technical changes with respect to ISO 10651-3:

- extending 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;
- modifying the tests for environmental conditions (via IEC 60601-1-12);
- modifying the tests for ALARM CONDITIONS (via IEC 60601-1-8); and
- modifying the tests for electromagnetic disturbances (via IEC 60601-1-2).

[1] Numbers in square brackets refer to the Bibliography.

This document includes the following significant technical additions:

- 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; and
- consideration of contamination of the breathing gas delivered to the PATIENT from the GAS PATHWAYS.

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.

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, IN THIS PARTICULAR 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.);
- "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 attention of users of this standard are 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 committees that the content of this publication be adopted for implementation nationally not 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 2-84: Particular requirements for basic safety and essential performance of ventilators for the emergency medical services environment

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 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 for VENTILATOR-DEPENDENT PATIENTS;

— for use in the EMS ENVIRONMENT; and

— for invasive or non-invasive ventilation.

NOTE 1 An EMS VENTILATOR can also be used for transport within a PROFESSIONAL HEALTHCARE FACILITIES.

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

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

This part of ISO 80601 does not specify the requirements for

— VENTILATORS or ACCESSORIES intended for VENTILATOR-DEPENDENT PATIENTS in critical care applications, which are given in ISO 80601-2-12 [3].

— VENTILATORS or ACCESSORIES intended for VENTILATOR-DEPENDENT PATIENTS in the HOME HEALTHCARE ENVIRONMENT, which are given in ISO 80601-2-72 [4].

— VENTILATORS or ACCESSORIES intended for anaesthetic applications, which are given in ISO 80601-2-13 [5].

— 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 [6] and ISO 80601-2-80 [7].

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

— OPERATOR-powered resuscitators, which are given in ISO 10651-4 [9].

— gas-powered emergency resuscitators, which are given in ISO 10651-5 [10].

— continuous positive AIRWAY PRESSURE (CPAP) ME EQUIPMENT.

— high-frequency jet VENTILATORS (HFJVs).

— high-frequency oscillatory VENTILATORS (HFOVs) [11].

— cuirass or "iron-lung" VENTILATORS.

This part of ISO 80601 is a particular standard in the IEC 60601-1 and ISO/IEC 80601 series of documents.

201.1.2 Object

Replacement:

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

NOTE 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.

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[2] and Clause 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 [13] 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.

---

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

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 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 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 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 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 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:

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

ISO 7010:2011+AMD1:2012+AMD2:2012+AMD3:2012+AMD4:2013+AMD5:2014 +AMD6:2014+AMD7:2016, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

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

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 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*

EN 15986:2011, *Symbols for medical devices containing phthalates*

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

ISO 18082:2014, *Anaesthetic and respiratory equipment -- Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

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 80601-2-55:— (Ed 2)[3], *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 60601-1-12:2014, *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 4135:2001 [14], ISO 7010:2011, ISO 7396-1:2016, ISO 8836:2014 [15], ISO 9000:2015 [16], ISO 9360-1:2000, ISO 17510:2015 [17], ISO 17664:2017, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010, IEC 60601-1-8:2006+AMD1:2012, IEC 62304:2006+AMD1:2015, IEC 62366-1:2015, ISO 80601-2-12:— [3], ISO 80601-2-55:—[4], 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 in Annex DD.

[3] Under preparation. Stage at the time of publication: ISO FDIS 80601-2-55:2017.

[4] Under preparation. Stage at the time of publication: ISO FDIS 80601-2-55:2017.