MALAYSIAN STANDARD

MS IEC 60601-2-12:2007

MEDICAL ELECTRICAL EQUIPMENT - PART 2-12: PARTICULAR REQUIREMENTS FOR THE SAFETY OF LUNG VENTILATORS - CRITICAL CARE VENTILATORS (IEC 60601-2-12:2001, IDT)

ICS: 11.040.10

Descriptors: medical electrical equipment, particular requirements, safety, lung ventilators, critical care

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Committee representation

The Industry Standards Committee on Medical Devices (ISC R) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Association of Malaysian Medical Industries
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Institut Penyelidikan Teknologi Nuklear Malaysia
Lembaga Perlesenan Tenaga Atom
Malaysian Medical Association
Malaysian Medical Devices Association
Malaysian Organization of Pharmaceutical Industry
Ministry of Health Malaysia
Persatuan Pengguna-pengguna Standard Malaysia
Pharmaceutical Association of Malaysia
Radiation Physics, Biophysics and Medical Physics Sub-Group of Institute of Physics Malaysia
SIRIM QAS International Sdn Bhd (Product Certification Section)
Universiti Kebangsaan Malaysia (Faculty of Allied Health Sciences)
Universiti Teknologi Malaysia (Faculty of Science)

The Technical Committee on Anaesthetic/Respiratory and Electromechanical Devices which recommended the adoption of the IEC Standard consists of representatives from the following organisations:

Academy of Medicine of Malaysia (College of Anaesthesiologists)

Biomedical Engineering Association Malaysia

Malaysian Medical Association

Malaysian Medical Devices Association

Ministry of Health Malaysia (Biomedical Engineering Section)

Ministry of Health Malaysia (Mechanical Engineering Section)

SIRIM Berhad (Secretariat)

Universiti Malaya (Biomedical Engineering Department)

Universiti Teknologi Malaysia (Faculty of Science)

Universiti Teknologi MARA (Electrical Engineering Faculty)

NATIONAL FOREWORD

The adoption of the IEC Standard as a Malaysian Standard was recommended by the Technical Committee on Anaesthetic/Respiratory and Electromechanical Devices under the authority of the Industry Standards Committee on Medical Devices.

This Malaysian Standard is identical with IEC 60601-2-12:2001, *Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators*, published by the International Electrotechnical Commission (IEC). However, for the purposes of this Malaysian Standard, the following apply:

a) in the source text, "this International Standard" should read "this Malaysian Standard";

b) the comma which is used as a decimal sign (if any), to read as a point; and

c) reference to International Standards should be replaced by equivalent Malaysian Standards as follows:

Referenced International Standards	Corresponding Malaysian Standards
IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for safety*	MS IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
IEC 60601-1-1, *Medical electrical equipment - Part 1: General requirements for safety - Section 1 - Collateral standard: Safety requirements for medical electrical systems*	MS IEC 60601-1-1, *Medical electrical equipment - Part 1: General requirements for safety - Section 1 - Collateral standard: Safety requirements for medical electrical systems*
IEC 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests*	MS IEC 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests*

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.

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, 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: Electro-medical 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

2.1.118
maximum working pressure (P_W max)
highest pressure at the PATIENT CONNECTION PORT during NORMAL USE, irrespective of the setting of controls, other than the control intended to adjust this pressure

NOTE Even if not adjustable, this maximum is equal to or less than the MAXIMUM LIMITED PRESSURE.

2.1.119
minimum limited pressure (P_{LIM} min)
lowest pressure at the PATIENT CONNECTION PORT during NORMAL USE and under a SINGLE FAULT CONDITION

NOTE This pressure may be sub-atmospheric.

2.1.120
minute volume ($\dot{V}$)
volume of gas per minute entering or leaving the lungs of the PATIENT

2.1.121
operator's position
intended location and orientation of the OPERATOR with respect to the EQUIPMENT for NORMAL USE according to the instructions for use

2.1.122
patient connection port (of the VENTILATOR BREATHING SYSTEM)
port of the VENTILATOR BREATHING SYSTEM to which the PATIENT can be connected

[ISO 4135:1995, definition 4.2.16]

NOTE Interface between the VENTILATOR BREATHING SYSTEM and the PATIENT.

2.1.123
respiratory pressure
pressure at the PATIENT CONNECTION PORT

2.1.124
suspended
state of an alarm system where OPERATOR action has temporarily caused an otherwise enabled alarm system to disable all auditory or all auditory and visual alarm signals for a fixed interval

2.1.125
ventilator
automatic EQUIPMENT that is intended to augment or provide ventilation of the lungs of the PATIENT when connected to the airway of the PATIENT

2.1.126
ventilator breathing system (VBS)
breathing system bounded by the LOW PRESSURE GAS INPUT PORT(S), the GAS INTAKE PORT(S) and the PATIENT CONNECTION PORT, together with the FRESH GAS INTAKE and EXHAUST PORT(S), if these are provided

[ISO 4135:1995, definition 4.1.6 modified]

3 General requirements

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

*** 3.1**

Addition:

Any fault that can lead to a hazard and that is not detected by intrinsic means or by periodic inspection (e.g. an oxidant leak, software defect) shall be regarded as a NORMAL CONDITION and not a SINGLE FAULT CONDITION.

3.4

Addition:

An equivalent degree of safety may be demonstrated by means of a risk analysis, in accordance with ISO 14971.

4 General requirements for tests

This clause of the General Standard applies.

5 Classification

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

5.2

Addition:

NOTE A VENTILATOR may have APPLIED PARTS of different types.

6 Identification, marking and documents

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

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

e) Indication of origin

Addition (after the existing sentence):

The name and address of the manufacturer or authorized representative, as applicable, shall also be marked.

k) Mains power output

Replacement:

If provided, AUXILIARY MAINS SOCKET OUTLET(S) of EQUIPMENT shall be marked with the maximum allowed output in amperes or volt-amperes.

q) Physiological effects

Addition (between the first and second paragraphs)

If applicable, a warning that latex is used.

Addition:

aa) Any HIGH PRESSURE GAS INPUT PORT shall be marked with the name or symbol of gas in accordance with ISO 5359 and with the supply pressure range and the nominal maximum flow requirements. If gas-specific color-coding of flow control or flexible hoses is provided, it shall be in accordance with ISO 32.

bb) If OPERATOR accessible ports are provided, they shall be marked. The following terms should be used.

- INFLATING GAS INPUT PORT: 'Inflating Gas Input'
- MANUAL VENTILATION PORT: 'Bag'
- GAS OUTPUT PORT: 'Gas Output'
- GAS RETURN PORT: 'Gas Return'
- GAS EXHAUST PORT: 'Exhaust'

  Alternatively, other terms or symbols may be used in the above and explained in the instructions for use.

- EMERGENCY AIR INTAKE PORT: 'WARNING: Emergency Air Intake – Do Not Obstruct'

cc) Any particular storage and/or handling instructions.

dd) Any particular warnings and/or precautions relevant to the immediate operation of the VENTILATOR.

ee) Where appropriate, an indication of the date by which the EQUIPMENT or ACCESSORY shall be used expressed as the year and month.

NOTE Symbol 3.12 from ISO 15223:2000 may be used.

ff) Packages containing breathing attachments intended for single use shall be clearly marked with the following, as far as applicable:

- A description of the contents.
- The words "SINGLE USE", “DO NOT REUSE”, Symbol 1051 from ISO 7000:1989 or Symbol 3.2 from ISO 15223:2000.
- The word "STERILE," if applicable”, or one of Symbols 3.20 to 3.24 from ISO 15223:2000.
- The name or trademark and address of the manufacturer, supplier, or authorized representative.
- An identification reference to the type, or Symbol 3.15 from ISO 15223:2000.
- An identification reference to the batch or serial number or Symbol 3.14 or 3.16 from ISO 15223:2000.
- Packages containing latex shall be clearly marked with the word ‘LATEX’.

gg) Packages containing breathing attachments intended for reuse shall be clearly marked with the following:

- A description of the contents.
- The name or trademark and address of the manufacturer, supplier, or authorized representative.
- An identification reference to the type, or Symbol 3.13 from ISO 15223:2000.
- An identification reference to the batch or serial number or Symbols 3.14 or 3.16 from ISO 15223:2000.
- Recommended methods of cleaning, disinfection and sterilization.

NOTE Some breathing attachments may contain recommended methods for cleaning, disinfection and sterilization in the instructions for use. See also 6.8.2 d).

- Packages containing latex shall be clearly marked with the word ‘LATEX’.

hh) All FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a tool shall be durably marked with a CLEARLY LEGIBLE arrow indicating the direction of the flow.

6.3 g)

Addition:

– Pressure:
  - cm H_2O

6.6 Identification of medical gas cylinders and connections

Replacement:

a) If gas-specific color-coding is used (e.g., for flow controls, flexible hoses, gas cylinders, etc.) it shall be in accordance with ISO 32. See also 56.3 a).

6.8.2 Instructions for use

6.8.2 d) Cleaning, disinfection and sterilization of parts in contact with the PATIENT

Addition (as a second paragraph):

If applicable, the instructions for use shall contain:

- information about cleaning and sterilization prior to first use;
- information about cleaning, disinfection and sterilization and any restriction concerning re-use;
- instructions which indicate the maximum number of processes for each reusable component or visual functional pass/fail criteria to be used in determining when a component needs replacement.

Device packaging and/or labelling shall differentiate between the same or similar products placed on the market by the same manufacturer, both sterile and non-sterile. See also 6.1 ff) 3.

Addition:

aa) Additional general information

The instructions for use shall include the following:

1. * A statement to the effect that antistatic or electrically conductive hoses or tubing shall not be used.
2. * If the VENTILATOR has provisions for an INTERNAL and/or external reserve ELECTRICAL POWER SOURCE, the manufacturer shall disclose in the appropriate documentation at least the following data (see also 49.101 and 49.102):
   - the ampere-hour rating;
   - the voltage requirement;
   - the current requirement;
   - the operational time from the power source after it has become fully charged;
   - the means for determining the status of the reserve power source; and
   - the means by which the reserve power source can be tested.
3. If the VENTILATOR is provided with a reserve power supply, the functioning after a switchover to the reserve power supply shall be described.
4. If the VENTILATOR is designed to operate with high-pressure gas(es), the supply pressure and flow range(s) shall be stated.

5. A statement as to whether any portion of the gas supplied to a HIGH PRESSURE GAS INPUT PORT is used as FRESH GAS.
6. A method for testing the function of the ALARM SYSTEM for each of the ALARM CONDITIONS specified in this Standard.
7. The intended use of the VENTILATOR.
8. A statement to the effect that, while the VENTILATOR is in use, an alternative means of ventilation should always be available.
9. If ports are non-conical, this information shall be given with the instructions for use, or a marking shall be made. See also 56.3 dd) 2 ii).
10. Instructions and information necessary to ensure that the VENTILATOR is installed correctly and is in safe and correct working order.
11. Specifications about the nature and frequency of maintenance operations necessary to ensure continuing safe and correct operation. This requirement also applies to ACCESSORY components.
12. For each control and measured variable provided on the VENTILATOR, a listing of the applicable range, resolution and accuracy. See also 51.107.

NOTE The accuracy should be expressed in the form of maximum zero error quoted in appropriate units, plus a sensitivity error quoted, e.g., as a percentage of reading.

13. * If the VENTILATOR is specified to be used in environmental conditions which extend beyond those specified in 10.2.1 of this Standard and performance is affected by this, the manufacturer shall disclose the extended limits and how the VENTILATOR will respond.

NOTE Critical care VENTILATORS are intended for hospital use and no such specification is expected.

14. The means of accomplishing automatic record keeping or, if applicable, that automatic record keeping is not supported.
15. The ranges of any supply that is required for NORMAL USE of the VENTILATOR. See also 49.101.
16. Warning statement to the effect that the VENTILATOR shall not be covered or positioned in such a way that the operation or performance of the VENTILATOR is adversely affected (e.g., positioned next to a curtain that blocks the flow of cooling air, thereby causing the EQUIPMENT to overheat).
17. If an alarm limit is set automatically, the alarm limit(s) algorithm or default value(s) shall be disclosed.
18. The inspiratory and expiratory pressure drop measured at the PATIENT CONNECTION PORT at 60 l/min for VENTILATORS intended for providing tidal volumes greater than 300 ml, or 30 l/min for tidal volumes between 300 ml and 30 ml, or 5 l/min for tidal volumes less than 30 ml, when the recommended breathing system is in use and normal ventilation is compromised by the total or partial loss of power supply. See 49.103.
19. A statement to the effect that when adding attachments or other components or sub-assemblies to the VENTILATOR BREATHING SYSTEM, the pressure gradient across the VENTILATOR BREATHING SYSTEM, measured with respect to the PATIENT CONNECTION PORT, may increase.

6.8.3 Technical description

a) * General

Addition:

– for all measured and/or computed variables that are displayed or used for control, a general description of the filtering and/or smoothing techniques, as applicable;
– if there is a facility for sub-atmospheric pressure in the expiratory phase, the limiting pressure and generated pressure, if applicable, shall be listed for the inspiratory and expiratory phase;

– a technical description of the means of triggering shall be provided if applicable;

– the conditions under which any measured or displayed flow, volume or ventilation is to be expressed, e.g., Ambient Temperature and Pressure Dry (ATPD), Body Temperature and Pressure Saturated (BTPS) etc.;

– the principle by which each VENTILATOR alarm condition, essential for the safe operation of the VENTILATOR, is detected, their priority level(s), and the algorithms that cause the annunciation of a given priority level. If priority levels escalate and de-escalate, those algorithms shall also be disclosed. See 49.101, 49.102, 50.101.2, 51.106, 51.107, 51.108, and 56.104;

– the performance characteristics necessary for safe operation of the VENTILATOR with VENTILATOR BREATHING SYSTEM(S), breathing attachments, and other components or sub-assemblies (e.g., breathing tubes, humidifier, filter, etc.) recommended by the manufacturer for inclusion in the VENTILATOR BREATHING SYSTEM;

NOTE Such characteristics may include pressure-flow relationships, compliance and internal volume.

– if provided, disclosure of the characteristics of the bacterial filter;

– a pneumatic diagram of the VENTILATOR including a diagram for each VENTILATOR BREATHING SYSTEM either supplied or recommended by the manufacturer;

– disclosure of any restrictions on the sequence of components placed within the VENTILATOR BREATHING SYSTEM, e.g., where such components are FLOW-DIRECTION SENSITIVE;

– interdependence of controls, if applicable;

– a listing of the following pressures:

- MAXIMUM LIMITED PRESSURE (P_{lim}max);
- range of values to which the MAXIMUM WORKING PRESSURE (P_w max)can be set and the means by which the maximum is assured (e.g., pressure cycling, pressure limiting, pressure generation);
- a statement whether negative (sub-atmospheric) pressure is available in the expiratory phase.

7 Power input

This clause of the General Standard applies.

SECTION TWO – ENVIRONMENTAL CONDITIONS

8 Basic safety categories

This clause of the General Standard applies.

9 Removable protective means

This clause of the General Standard applies.

10 Environmental conditions

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

10.2 Operation

Addition (add before the semicolon):

or any extension of these conditions as specified by the manufacturer in the ACCOMPANYING DOCUMENTS. See also 6.8.2 aa) 13.

10.2.2 Power Supply

Addition:

aa) The VENTILATOR shall comply with this standard throughout the range of INTERNAL or external ELECTRICAL POWER SOURCE variation stated by the manufacturer.

10.101 Pneumatic driving power supplies

If the VENTILATOR is intended to be connected to a medical gas pipeline system complying with ISO 7396, it shall operate and meet the requirements of this standard throughout a range of 280 kPa to 600 kPa and shall cause no safety hazard with inlet pressures up to 1 000 kPa. The gas flow measured at the VENTILATOR'S HIGH PRESSURE GAS INPUT PORT shall not exceed 60 l/min (time weighted average over 10 s) at a pressure of 280 kPa under NORMAL CONDITIONS. Further, the transient flow requirement shall not exceed the equivalent of 200 l/min for 3 s.

NOTE Flow values are expressed under ATPD conditions.

11

Not used.

12

Not used.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

13 General

This clause of the General Standard applies.

14 Requirements related to classification

This clause of the General Standard applies.

15 Limitation of voltage and/or energy

This clause of the General Standard applies.

16 ENCLOSURES and PROTECTIVE COVERS

This clause of the General Standard applies.

17 Separation

This clause of the General Standard applies.

18 Protective earthing, functional earthing and potential equalization

This clause of the General Standard applies.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies

19.4 * Tests

h) Measurement of the PATIENT LEAKAGE CURRENT

Addition:

101) *The PATIENT LEAKAGE CURRENT shall be measured from all parts that are defined as APPLIED PARTS for the purpose of this Particular Standard. All parts of the same type shall be connected together electrically with the exception of parts connected to the protective earth terminal that shall be tested separately from parts not so connected.*

20 Dielectric strength

This clause of the General Standard applies.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21 Mechanical strength

This clause of the General Standard applies.

22 Moving parts

This clause of the General Standard applies.

23 Surfaces, corners and edges

This clause of the General Standard applies.

24 Stability in NORMAL USE

This clause of the General Standard applies.

25 Expelled parts

This clause of the General Standard applies.

26 Vibration and noise

This clause of the General Standard applies.

27 Pneumatic and hydraulic power

This clause of the General Standard applies.

28 Suspended masses

This clause of the General Standard applies.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

29 X-radiation

This clause of the General Standard applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

This clause of the General Standard applies.

31 Microwave radiation

This clause of the General Standard applies.

32 Light radiation (including lasers)

This clause of the General Standard applies.

33 Infra-red radiation

This clause of the General Standard applies.

34 Ultra-violet radiation

This clause of the General Standard applies.

35 Acoustical energy (including ultrasonics)

This clause of the General Standard applies.

36 Electromagnetic compatibility

This clause of the General Standard applies.

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

37 Locations and basic requirements

This clause of the General Standard applies.

38 Marking, ACCOMPANYING DOCUMENTS

This clause of the General Standard applies.

39 Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT

This clause of the General Standard applies.

40 Requirements and tests for CATEGORY AP EQUIPMENT, parts and components thereof

This clause of the General Standard applies.

41 Requirements and tests for CATEGORY APG EQUIPMENT, parts and components thereof

This clause of the General Standard applies.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42 Excessive temperatures

This clause of the General Standard applies.

43 * Fire prevention

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

Addition:

In order to reduce the risk to PATIENTS, to other persons or to the surroundings due to fire, ignitable material, under NORMAL and SINGLE FAULT CONDITIONS, shall not at the same time be subjected to conditions in which:

- the temperature of the material is raised to its minimum ignition temperature, and
- an oxidant is present.

NOTE Air mixtures with a volume fraction of less than 25 % oxygen are not considered to be an oxidant.

The minimum ignition temperature is determined in accordance with IEC 60079-4 using the oxidizing conditions present under NORMAL and SINGLE FAULT CONDITIONS.

Compliance is checked by determining the temperature to which the material is raised under the NORMAL and SINGLE FAULT CONDITIONS.

If sparking can occur under NORMAL or SINGLE FAULT CONDITIONS, the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of NORMAL CONDITIONS with a SINGLE FAULT CONDITION.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

This clause of the General Standard applies.

44.3 Spillage

Addition:

The VENTILATOR shall be so constructed that the spillage does not cause a safety hazard.

44.7 Cleaning, sterilization and disinfection

Addition:

VENTILATOR BREATHING SYSTEM attachments and sub-assemblies intended for reuse shall be so constructed that they can be dismantled for cleaning, disinfection or sterilization.

If a claim is made in the labelling that a product is sterile, it shall have been sterilized using an appropriate, validated method as described in ISO 11134, ISO 11137 and ISO 11138, parts 1-3: *Sterilization of health care products* and ISO 11135, *Medical Devices – Validation and routine control of ethylene oxide sterilization*

Non-sterile device packaging systems shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.

44.8 Compatibility with substances used with the EQUIPMENT

Addition:

The VENTILATOR and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the EQUIPMENT or its components during use. Particular attention shall be paid to the toxicity of materials and their compatibility with substances and gases with which they enter into contact during NORMAL USE or routine procedures.

Compliance is checked by inspection of the information provided by the manufacturer.

45 Pressure vessels and parts subject to pressure

This clause of the General Standard applies except as follows:

The requirements given in Clause 45 of the General Standard do not apply to the VENTILATOR BREATHING SYSTEM.

46 Human errors

This clause of the General Standard applies.

NOTE IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability: Analysis, test and validation of human factors compatibility* is currently under development.

47 Electrostatic charges

This clause of the General Standard applies.

48 Biocompatibility

This clause of the General Standard applies.

49 Interruption of the power supply

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

Addition:

49.101 Power failure alarm system

The VENTILATOR shall have a supply failure high priority alarm condition whose signals comply with Clause 50.101, or that annunciate an auditory alarm signal of at least 120 s duration if the supply power falls below the values specified by the manufacturer. If the function of the VENTILATOR is maintained by the switchover to an INTERNAL ELECTRICAL POWER SOURCE these alarm signals shall not annunciate.

Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an information signal or a low-priority alarm signal complying with Clause 50.101.

NOTE Risk analysis will determine which signal is appropriate.

Compliance is checked by simulating a drop below the supply ratings as indicated in the instructions for use. See also 6.8.2 aa) 2.

49.102 INTERNAL ELECTRICAL POWER SOURCE

If the VENTILATOR has an INTERNAL ELECTRICAL POWER SOURCE, it shall be equipped with a means of determining the state of this power source.

As the INTERNAL ELECTRICAL POWER SOURCE depletes, but prior to the loss of all power, the VENTILATOR shall have an impending supply failure warning medium priority alarm condition that annunciates alarm signals complying with Clause 50.101. See also 6.8.3 a) seventh dash.

NOTE The alarm priority may escalate to high priority as the INTERNAL ELECTRICAL POWER SOURCE depletes.

Compliance is checked by reducing the power source(s) to values below the minimum value(s) specified by the manufacturer (electric and/or pneumatic) required for the intended use.

49.103 Spontaneous breathing during power failure

The VENTILATOR shall be designed so as to enable spontaneous breathing when normal ventilation is compromised as a result of electrical or pneumatic supply power being outside the values specified by the manufacturer. See 6.8.2 aa) 15. Resistance values during SINGLE FAULT CONDITION shall be disclosed in the ACCOMPANYING DOCUMENTS. See 6.8.2 aa) 18.

NOTE This requirement is to enable the PATIENT to breathe spontaneously under "power failure conditions" of the VENTILATOR.

Compliance is checked by simulating supply power conditions outside those specified for NORMAL CONDITIONS and measurement of flow, pressure, and resistance at the PATIENT CONNECTION PORT and comparing them to the values in the ACCOMPANYING DOCUMENTS.

49.104 Inadvertent operation of the on/off-switch

Means shall be provided to prevent accidental operation of the on/off-switch.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 Accuracy of operating data

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

Addition:

50.101 Alarms system

50.101.1 Alarm categories

The alarm signals for alarm conditions specified in this Particular Standard, shall have the characteristics specified in ISO 9703-1, ISO 9703-2, and ISO 9703-3.

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.

50.101.2 * Alarm system structures

The alarm system structure shall be either conventional, i.e., each alarm condition annunciates at a specified priority, or intelligent, e.g., alarm conditions annunciate at one priority then escalate and de-escalate as risk to the PATIENT increases or decreases. See Annex CC and 6.8.3 a) seventh dash.

50.101.3 Priority

When an alarm signal is initially annunciated, it shall have the priority specified by the manufacturer but can be subsequently changed.

50.101.4 INHIBITION

If an auditory alarm signal can be INHIBITED by the OPERATOR, there shall be a visual indication that it is in INHIBITION.

50.101.5 SILENCING and SUSPENDED alarm systems

If auditory alarm signals are provided with means for SILENCING or to be SUSPENDED by the OPERATOR, the SILENCING or SUSPENDED period shall not exceed 120 s. SILENCING shall not prevent the auditory alarm signal from annunciating a new or different alarm condition.

NOTE The auditory alarm signal should allow disabling automatically or by the OPERATOR until the VENTILATOR is connected to the PATIENT, to prevent nuisance alarm signals.

50.101.6 Alarm Settings

The settings of adjustable alarm settings shall be indicated either continuously or by OPERATOR action.

50.101.7 High priority alarm signals

When a high priority alarm signal has annunciated and when the alarm condition causing the auditory signal has cleared, there shall remain a visual signal indicating the previous alarm condition. If the auditory alarm signal is reset automatically, it shall not reset before one burst is completed.

The maximum time for which an auditory high-priority alarm signal can be silenced or SUSPENDED shall be 120 s.

NOTE The auditory alarm signal at minimum volume should be discernible to a person with normal hearing, above the background white noise level of 55 dB(A), at a distance of 3 m from the front of the VENTILATOR.

50.101.8 Medium-priority alarm signals

If the auditory alarm signal is reset automatically, it shall not reset before one burst is completed.

The maximum time for which an auditory medium-priority alarm signal can be silenced or SUSPENDED shall be 120 s.

50.101.9 Remote alarm signal capability

If an interface to a remote alarm signal extension is provided on a VENTILATOR, the interface shall be so designed that a failure in the remote circuit does not affect the correct functioning of the alarm system on the VENTILATOR.

51 Protection against hazardous output

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

Addition:

51.101 Failure of one gas in an air oxygen mixing system

For a failure of one gas supply in an air-oxygen mixing system, the VENTILATOR shall automatically switch to the remaining gas, and otherwise maintain NORMAL USE. This shall be accompanied by at least a low priority alarm signal with an auditory component complying with Clause 50.101.1.

51.102 Protection against inadvertent adjustments

Means of protection against inadvertent adjustment of controls that can create a hazardous output shall be provided.

NOTE Mechanical control techniques such as locks, shielding, friction-loading and detents are considered as suitable. For pressure-sensitive finger pads, capacitive finger switches and microprocessor-oriented “soft” controls, a specific sequence of key or switch operations is considered suitable.

Compliance is checked by visual inspection following the instructions for use.

51.103 Pneumatic pressure relief devices (maximum pressure limitation)

A means shall be provided to prevent the pressure at the PATIENT CONNECTION PORT from exceeding 125 hPa (125 cm H_2O) under NORMAL USE and SINGLE FAULT CONDITION.

51.104 Measurement of RESPIRATORY PRESSURE

The RESPIRATORY PRESSURE at the PATIENT CONNECTION PORT shall be indicated. The site(s) of actual measurement may be anywhere in the VENTILATOR BREATHING SYSTEM, but the displayed value shall be referenced to that at the PATIENT CONNECTION PORT. The value read by the OPERATOR shall be accurate within ± (2 % of the full scale reading + 4 % of the actual reading).

Compliance is checked by visual inspection and verification of accuracy.

51.105 Adjustable pressure limitation

A means shall be provided to prevent pressure in the breathing system in excess of the active limit value(s).

NOTE Depending on the types of breaths being delivered by the VENTILATOR, there may be more than one active pressure limit (e.g., during SIMV ventilation, volume control and pressure support may coexist, each with its own high pressure limit values).

Pressure limits shall be OPERATOR adjustable or specified by (within) an active breathing algorithm or a combination of both. If limit values are not directly adjustable by the OPERATOR, the algorithm(s) that determines the limit value(s) shall be described in the instructions for use. See also 6.8.3 a) seventh dash.

Each time an active limit value is reached, the VENTILATOR shall act to reduce the pressure in the breathing system to a level at or below the active PEEP value. The interval from the moment that the breathing system pressure equals the limit value to the moment that the pressure starts to decline shall not exceed 200 ms.

51.106 High-pressure alarm condition

The VENTILATOR shall annunciate a high priority alarm signal if a preset pressure limit is reached. The alarm limit may be independently adjustable or connected to the adjustable pressure limitation, as defined in 51.105. If independently adjustable it shall not be possible to set the alarm limit to a value higher than that of the adjustable pressure limitation.

NOTE PATIENT generated transient pressures (e.g. a cough) should not cause the alarm condition.

51.107 Measurement of expiratory volume and low-volume alarm condition

VENTILATORS intended to deliver tidal volumes above 100 ml shall be provided with a means for measuring expiratory tidal volume or expiratory MINUTE VOLUME. The accuracy of the tidal volumes greater than 100 ml or MINUTE VOLUMES greater than 3 l/min shall be ±15 % of their actual volumes.

A means shall be provided to annunciate a low volume alarm condition when the monitored volume violates the alarm limit. This alarm signal shall comply with Clause 50.101.1. This alarm signal shall be at least medium priority.

NOTE 1 A VENTILATOR may have an alarm system that in a low volume alarm condition first annunciates at low priority and if this state continues, escalates to higher priority. See 6.8.3 a) seventh dash.

If volume measurement for tidal volumes below 100 ml is provided, a means shall be included to annunciate a low volume alarm condition when monitored volume violates the alarm limit. This alarm signal shall comply with Clause 50.101, and shall be at least low priority. Accuracy below 100 ml or 3 l/min shall be disclosed in the instructions for use. See also 6.8.2 aa) 12.

A low limit value shall be adjustable or pre-adjusted.

NOTE 2 The low alarm limit may be set by the OPERATOR or may be specified by the active breathing algorithm or a combination of both. If limit values are not directly adjustable by the OPERATOR, the algorithm that determines the alarm limit values should be disclosed in the technical description. See also 6.8.3 a) seventh dash.

Compliance is checked by visual inspection and verification of accuracy using an apparatus described in Table 101.

NOTE 3 Depending on the types of ventilation patterns being delivered, there may be more than one active alarm limit.

Table 101 – Test conditions for expiratory volume tests

Adjustable parameter	Test condition		
	For VENTILATORS intended to deliver tidal volumes:		
	V_T > 300 ml	300 ml ≥ V_T ≥ 30 ml	V_T <30 ml
Tidal volume V_T (ml) as measured by means of pressure sensor on test lung ($V_T = C \times P_{max}$)	500	300	30
Frequency F (min^{-1})	10	20	30
I:E Ratio	1:2	1:2	1:2
Resistance R (kPa/(l/s))	0,5 kPa $(l/s)^{-1}$ ± 10 %	2 kPa $(l/s)^{-1}$ ± 10 %	5 kPa $(l/s)^{-1}$ ± 10 %
Isothermal compliance C (ml kPa^{-1})	500 ml kPa^{-1} ± 5 %	200 ml kPa^{-1} ± 5 %	10 ml kPa^{-1} ± 5 %
NOTE The accuracy for C and R applies over the ranges of the measured parameters.			

51.108 Continuing pressure alarm condition

A means of annunciating a high priority alarm signal shall be provided, complying with Clause 50.101, when the pressure in the VBS exceeds a limit for continuing positive pressure. The maximum delay before annunciation shall be 17 s.

NOTE Examples are alarm conditions to warn of an obstructed or partially obstructed return tube or excessively high CPAP or PEEP.

The means by which this alarm condition is detected and the structure of the detection algorithm shall be described in the technical description. See also 6.8.3 a) seventh dash.

Compliance is checked by using the method described in the technical description. See also 6.8.2 aa) 6.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

52 Abnormal operation and fault conditions

This clause of the General Standard applies except as follows:

52.5

Addition:

* A SINGLE FAULT CONDITION shall not cause a monitoring or alarm system and the corresponding ventilation control function to fail in such a way that the monitoring function becomes simultaneously ineffective, and thus fails to detect the loss of the monitored VENTILATOR function.

53 Environmental tests

This clause of the General Standard applies.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

54 General

This clause of the General Standard applies.

55 ENCLOSURES and covers

This clause of the General Standard applies.

56 Components and general assembly

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

56.3 Connections – General

Addition:

aa) * Gas leakage from connections

1. Means shall be provided to limit reverse gas flow from gas input ports into the supply system of the same gas to 100 ml/min under NORMAL USE.
2. The cross flow of gases from one to another HIGH PRESSURE INPUT PORT of a different gas type shall not exceed 100 ml/h under NORMAL USE or SINGLE FAULT CONDITIONS.

   If under SINGLE FAULT CONDITIONS the cross flow of gases from one to another can exceed 100 ml/h the ventilator shall be equipped with an auditory alarm signal. This cross flow shall not exceed 100 ml/min.

   Compliance is checked by inspection of the information provided by the manufacturer.

bb) High pressure gas input ports

The gas input port connector provided for the input of high pressure respiratory gases shall be either the body of an NIST fitting complying with the requirements of ISO 5359 or the male part of a quick connection complying with the requirements of ISO 5359.

cc) Connection to the medical gas supply system

If an OPERATOR detachable hose assembly is provided for connection between the VENTILATOR and the medical gas supply system, it shall comply with ISO 5359.

dd) VBS connectors

1. General

– VBS connectors, if conical, shall be either a 15 mm or a 22 mm connector complying with ISO 5356-1.

– Non-conical connectors shall not engage with conical connectors complying with ISO 5356-1 unless they comply with the engagement, disengagement and leakage requirements of that standard.

2. Statements specific to named ports

   i) FRESH GAS INTAKE PORT

   A FRESH GAS INTAKE PORT, if provided, shall not be compatible with connectors complying with ISO 5356-1 and ISO 5356-2.

ii) Gas output, GAS RETURN PORT, and PATIENT CONNECTION PORT connectors

The gas output, GAS RETURN PORT, and PATIENT CONNECTION PORT shall, if conical (see also 6.8.2 aa) 9), be one of the following:

- a 22 mm conical connector complying with ISO 5356-1 or ISO 5356-2;
- a 15 mm conical connector complying with ISO 5356-1;
- a coaxial 15 mm/22 mm conical connector complying with ISO 5356-1 or ISO 5356-2.

iii) MANUAL VENTILATION PORT

If a MANUAL VENTILATION PORT is provided, it shall be either a 22 mm conical connector complying with ISO 5356-1 or a male cylindrical connector that will accept a breathing tube complying with ISO 5367.

iv) EMERGENCY AIR INTAKE PORT

An EMERGENCY AIR INTAKE PORT shall be provided and shall not accept any connector complying with ISO 5356-1 or 5356-2.

NOTE An EMERGENCY AIR INTAKE PORT should be designed to prevent obstruction when the VENTILATOR is in use.

v) FLOW-DIRECTION-SENSITIVE COMPONENT connectors

Any FLOW-DIRECTION SENSITIVE, OPERATOR detachable component of the VENTILATOR BREATHING SYSTEM shall be so designed that it cannot be fitted in such a way that it presents a hazard to the PATIENT.

vi) ACCESSORY port

If an ACCESSORY port is provided, it shall not be compatible with connectors specified in ISO 5356-1 or 5356-2 and shall be provided with a means to secure engagement and closure.

NOTE This port is generally used for sampling of gases or for introduction of therapeutic aerosols.

vii) Monitoring probe port

If a port is provided for introduction of a monitoring probe, it shall not be compatible with connectors as specified in ISO 5356-1 or 5356-2, and shall be provided with a means to secure the probe in position and a means to secure closure after removal of the probe.

viii) GAS EXHAUST PORT

If a 30 mm connector is provided complying with ISO 5356-1, it shall be suitable for connection to anaesthesia gas scavenging systems (AGSS) complying with ISO 8835-3.

Compliance is checked by inspection.

56.8 Indicators

Addition:

Visual displays shall be clearly visible and legible.

Compliance with the requirements of 6.3 of the General Standard is checked by inspection and application of the durability test of 6.1 and the visibility and legibility test of Annex BB.

Addition:

56.101 Reservoir bags and breathing tubes

a) Any reservoir bags intended for use in the VENTILATOR BREATHING SYSTEM shall comply with ISO 5362.

b) Breathing tubes intended for use in the VENTILATOR BREATHING SYSTEM shall comply with ISO 5367.

56.102 Humidifiers and heat and moisture exchangers

Any humidifier or heat and moisture exchanger, either incorporated into the VENTILATOR or recommended for use with the VENTILATOR, shall comply with ISO 8185 or ISO 9360 respectively.

56.103 Pulse oximeters and capnometers

Any pulse oximeter or capnometer, either incorporated into the VENTILATOR or recommended for use with the VENTILATOR, shall comply with ISO 9919 or ISO 9918, respectively.

56.104 Oxygen monitor and alarm condition

The VENTILATOR shall be equipped with an oxygen monitor for the measurement of inspiratory oxygen concentration, e.g., in the inspiratory limb or at the PATIENT CONNECTION PORT. The oxygen monitor shall comply with ISO 7767 and shall, in addition, be provided with a high alarm limit. The high alarm limit shall have at least a medium priority complying with Clause 50.101.

NOTE 1 The alarm limits may be set by the OPERATOR or may be derived from the set oxygen concentration or a combination of both. If limit values are not directly adjustable by the OPERATOR, the algorithm that determines the alarm limit values should be disclosed in the technical description.

NOTE 2 If the oxygen monitor fails, it may be disabled, provided that a visual information signal is displayed.

56.105 Integrated monitoring

Any monitoring devices integrated into the VENTILATOR not referenced in this standard shall comply with the relevant Particular Standard.

56.106 Gas mixing system

Any gas mixing system, either incorporated into the VENTILATOR or recommended for use with the VENTILATOR, shall be in accordance with the relevant requirements of ISO 11195.

56.107 Leakage from complete VBS

The leakage from the VBS shall not exceed 200 ml/min at 50 hPa for VENTILATORS intended to provide tidal volumes greater than 300 ml, or 100 ml/min at 40 hPa for tidal volumes between 300 ml and 30 ml, or 50 ml/min at 20 hPa for tidal volumes less than 30 ml.

Compliance is determined by the following test:

Set up the VBS for the intended application as recommended by the manufacturer. Seal all ports. Connect the pressure measuring device and introduce the air into the breathing system until a pressure of 50 hPa (50 cm H_2O) for VBS intended to provide tidal volumes greater than 300 ml, 40 hPa (40 cm H_2O) for VBS for tidal volumes between 300 ml and 30 ml, or 20 hPa (20 cm H_2O) is reached for VBS for tidal volumes less than 30 ml. Adjust the flow of air to stabilize the pressure and record the leakage flow.

57 MAINS PARTS, components and layout

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

57.2 * MAINS CONNECTORS, APPLIANCE INLETS and the like

e) AUXILIARY MAINS SOCKET OUTLETS

Amendment (add in the second paragraph, following TROLLEYS):

or ventilators

Addition:

The VENTILATOR and, if provided, each individual AUXILIARY MAINS SOCKET OUTLET or the group of AUXILIARY MAINS SOCKET OUTLETS shall be provided with separate fuses or over-current releases, as required for EQUIPMENT in 57.6 of the General Standard,.

NOTE The requirements in IEC 60601-1-1 also apply to AUXILIARY MAINS SOCKET OUTLETS.

Replacement (replace the compliance test):

Compliance is checked by inspection and by loading all individual AUXILIARY MAINS SOCKET OUTLETS up to the maximum of their rating or the group rating. Each individual AUXILIARY MAINS SOCKET OUTLET shall in turn additionally be overloaded by a factor of between 5 and 10. The VENTILATOR shall maintain its normal function.

57.3 * Power Supply Cords

a) Application

Addition:

– The mains supply cord of an electrically powered VENTILATOR shall be non-detachable or shall be protected against accidental disconnection from the VENTILATOR.

– Compliance shall be checked by inspection and, for a VENTILATOR when provided with an appliance coupler, by the following test:

Subject the detachable cord for 1 min to an axial pull of force as shown in Table 102.

During the test, the mains connector shall not become disconnected from the appliance inlet.

Table 102 – Axial pull force

Mass of EQUIPMENT kg	**Pull** N
Up to and including 1	30
Over 1, up to and including 4	60
Over 4	100

58 Protective earthing – Terminals and connections

This clause of the General Standard applies.

59 Construction and layout

This clause of the General Standard applies.

Annexes

The appendices of the General Standard apply except as follows:

Appendix L

References – Publications mentioned in this standard

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

Addition:

The following normative documents contain provisions that, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC Standards:

Addition:

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres – Part 4: Method of test for ignition temperature*
Amendment 1, 1995

IEC 60079-4A:1970, *Electrical apparatus for explosive gas atmospheres – Part 4: Method of test for ignition temperature – First supplement*

Amendment:

Replace the existing references to the following publications:

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1, 1991
Amendment 2, 1995

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 1-4: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems*
Amendment 1, 1999.

Amendment:

Replace the reference to IEC 60417 by the following:

IEC 60417-1:2000, *Graphical symbols for use on equipment – Part 1: Overview and application*

IEC 60417-2: 1998, *Graphical symbols for use on equipment – Part 2: Symbol originals*
Amendment 1, 2000

ISO Standards

Addition:

ISO 4135: 1995, *Anaesthesiology – Vocabulary*

ISO 5356-1:1996, *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

ISO 5356-2:1987, *Anaesthetic and respiratory equipment – Conical connectors – Part 2: Screw-threaded, weight-bearing connectors*

ISO 5359:2000, *Low-pressure hose assemblies for use with medical gas systems*

ISO 5362:2000, *Anaesthetic reservoir bags*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*

ISO 7396:1987, *Non-flammable medical gas pipeline systems*

ISO 7767:1997, *Oxygen monitors for monitoring patient breathing mixtures – Safety requirements*

ISO 8835-3:1997, *Inhalational anaesthesia systems – Part 3: Anaesthetic gas scavenging systems – Transfer and receiving systems*

ISO 9360-1:2000, *Anaesthetic and respiratory equipment – Heat and moisture exchangers for use in humidifying respired gases in humans, Part 1: Heat and moisture exchangers for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment – Heat and moisture exchangers for use in humidifying respired gases in humans—Part 2: Heat and moisture exchangers for use with tracheostomized patients having tidal volumes of 250 ml or greater*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals – Part 1: Visual alarm signals*

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals – Part 1: Auditory alarm signals*

ISO 9703-3:1998, *Anaesthesia and respiratory care alarm signals – Part 3: Guidance on application of alarms*

ISO 9918:1993, *Capnometers for use with humans – Requirements*

ISO 9919:1992, *Pulse oximeters for medical use – Requirements*

ISO 11134:1994, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*

ISO 11135:1994, *Medical devices – Validation and routine control of ethylene oxide sterilization*

ISO 11137:1995, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*

ISO 11138-1:1994, *Sterilization of health care products – Biological indicators – Part 1: General*

ISO 11138-2:1994, *Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization*

ISO 11138-3:1995, *Sterilization of health care products – Biological indicators – Biological indicators for moist heat sterilization*

ISO 14971:2000, *Medical devices — Risk management — Application of risk management to medical devices*

ISO 15223:2000, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied*

Amendment:

Replace the reference to ISO 8185 by the following:

ISO 8185:1997, *Humidifiers for medical use – General requirements for humidification systems*

Annex AA
(informative)

Rationale

This annex provides a rationale for some requirements of this Particular Standard and is intended for those who are familiar with the subject of this Particular Standard but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this Particular Standard necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this Particular Standard. The numbering is, therefore, not consecutive.

AA.2.1.5 APPLIED PART

The definition of APPLIED PART in this Particular Standard is the basis for clarification of requirements for, and measurement of, PATIENT LEAKAGE CURRENT.

In error, it is possible that antistatic tubing or other tubing that is conductive could be used in the breathing system of a VENTILATOR.

It is not possible however, to include in this Particular Standard any requirements on LEAKAGE CURRENTS from electrically operated attachments, such as humidifiers and heating elements, that may be connected in the breathing system, because the types of such attachments that will be used in clinical work with a type of VENTILATOR cannot be anticipated by a manufacturer or a test house.

However, parts integrated with the VENTILATORs, such as temperature and carbon dioxide sensors, that are intended to come into contact with the PATIENT and that are connected to the VENTILATOR, are considered as parts for which requirements on LEAKAGE CURRENTS can be specified in this Particular Standard. Such parts are therefore included in the definitions of the APPLIED PART.

AA.3.1) EQUIPMENT

Software errors, should they occur, should not cause a safety hazard to the PATIENT, OPERATOR, or the USER.

This requirement, however, is equivalent to that of 3.1 of the General Standard that effectively states that all devices shall cause no safety hazard under NORMAL CONDITIONS and a SINGLE FAULT CONDITION.

It is, therefore, not only logical but also prudent to handle an undetected software defect that leads to a hazardous condition as a NORMAL CONDITION in order to amply accommodate software controlled devices within the framework of the General Standard and IEC 60601-1-4.

This approach is advisable, especially with respect to a failure mode effect analysis, to prove compliance with 3.1 of the General Standard.

A fault that is not detected can exist for a long time. Under these circumstances it is not acceptable to regard a further fault as a second fault that can be disregarded. Such a first fault must be regarded as a NORMAL CONDITION.

An undetected oxygen leak is an important example. It should be considered as a NORMAL CONDITION if it is not detected by an alarm system or by periodic inspection or unless the system is considered infallible.

AA.6.8.2 aa) 1

The use of antistatic and/or electrically conductive materials in the breathing system of VENTILATORS is not considered as contributing to any higher degree of safety. On the contrary, the use of such material increases the hazard of electrical shock to the PATIENT.

AA.6.8.2 aa) 2

The operating time may vary considerably and be affected by temperature and both the charging and the discharge rate of the battery.

AA.6.8.2 Instructions for Use

aa) 13

The General Standard specifies a set of ambient conditions (temperature, relative humidity, barometric pressure, power supply, etc.) under which EQUIPMENT shall comply with the requirements of the standard. These conditions represent the typical environment within a hospital but the manufacturer may specify an extension of these conditions.

If the manufacturer specifies that the EQUIPMENT may be used in a wider range of conditions than those specified in Clause 10.2.1 of this Standard, then that EQUIPMENT shall not cause a safety hazard to the PATIENT or OPERATOR if used outside the environmental conditions, i.e., all safety mechanisms shall remain functional, but the performance parameters may degrade below their specified values.

AA.6.8.3 a) General

No mention of PATIENT parameter or machine parameter is given here because this distinction exists in the General Standard.

Examples of machine parameters are "stroke volume" rather than "tidal volume", "generated pressure" rather than "airway pressure", "set ventilation" rather than "expired ventilation", "return-port pressure" rather than "airway pressure" (as, in this last instance, it is especially important to distinguish between these in some VENTILATORS intended to deliver tidal volumes equal or less than 30 ml).

Some fault conditions, e.g., obstruction or leaks, can cause serious differences between volumes and pressures in the VENTILATOR and the corresponding volumes and pressures in the PATIENT; but other fault conditions, e.g., excessive secretions or the accumulation of condensation in a pressure line, can cause serious errors in directly measured PATIENT parameters.

AA.6.8.3 a) 4th dash

Some changes in the conditions and composition of the gas at the sensor can alter the flow or volume-sensitivity of some types of sensor. Also, changes in the conditions in the sensor may alter the correction required to express the flow, volume or ventilation under some standard conditions. For example, a volume-displacement-type meter, whenever it is operating normally, will indicate the volume that has passed through it, expressed in terms of the conditions within it, irrespective of those conditions or of the composition of the gas. However, if a pneumotachograph sensor at the expiratory port is used to drive a display of "expired tidal volume" expressed at BTPS on the assumption that typical expired air, saturated at 30 °C, is passing through the pneumotachograph, then, if the temperature of the gas is less than 30 °C, the indication will be less than the true expired volume at BTPS.

Also, if the composition of the gas changes, the indication will change in proportion to the viscosity of the mixture (–8 % for a change from a mixture consisting of 50 percentage by volume of nitrogen and 50 percentage by volume of oxygen to 50 percentage by volume of nitrous oxide and 50 percentage by volume of oxygen). Conversely, if a display of volume is derived from an inherently mass-flow-sensitive device, the indicated volume will change in proportion to the density of the mixture in the sensor (+27 % for a change from a mixture consisting of 50 percentage by volume of nitrogen and 50 percentage by volume of oxygen to 50 percentage by volume of nitrous oxide and 50 percentage by volume of oxygen).

AA.19.4 h) Tests

See the rationale for AA.2.1.5.

AA.43 Fire prevention

Reports of fire caused by EQUIPMENT are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements that are necessary in order to start a fire:

- ignitable material (fuel),
- temperature equal to or above the minimum ignition temperature of the material, or sparks with energy dissipation equal to or above the minimum ignition energy of the materials, and
- an oxidant.

Therefore, following the basic safety concepts of the General Standard, the objective in the design of the EQUIPMENT must be to ensure that under both NORMAL and SINGLE FAULT CONDITIONS and under the oxidizing conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur provided it is self-limiting so that no hazard is created, to the PATIENT, to other persons or to the surroundings, because its effect is limited by limitation of the supply of oxidant or fuel or by the use of fire extinguishing materials, and that the PATIENT is not exposed to any toxic products resulting from the ignition.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although usually only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required, these may be determined using the methods and apparatus described in IEC 60079-4.

In considering the ignitable materials, particular attention should be paid to materials that may accumulate during prolonged use, e.g., airborne particles of paper or cotton.

The effect of sparks in environments containing oxidants is quite different from that in explosive gas mixtures. Spark energy is the most potent form of energy in igniting explosive gas mixtures, while in environments containing oxidants thermal energy is more fundamental. It is possible that at higher power levels sufficient spark energy can be dissipated in the interface between sparking conductors to allow their temperature to be raised above the minimum ignition temperatures of the conductors or their surroundings, so that sustained burning occurs, but there is at present no documented evidence as to the power level at which this might occur for different materials and environments. Where the potential spark power dissipation deviates from well established safe practice, therefore, specific spark tests should be conducted simulating the most unfavourable environment that can be reasonably foreseen.

The accumulating materials mentioned above are particularly susceptible to ignition by spark energy because of their low ignition temperatures and very low thermal capacity coupled with poor conductance.

In certain standards currently in use, the requirements to minimize fire risk are based on limitation of temperature, electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen that is given in the American NFPA publication 53M as 310° C. The assumption was therefore made that 300° C was an acceptable temperature limit in medical EQUIPMENT with oxygen enriched atmospheres.

The origin of the electrical energy values that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards. IEC 60601-2-13 introduced a 10 VA power limitation, along with other requirements, and to the knowledge of this committee, no fires have occurred with EQUIPMENT designed to conform to these standards. However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either overly restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any "fuel" present.

It is now generally accepted that there are no single or universally applicable ranges of temperatures, energy and concentration of oxidant that can ensure safety under all circumstances. Ultimately, electrical energy is only significant with respect to its ability to raise the temperature of ignitable materials, and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under SINGLE FAULT CONDITIONS in a typical electrical circuit the possible number of failure modes is very high. In this case full assurance of safety may only be possible by the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e., material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under NORMAL CONDITIONS and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a SINGLE FAULT CONDITION.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under a SINGLE FAULT CONDITION.

The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

AA.50.101.2 Alarm system structure

The development of "intelligent" alarm systems is under consideration (see also Annex CC). The requirements in Clause 50.101 are not intended to prohibit their development and use.

AA.52.5 Arrangement of functions

This clause prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

AA.56.3 aa) Gas leakage from connections

These conditions are necessary to maintain PATIENT safety by protecting the gas supply system from contamination.

AA.57.2) MAINS CONNECTORS, APPLIANCE INLETS and the like

A short circuit of any one of the other EQUIPMENT(S) connected at the AUXILIARY MAINS SOCKET-OUTPUTS must not affect the NORMAL USE of the life-support function of the VENTILATOR and should not affect the NORMAL USE of other EQUIPMENT connected at the AUXILIARY MAINS SOCKET-OUTPUTS.

AA.57.3) Power supply cords

Accidental disconnection can be hazardous for the PATIENT.

AA.BB.2 Visibility of visual indications

The ability to discriminate between the types of visual displays and indicators listed in BB.2 from a distance of 4 m will allow the OPERATOR to decide which VENTILATOR to respond to first in a facility with many VENTILATORS when simultaneous alarms occur (without first having to go to the position 1 m from the control panel).

Annex BB
(normative)

Legibility and visibility of visual indications

BB.1 General testing conditions

a) The OPERATOR has a visual acuity of 1 (corrected if necessary);

b) the viewpoint is at a distance d and at any point within the base of a cone subtended by an angle of 30° to the axis normal to the center of the plane of display of the monitoring display or visual indication or at the intended OPERATOR'S POSITION, and;

c) the ambient illuminance covers the range of 100 lx to 1 500 lx

BB.2* Visibility

Visual indications and visual alarm signals shall be perceived correctly and discriminated between under the conditions given in BB.1 for a distance d = 4 m.

BB.3 Legibility

The quantitative value(s) and function(s) on indicators and visual alarm signals displayed by the visual indications or graphic displays shall be correctly perceived by the OPERATOR in the conditions given in BB.1 for a distance d = 1 m.

Annex CC
(informative)

Intelligent alarm systems

It is too limiting to promulgate an intelligent alarm system (ISO 9703-3) yet constrain it by the alarm system requirements left over from earlier technologies.

It has been suggested that the requirements for PATIENT alarm conditions (i.e., pressure, volume and other similar parameters) specify a two-tier structure: one for conventional alarm systems still abiding by ISO 9703-1 and ISO 9703-2 and one for intelligent alarm systems. Intelligent alarm systems escalate and de-escalate, at the least.

The escalation/de-escalation concept lies at the heart of the intelligent alarm system. Given that the escalation concept applies, then every alarm condition can assume the high-urgency level if self-correction does not occur or if a clinician does not correct the problem at the low or medium level. Once an alarm limit has been violated, escalation to the high urgency level is assured unless the alarm condition returns to the normal range.

Escalation may be driven by several factors, for example, rate of change, number of successive violations, number of violations out of X events, the rate of the value of the alarm condition to the alarm limit, to name a few; but time alone must be one of the factors. Even if the current value of an alarm condition only exceeds the alarm limit by one percent, persistence alone will drive the urgency level from low to high. This recognition suggests that, with the exception of immediately life-threatening situations, most, if not all, alarm conditions should start at the low-urgency level and escalate to the high urgency level.

If the above arguments are valid, they provide a rationale for freeing an intelligent-alarm system design from the rigid constraints of a conventional design. See also 50.101.

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Terminology – Index of defined terms

Acknowledgements

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