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STN	**Zdravotnícke elektrické prístroje Časť 2-12: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti ventilátorov na intenzívnu starostlivosť (ISO 80601-2-12: 2023)**	**STN EN ISO 80601-2-12** 85 2101

Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO 80601-2-12:2023)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/24

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EN ISO 80601-2-12

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English Version

Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO 80601-2-12:2023)

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 80601-2-12:2023)

Medizinische elektrische Geräte - Teil 2-12: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Beatmungsgeräten für die Intensivpflege (ISO 80601-2-12:2023)

This European Standard was approved by CEN on 1 September 2023.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword..... 3

European foreword

This document (EN ISO 80601-2-12:2023) 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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

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

This document supersedes EN ISO 80601-2-12:2020.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-12:2023 has been approved by CEN as EN ISO 80601-2-12:2023 without any modification.

INTERNATIONAL STANDARD **ISO 80601-2-12**

Third edition
2023-11

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
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

Foreword v
Introduction vii
201. 1 Scope, object and related standards 1
201. 1.1 Scope 1
201. 1.2 Object 3
201. 1.3 Collateral standards 3
201. 1.4 Particular standards 3
201. 2 Normative references 4
201. 3 Terms and definitions 6
201. 4 General requirements 25
201. 5 General requirements for testing of *ME equipment* 29
201. 6 Classification of *ME equipment* and *ME systems* 30
201. 7 *ME equipment* identification, *marking* and documents 30
201. 8 Protection against electrical *hazards* from *ME equipment* 37
201. 9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 37
201. 10 Protection against unwanted and excessive radiation *hazards* 41
201. 11 Protection against excessive temperatures and other *hazards* 41
201. 12 Accuracy of controls and instruments and protection against hazardous outputs 45
201. 12.1 Accuracy of controls and instruments 45
201. 13 *Hazardous situations* and fault conditions for *ME equipment* 63
201. 14 *Programmable electrical medical systems* (*PEMS*) 65
201. 15 Construction of *ME equipment* 66
201. 16 *ME systems* 70
201. 17 Electromagnetic compatibility of *ME equipment* and *ME systems* 70
201. 101 Gas connections 70
201. 102 Requirements for the *VBS* and *accessories* 74
201. 103 Spontaneous breathing during loss of ventilation 76
201. 104 Indication of duration of operation 76
201. 105 *Functional connection* 77
201. 106 Display loops 77
201. 107 Timed ventilatory pause 78
202 Electromagnetic disturbances — Requirements and tests 80
206 Usability 81
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems 83
Annex C (informative) Guide to *marking* and labelling requirements for *ME equipment* and *ME systems* 86

Annex D (informative) *Symbols* on *marking* **92**
Annex AA (informative) Particular guidance and rationale **94**
Annex BB (informative) Data interfaces **134**
Annex CC (informative) Reference to the IMDRF *essential principles* and labelling guidances **143**
Annex DD (informative) Reference to the *essential principles* **146**
Bibliography **149**
Alphabetized index of defined terms **154**

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 or www.iec.ch/members_experts/refdocs).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC 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) or the IEC list of patent declarations received (see https://patents.iec.ch).

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. In the IEC, see www.iec.ch/understanding-standards.

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, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 80601-2-12:2020), which has been technically revised.

The main changes are as follows:

— alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and IEC 60601-1-8:2006+AMD1:2012+AMD2:2020.

— added requirements for the display legibility for *operators* wearing personal protective equipment;

— added requirements for display during calibration of gas monitors;

— clarified *maximum limited pressure* requirements;

— clarified high *airway pressure alarm condition* requirements;

— added requirements for *ventilator system recovery*;

— added requirements and definitions for *cybersecurity*; and

— harmonization with ISO 20417, where appropriate.

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

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 and www.iec.ch/national-committees.

Introduction

In referring to the structure of this document, the term

— “clause” means one of the four 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 201.12 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 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.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" is used to describe a possibility or capability.

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.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

INTERNATIONAL STANDARD **ISO 80601-2-12:2023(E)**

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+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

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

— intended for use in an environment that provides specialized care for *patients* whose conditions can be life-threatening and who can require comprehensive care and constant monitoring in a *professional healthcare facility;*

NOTE 2 For the purposes of this document, such an environment is referred to as a critical care environment. *Ventilators* for this environment are considered life-sustaining.

NOTE 3 For the purposes of this document, such a critical care *ventilator* can provide ventilation during transport within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

NOTE 4 A critical care *ventilator* intended for use in transport within a *professional healthcare facility* is not considered as an *emergency medical services environment ventilator*.

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

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

A critical care *ventilator* is not considered to use a *physiologic closed-loop-control system* unless it uses a physiological *patient* variable to adjust the *artificial ventilation* therapy settings.

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

NOTE 5 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+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 6 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document is not applicable to *ME equipment* or an *ME system* operating in a *ventilator-operational mode* solely intended for *patients* who are not dependent on *artificial ventilation*.

NOTE 7 A critical care *ventilator*, when operating in such a *ventilator-operational mode*, is not considered life-sustaining.

This document is not applicable to *ME equipment* that is intended solely to augment the ventilation of spontaneously breathing *patients* within a *professional healthcare facility*.

This document does not specify the requirements for:

NOTE 8 See ISO/TR 21954 for guidance on the selection of the appropriate *ventilator* for a given *patient*.

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13;

— *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84;

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

— *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79 and ISO 80601-2-80;

— obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70;

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

— high-frequency *ventilators*, which are given in ISO 80601-2-87;

NOTE 9 A critical care *ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilator-operational modes*.

— respiratory high-flow therapy equipment, which are given in ISO 80601-2-90;

NOTE 10 A critical care *ventilator* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

— oxygen therapy constant flow *ME equipment*; and

— cuirass or “iron-lung” ventilation equipment.

201.1.2 Object

Replacement:

The object of this document is to establish *basic safety* and *essential performance* requirements for a *ventilator,* as defined in 201.3.306, and its *accessories*.

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*.

NOTE 1 This document has been prepared to address the relevant *essential principles*[42] and labelling[43] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex DD.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745.