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BS EN ISO 80601-2-12:2011

Incorporating corrigendum October 2011

BSI Standards Publication

Medical electrical equipment

Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO 80601-2-12:2011)

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This British Standard is the UK implementation of EN ISO 80601-2-12:2011. It is identical to ISO 80601-2-12:2011, incorporating corrigendum October 2011. It supersedes BS EN 794-1:1997+A2:2009 and BS EN 60601-2-12:2006, which are withdrawn.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by ISO corrigendum October 2011 is indicated in the text by ⟦AC1⟩ ⟨AC1⟧.

The UK participation in its preparation was entrusted by Technical Committee CH/121, Anaesthetic and respiratory equipment to Subcommittee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

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

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

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Date	Text affected
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Supersedes EN 794-1:1997+A2:2009

English Version

Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO/IEC 80601-2-12:2011)

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 (ISO/IEC 80601-2-12:2011)

Medizinische elektrische Geräte - Teil 2-12: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Beatmungsgeräten für die Intensivpflege (ISO/IEC 80601-2-12:2011)

This European Standard was approved by CEN on 5 February 2011.

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

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Foreword

This document (EN ISO 80601-2-12:2011) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

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

This document supersedes EN 794-1:1997+A2:2009, EN 60601-2-12:2006.

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 third edition of IEC 60601-1.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO/IEC 80601-2-12:2011 has been approved by CEN as a EN ISO 80601-2-12:2011 without any modification.

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Annex ZA
(informative)

Relationship between this Document and the Essential Requirements of EU Directive 93/42/EEC

This Document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this document is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this document given in Table ZA.1, within the limits of the scope of this document, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this Document and Directive 93/42/EEC

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
All	1, 2, 3	
201.4	1	
201.7	5, 8.6, 8.7, 10.3, 11.4.1,12.7.4, 12.8.2, 12.9, 13.1, 13.2, 13.3, 13.4, 13.5, 13.6	
201.7.2.3	13.1, 13.2	
201.7.2.101 a)	13.3 i)	
201.7.2.101 b)	13.3 j), 13.3 k)	
201.7.2.101 c), 201.7.2.101 d)	13.1	
201.7.2.101 e)	13.3 j), 13.3 k)	
201.7.2.101 f)	13.3 e)	
201.7.2.101 g)	13.3 k)	
201.7.2.101 h)	13.3 k)	
201.7.2.4.101	13.1, 13.3 e), 13.3 i), 13.3 j), 13.3 k)	
201.7.2.13.101	13.1, 13.2, 13.3 k)	
201.7.2.17.101 a)	13.2, 13.3 b), 13.3 c), 13.3 d), 13.3 f), 13.5	
201.7.2.17.101 b)	13.2, 13.3 b), 13.3 d), 13.5	
201.7.9.1	13.3 a)	
201.7.9.2.8.101	13.6 d)	
201.7.9.2.9.101	13.6 b)	
201.7.9.2.1 a)	13.6 h), 13.6 i)	
201.7.9.2.1 b)	13.6 q)	
201.7.9.2.2.101	13.1, 13.6 a)	

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Table ZA.1 — (*continued*)

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.7.9.2.9.101	13.6 a), 13.6 b), 13.6 c), 13.6 d)	
201.7.9.2.12	13.6 h), 13.6 i)	
201.7.9.2.14.101	13.6 c)	
201.8	9.1, 9.2, 9.3, 12.6, 12.7.4	
201.9	7.1, 9.1, 9.2, 12.7.1, 12.7.2, 12.7.3	
201.10	11.1.1, 11.3	
201.11	7.1, 7.2, 7.3, 7.5, 7.6, 8.1, 8.5, 9.1, 9.3, 12.7.5	
201.11.6.4	7.5	
201.11.8	12.2, 12.3	
201.12	9.2, 10.1, 10.2, 11.1.1, 11.3, 12.3, 12.4, 12.8.1, 12.8.2, 12.9	
201.12.1	3, 4	
201.12.4	3, 4, 12.4, 12.8	
201.13	1, 2, 4, 7.5, 7.6, 9.3	And via IEC 60601-1-6
201.14	9.1, 12.1, 12.1 a)	
201.15	4, 9.1, 9.2, 9.3, 12.6, 12.7.1, 12.7.4, 12.7.5	
201.16	9.1, 12.6, 12.7, 13.1	
201.17	11.1.1, 12.5	
201.101	9.1, 9.2, 12.7.4, 12.8.1	
201.102	3, 4, 9.1, 13.6 c)	
201.103	2, 6	
201.104	12.9	
201.105	2, 3, 4	
201.106	1, 2, 9.1, 9.2	And via IEC 60601-1-6
201.107	1, 12.9	And via IEC 60601-1-6
201.108	1, 3, 9.1, 9.2	And via IEC 60601-1-6
202	9.2, 11.1.1, 12.5	
206	1, 9.2, 12.9	And via IEC 60601-1-6
208	12.4	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this International Standard.

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For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR of 2006/42/EC	Qualifying remarks/Notes
201.12.1	1.1.4	And via IEC 60601-1
–	1.1.8	
201.12.1, 201.12.101	1.2.2	And via IEC 60601-1 and IEC 60601-1-6
201.7.2.101 c), 201.7.2.101 d), 201.101.2, 201.101.3, 201.101.4	1.5.4	
–	1.6.1	Via IEC 60601-1
–	1.6.2	Via IEC 60601-1
–	1.6.3	Via IEC 60601-1
–	3.4.5	Via IEC 60601-1
201.7.2.101 i)	3.6.2	And via IEC 60601-1

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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.

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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.

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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.

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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.

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