INTERNATIONAL STANDARD

IEC 60601-2-12

[ISO 10651-1]

Second edition
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Medical electrical equipment –

Part 2-12:
Particular requirements for the safety of lung ventilators – Critical care ventilators

Appareils électromédicaux –

Partie 2-12:
Règles particulières de sécurité pour ventilateurs pulmonaires – Ventilateurs pour utilisation en soins intensifs

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-12: Particular requirements for the safety of lung ventilators – Critical care ventilators

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization, comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters, expressing as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides, and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. IEC shall not be held responsible for identifying any such patent rights.

International Standard IEC 60601-2-12 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

ISO TC 121/SC 3, Lung ventilators and related equipment, also participated in the preparation of this standard.

This second edition replaces the first edition of IEC 60601-2-12:1988, *Medical electrical equipment – Part 2: Particular requirements for the safety of lung ventilators for medical use*, and ISO 10651-1:1993, *Lung ventilators for medical use – Part 1: Requirements*.

The text of this particular Standard is based on the following documents:

FDIS	Report on voting
62D/414/FDIS	62D/440/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

Annex BB forms an integral part of this standard.

Annexes AA and CC are for information only.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– notes, explanations, advice, introductions, general statements and references: smaller roman type;

– *test specifications: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2004. At this date, the publication will be:

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

NOTE IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for safety – Collateral Standard: General requirements and guidelines for the application of alarms in medical electrical equipment* is currently under development. This Standard will require maintenance to conform to that Collateral Standard.

INTRODUCTION

Critical care VENTILATORS are an essential medical device in every intensive care unit (ICU). Approximately half of all PATIENTS in ICUs receive partial to full ventilatory support with this EQUIPMENT. Given the vulnerable status of these PATIENTS, EQUIPMENT safety is of fundamental importance. Accordingly, this Particular Standard, by building on other standards and specifically on IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety*, herein referred to as the "General Standard", sets the minimum requirements that should be met by every critical care VENTILATOR that is designed after the publication of this Particular Standard.

A rationale for the most important requirements is given in Annex AA.

Continuous positive airway pressure (CPAP) devices, sleep apnea therapy devices, support-care VENTILATORS, anaesthesia, emergency and transport VENTILATORS, jet and high frequency VENTILATOR and oscillators are not covered by this Particular Standard, nor are devices that may be used within hospitals, intended solely to augment the ventilation of spontaneously breathing PATIENTS.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-12: Particular requirements for the safety of lung ventilators – Critical care ventilators

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1 Scope

Addition:

This Particular Standard specifies the safety requirements for VENTILATORS, as defined in 2.1.125, intended for use in critical care settings.

Continuous positive airway pressure (CPAP) devices, sleep apnea therapy devices, support-care VENTILATORS, emergency and transport VENTILATORS, jet and high frequency VENTILATORS and oscillators are outside the scope of this Particular Standard, nor are devices that may be used within hospitals, intended solely to augment the ventilation of spontaneously breathing PATIENTS. Standards for other types of VENTILATORS, e.g. high frequency jet and oscillation ventilators, are under consideration.

Requirements for VENTILATORS intended for anaesthetic applications are given in IEC 60601-2-13.

1.2 Object

Addition:

The object of this standard is to specify particular safety requirements for VENTILATORS intended for use in critical care settings.

1.3 Particular standards

Addition:

This Particular Standard refers to IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the “General Standard”.

The General Standard takes into account a set of Collateral Standards:

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety, Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety, 4. Collateral standard: Programmable electrical medical systems*
Amendment 1[1]

[1] There exists a consolidated edition 1.1 (2000) that includes IEC 60601-1-4 (1996) and its amendment 1 (1999).