INTERNATIONAL STANDARD

IEC 60601-2-12

[ISO 10651-1]

Second edition
2001-10

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 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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, express 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), herein 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]

The term "this Standard" covers this Particular Standard, used together with the General Standard and the Collateral Standards.

The numbering of sections, clauses, and subclauses of this Particular Standard corresponds with that of the General Standard. 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 the General Standard is replaced completely by the text of this Particular Standard.
– "Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.
– "Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures that are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk *. These rationales can be found in an informative Annex AA.

Annexes AA and CC are not normative parts of this Particular Standard and only provide additional information; they can never be the subjects of testing.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or specified Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or a Collateral Standard takes precedence over the corresponding general requirement(s).

2 Terminology and definitions

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

*** 2.1.5**
applied part

Addition:

or any part of the VENTILATOR intended to be connected to the breathing system

---

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

Additional definitions:

2.1.101
bacterial filter
device that removes bacteria and particulate matter from the gas stream

[ISO 4135:1995, definition 4.1.7 modified]

2.1.102
clearly legible
visual attribute of information displayed by the EQUIPMENT that allows the OPERATOR to discern (or identify) qualitative or quantitative values or functions under a specific set of environmental conditions

2.1.103
emergency air intake port
dedicated intake port through which ambient air may be drawn when the supply of FRESH GAS is insufficient or absent

[ISO 4135:1995, definition 4.2.2 modified]

2.1.104
flow-direction-sensitive component
VENTILATOR component through which the gas flow has to be in one direction only for its proper functioning and/or PATIENT safety

[ISO 4135:1995, definition 4.1.13]

2.1.105
fresh gas
gas supplied to the VENTILATOR BREATHING SYSTEM. It excludes the following:

– air drawn through the EMERGENCY AIR INTAKE PORT;
– air drawn through leaks in the VENTILATOR BREATHING SYSTEM;
– expired gas from the PATIENT

2.1.106
fresh gas intake port
intake port, other than the EMERGENCY AIR INTAKE PORT, through which FRESH GAS may be drawn into the VENTILATOR BREATHING SYSTEM

[ISO 4135:1995, definition 4.2.6 modified]

2.1.107
gas exhaust port
that port of a VENTILATOR from which gas is discharged to the atmosphere either directly or via a gas scavenging system

[ISO 4135:1995, definition 4.2.7]

2.1.108
gas intake port
port through which gas is drawn into the VENTILATOR BREATHING SYSTEM

2.1.109
gas output port
port through which gas is delivered at RESPIRATORY PRESSURES via the inspiratory limb to the PATIENT CONNECTION PORT

[ISO 4135:1995, definition 4.2.8 modified]

2.1.110
gas return port
port through which gas is returned at RESPIRATORY PRESSURES via the expiratory limb from the PATIENT CONNECTION PORT

[ISO 4135:1995, definition 4.2.9 modified]

2.1.111
high pressure gas input port
input port to which gas may be supplied at a pressure greater than 100 kPa

[ISO 4135:1995, definition 4.2.10 modified]

2.1.112
inflating gas
FRESH GAS that may also power the VENTILATOR

2.1.113
inflating gas input port
input port to which INFLATING GAS is supplied

[ISO 4135:1995, definition 4.2.11]

NOTE An input port is a port to which gas is supplied under positive pressure and through which the gas is driven by this pressure. The gas may be supplied either at a controlled pressure or at a controlled flow.

2.1.114
inhibition
(disabled)
state in which an alarm system or part of an alarm system can not annunciate alarm signals

NOTE 1 INHIBITION may apply to an individual alarm condition, to a group of alarm conditions, or to the entire alarm system of the EQUIPMENT.

NOTE 2 INHIBITION may be invoked by the OPERATOR or by the EQUIPMENT (for instance, in a warm-up mode or when no PATIENT is connected).

NOTE 3 The duration of INHIBITION is always indefinite. Only direct action by the OPERATOR or a change in the EQUIPMENT caused by the OPERATOR (for instance, the end of a warm-up mode or when a PATIENT is connected) will revoke INHIBITION.

2.1.115
low-pressure gas input port
input port to which gas is supplied at a pressure not exceeding 100 kPa

[ISO 4135:1995, definition 4.2.14]

2.1.116
manual ventilation port
port to which a device may be connected for manual inflation of the lungs

[ISO 4135:1995, definition 4.2.15 modified]

2.1.117
maximum limited pressure (P_{LIM} max)
Highest pressure at the PATIENT CONNECTION PORT during NORMAL USE and under a SINGLE FAULT CONDITION