

INTERNATIONAL STANDARD

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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
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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 <i>ME equipment</i>	29
201. 6 Classification of <i>ME equipment</i> and <i>ME systems</i>	30
201. 7 <i>ME equipment</i> identification, marking and documents	30
201. 8 Protection against electrical hazards from <i>ME equipment</i>	37
201. 9 Protection against mechanical hazards of <i>ME equipment</i> and <i>ME systems</i>	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 <i>ME equipment</i>	63
201. 14 Programmable electrical medical systems (PEMS)	65
201. 15 Construction of <i>ME equipment</i>	66
201. 16 <i>ME systems</i>	70
201. 17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	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 <i>ME equipment</i> and <i>ME systems</i>	86

Annex D (informative) <i>Symbols on marking</i>	92
Annex AA (informative) Particular guidance and rationale	94
Annex BB (informative) Data interfaces	134
Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances	143
Annex DD (informative) Reference to the <i>essential principles</i>	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.