INTERNATIONAL STANDARD

**ISO 8835-4**

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# Inhalational anaesthesia systems —

## Part 4: Anaesthetic vapour delivery devices

*Systèmes d'anesthésie par inhalation —*

*Partie 4: Dispositifs d'alimentation en vapeur anesthésique*



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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 8835-4 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

ISO 8835 consists of the following parts, under the general title *Inhalational anaesthesia systems*:

— *Part 2: Anaesthetic breathing systems for adults*

— *Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

— *Part 4: Anaesthetic vapour delivery devices*

— *Part 5: Anaesthetic ventilators*

NOTE ISO 8835-1 was withdrawn and has been revised as IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13, Particular requirements for the safety and essential performance of anaesthetic systems.*

# Introduction

This part of ISO 8835 is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE 1 Definitions of Collateral Standards and Particular Standards can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this part of ISO 8835, the following drafting conventions have been applied.

This part of ISO 8835 uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard [ as supplemented by the Collateral Standards], are specified by the use of the following words.

— “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list item, note, table, figure) additional to the General Standard.

— “Amendment” means that existing text of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this part of ISO 8835: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this part of ISO 8835, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— test methods: *italic type*;

— terms defined in the General Standard IEC 60601-1:1988, Clause 2, or in this Particular Standard: **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

NOTE 2 Attention is drawn to ISO/TS 18835 concerning draw-over vaporizers.

# Inhalational anaesthesia systems —

# Part 4:
# Anaesthetic vapour delivery devices



## 1 Scope

IEC 60601-1:1988, Clause 1 applies except as follows.

*Addition:*

This part of ISO 8835 specifies particular requirements for the essential performance of anaesthetic vapour delivery devices (AVDDs), as defined in 3.1. This part of ISO 8835 is applicable to AVDDs which are a component of an anaesthetic system and are intended to be continuously operator-attended. This part of ISO 8835 gives specific requirements for AVDDs which are supplementary to the applicable general requirements in IEC 60601-2-13.

This part of ISO 8835 is not applicable to AVDDs intended for use with flammable anaesthetics, as determined by Annex CC, and AVDDs intended for use within anaesthetic breathing systems (e.g. draw-over vaporizers).

The requirements of this part of ISO 8835 which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 5360, *Anaesthetic vaporizers — Agent-specific filling systems*

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

ISO 11196, *Anaesthetic gas monitors*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres. Part 4: Method of test for ignition temperature*

IEC 60079-11, *Electrical apparatus for explosive gas atmospheres — Part 11: Intrinsic safety "i"*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

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

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability*

IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, IEC 60601-2-13 and the following apply.

**3.1**
**anaesthetic vapour delivery device**
**AVDD**
device which provides the vapour of an anaesthetic agent in a controllable concentration

**3.2**
**legible**
property of displayed qualitative or quantitative information, values, functions and markings that can be discriminated and identified under a specific set of environmental conditions

NOTE See 6.101 for testing for legibility.

## 4 General requirements and general requirements for tests

IEC 60601-1:1998, Clauses 3 and 4 apply, except as follows

*Addition:*

### 4.101 Other test methods

Test methods other than those specified in this part of ISO 8835, but of equal or greater accuracy, may be used to verify compliance with requirements.

## 5 Classification

IEC 60601-1:1988, Clause 5 applies.

## 6 Identification, marking and documents

IEC 60601-2-13:2003, Clause 6 applies, except as follows.

*Additions:*

6.1 aa) The **AVDD** shall be labelled with the words “before use read instructions for use”, or Symbol #14 from IEC 60601-1:1988, Table D.1.

### 6.3 Marking of controls and instruments

*Additions:*

aa) Controls for anaesthetic vapour output shall be marked with an indication how to increase vapour output. (See 101.3 for rotary controls)

bb) Either the maximum and minimum filling levels shall be marked on the liquid level indicator, or the actual usable volume shall be displayed.

cc) The filling port shall be marked with the generic name of the anaesthetic agent. The control activating the delivery of a specific anaesthetic agent shall be marked with the generic name in full spelling or in abbreviated form as given in the following list:

- Desflurane: “DES”
- Enflurane: “ENF”
- Halothane: “HAL”
- Isoflurane: “ISO”
- Sevoflurane: “SEV”

If colour coding is used, it shall be in accordance with Annex BB.

dd) The units in which the control of the **AVDD** is graduated shall be indicated.

ee) Graduated controls shall be marked with “0” or “Off”, or with both if the “0” position is not also the “Off” position, or with “Standby” if the “Off” position is not provided.

NOTE If the **AVDD** is set at “Off” or “Standby”, no anaesthetic vapour is intentionally being added to the output flow. “Standby” set on an electrically operated **AVDD** indicates that the **AVDD** is enabled. “0” setting indicates that no more than the manufacturer's prescribed tolerance of anaesthetic vapour is being added to the output flow.

#### 6.8.2 Instructions for use

*Additions:*

aa) The instructions for use of the **AVDD** shall contain a statement to the effect that the **AVDD** is intended to be used with

- an anaesthetic agent monitor complying with ISO 11196, and
- an anaesthetic gas scavenging transfer and receiving system in accordance with ISO 8835-3.

bb) The instructions for use of the **AVDD** shall contain

1) instructions for fitting the **AVDD**, if appropriate,

2) the performance of the **AVDD**, if applicable, including the effects of variation in ambient temperature, ambient pressure, resistance to flow, tilting, back-pressure, sub-atmospheric pressure, input flow and gas mixture over the range of operating conditions specified by the manufacturer,

3) instructions for filling the **AVDD**,

4) the volume of anaesthetic agent required to fill the reservoir of the **AVDD** from the minimum to the maximum filling level, and the total capacity,

NOTE The anaesthetic agent bottle can be used as the anaesthetic agent reservoir.

5) if the **AVDD** should not be used at a setting between “Off” and the first graduation above zero, a statement to this effect,

6) the carrier gas, gas flowrate(s) and analytical technique(s) recommended for measuring the output of the **AVDD**,

7) advice on handling, transportation and storage.

### 6.101 Test method for legibility

Legible indications shall be correctly perceived by an **operator** with a visual acuity of 0 on the log MAR scale or 66 (20/20) vision (corrected if necessary) from a distance of 1 m ± 10 % at a light level of 215 lux ± 65 lux, when viewing the information, markings, etc. perpendicular to and including 15° above, below, left and right of the normal line of sight of the **operator**.

## 7 Power input

IEC 60601-1:1988, Clause 7 applies.

## 8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

## 9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

## 10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies.

## 11 Not used

IEC 60601-1:1988, Clause 11 applies.

## 12 Not used

IEC 60601-1:1988, Clause 12 applies.

## 13 General

IEC 60601-1:1988, Clause 13 applies.

## 14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies.

## 15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

## 16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

## 17 Separation

IEC 60601-1:1988, Clause 17 applies.

## 18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

## 19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies.

## 20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies.

## 21 Mechanical strength

IEC 60601-1:1988, Clause 21 applies.

## 22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

## 23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23 applies.

## 24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

## 25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.

## 26 Vibration and noise

IEC 60601-1:1988, Clause 26 applies.

## 27 Pneumatic and hydraulic power

IEC 60601-1:1988, Clause 27 applies.

## 28 Suspended masses

IEC 60601-1:1988, Clause 28 applies.

## 29 X-radiation

IEC 60601-1:1988, Clause 29 applies.

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

IEC 60601-1:1988, Clause 30 applies.

## 31 Microwave radiation

IEC 60601-1:1988, Clause 31 applies.

## 32 Light radiation (including lasers)

IEC 60601-1:1988, Clause 32 applies.

## 33 Infra-red radiation

IEC 60601-1:1988, Clause 33 applies.

## 34 Ultraviolet radiation

IEC 60601-1:1988, Clause 34 applies.

## 35 Acoustical energy (including ultrasonics)

IEC 60601-1:1988, Clause 35 applies.

## 36 Electromagnetic compatibility

IEC 60601-1:1988, Clause 36 applies, except as follows:

*Addition:*

IEC 60601-1-2:2001 applies.

## 37 Locations and basic requirements

IEC 60601-1:1988, Clause 37 does not apply.

## 38 Marking and accompanying documents

IEC 60601-1:1988, Clause 38 does not apply.

## 39 Common requirements for category AP and category APG equipment

IEC 60601-1:1988, Clause 39 does not apply.

NOTE AP = anaesthetic proof, APG = anaesthetic proof gas.

## 40 Requirements and tests for category AP equipment, parts and components thereof

IEC 60601-1:1988, Clause 40 does not apply.

## 41 Requirements and tests for category APG equipment, parts and components thereof

IEC 60601-1:1988, Clause 41 does not apply.

## 42 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies.

## 43 Fire prevention

IEC 60601-1:1988, Clause 43 applies, except as follows.

*Addition:*

* In order to reduce the risk to **patients**, other persons or the surroundings due to fire, ignitable material in an **oxygen-rich environment**, 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.

The minimum ignition temperature shall be 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 **normal** and **single fault conditions**.*

If sparking can occur under **normal** or **single fault condition(s),** 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** condition(s) with a **single fault**.*

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

IEC 60601-1:1988, Clause 44 applies, except as follows.

*Amendment:*

### 44.3 Spillage

The **AVDD** and its components shall be so constructed that spillage does not wet component parts which when wetted can cause a **safety hazard**.

*Compliance shall be tested in accordance with 44.3 of IEC 60601-1:1988.*

### 44.8 Compatibility with substances used with the equipment

*Replacement:*

The **AVDD** and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the equipment or its components during **normal use**.

Particular attention should 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, including filling procedures.

*Evidence shall be provided by the manufacturer upon request.*

## 45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45 applies.

## 46 Human errors

*Replacement:*

IEC 60601-1-6 applies.

## 47 Electrostatic charges

IEC 60601-1:1988, Clause 47 applies.

## 48 Biocompatibility

IEC 60601-1:1988, Clause 48 applies.

## 49 Interruption of the power supply

IEC 60601-1:1988, Clause 49 applies.

## 50 Accuracy of operating data

IEC 60601-1:1988, Clause 50 applies.

## 51 Protection against hazardous output

IEC 60601-1:1988, Clause 51 applies, except as follows.

*Additions:*

### 51.101 * Delivered vapour concentration

When the **AVDD** is tested by the method given in 51.102 with the carrier gas and the analytical technique recommended by the manufacturer [see 6.8.2 bb) 6)], the following requirements shall be met.

a) The delivered concentration at all graduations other than "Off", "Standby", or the "0" position if this is also the "Off" position, from the **AVDD** shall not deviate by more than +30 % or –20 % from the concentration setting or by more than +7,5 % or –5 % of the maximum setting, whichever is the greater.

b) The delivered concentration when the **AVDD** control is in the "Off" position, the "Standby" position or the "0" position if this is also the "Off" position, shall not exceed 0,05 % (volume fraction).

### *51.102 Determination of vapour concentration delivered by AVDD*

***51.102.1*** *Test the **AVDD** on a calibrated test rig capable of supplying the necessary gas flowrate and pressures required by the test conditions, or on an anaesthetic system with the anaesthetic ventilator and anaesthetic breathing system supplied or recommended by the manufacturer or supplier.*

*Connect an anaesthetic vapour analyser to the fresh gas outlet of the anaesthetic system, or to the inlet of the anaesthetic breathing system if there is no fresh gas outlet or, if applicable, to the inspiratory port of the anaesthetic ventilator.*

*Check to ensure that the components downstream of the **AVDD** will not affect the test results, for example by absorbing volatile agents, by imposing time delays on response, or by leakage.*

***51.102.2*** *Condition the calibrated test rig or the anaesthetic system, as applicable, with the specified test equipment and anaesthetic agent in the test room for at least 3 h at (20 ± 3) °C, and maintain this temperature throughout the test procedure.*

***51.102.3*** *Fill the **AVDD** with the appropriate anaesthetic agent to approximately half of the maximum usable volume, and leave it to stand for at least 45 min.*

*If the manufacturer recommends that when power is applied to the **AVDD**, a warm-up period be allowed before use, power shall be applied for at least that period before testing. This period may be within the 45 min.*

***51.102.4*** *With the **AVDD** control in the "Off", "0" or, if applicable, "Standby" position, set the gas flowrate through the anaesthetic system to (2 ± 0,2) l/min and adjust the anaesthetic ventilator to give (15 ± 2) breaths/min at an I:E ratio of 1:2 ± 20 % with the inspiratory flow control set to maximum.*

*For an anaesthetic system in which the fresh gas flow is determined by the anaesthetic ventilator settings, set these to give a minute volume of (2 ± 0,2) l.*

*Introduce a maximum pressure fluctuation of (2 ± 0,3) kPa (above ambient) at the fresh gas outlet, ensuring that the decay time during the expiration period (from 100 % of the fresh gas outlet pressure at the end of the inspiration period to 33 % of this pressure) is less than 0,6 s.*

*NOTE This can be achieved by using a test lung having a compliance of 0,2 l/kPa and an appropriate resistance.*

*Maintain the pressure fluctuations for 3 min, and after that time measure the concentration of anaesthetic vapour delivered over a further 1 min period while maintaining the pressure fluctuation. Calculate the average vapour concentration in the total delivered gas flow.*

***51.102.5** Repeat the procedure described in 51.102.4 with the **AVDD** set to each of the other settings, and in the order given in Table 101. If the **AVDD** is not marked with the concentration settings given in Table 101, use the nearest settings on the **AVDD**. If any setting given in Table 101 is equidistant between settings on the **AVDD**, use the lower setting on the **AVDD**.*

**Table 101 — Settings to be used for testing delivered concentration**

| Order of test | Setting (% volume fraction of anaesthetic vapour) |
|---|---|
| 1 | Off, Standby, and zero, if separately marked |
| 2[a] | lowest graduation above zero |
| 3 | 10 % FS |
| 4 | 20 % FS |
| 5 | 50 % FS |
| 6 | 75 % FS |
| 7 | maximum graduation (full scale) |

[a] If 10 % of full scale (FS) is the lowest graduation, step 2 is omitted.

***51.102.6** Repeat the procedure in 51.102.4 and 51.102.5, using a fresh gas flowrate of (8 ± 0,8) l/min and a pressure fluctuation at the fresh gas outlet of (5 ± 0,4) kPa.*

*For an anaesthetic system in which the fresh gas flowrate is determined by the ventilator settings, set these to give a minute volume of (8 ± 0,8) l.*

### *51.103 Vapour output during and after oxygen flush*

** When the **AVDD** is tested as described in 51.104, the output of anaesthetic vapour shall not increase by more than 20 %.*

### *51.104 Determination of delivered vapour output during and after oxygen flush*

***51.104.1** Follow the test procedure in 51.102.6. Instead of introducing a pressure fluctuation at the fresh gas outlet, measure the output of anaesthetic vapour (concentration of vapour × volume of gas) for 1 min before, during a 10 s activation of the oxygen flush, and for 30 s after the oxygen flush activation.*

*Compare these three measurements, expressed as volume flowrate (volume of vapour per unit of time).*

*NOTE The volume of gas can be determined for example, by integrating flow or by collecting the gas during the specified period.*

***51.104.2** Repeat the test procedure in 51.104.1 using a steady sub-atmospheric pressure of 10 kPa.*

*Compare these three measurements, expressed as volume flowrate (volume of vapour per unit of time).*

## 52 Abnormal operation and fault conditions

IEC 60601-1:1988, Clause 52 applies.

## 53 Environmental tests

IEC 60601-1:1988, Clause 53 applies.

## 54 General

IEC 60601-1:1988, Clause 54 applies.

## 55 Enclosures and covers

IEC 60601-1:1988, Clause 55 applies.

## 56 Components and general assembly

IEC 60601-1:1988, Clause 56 applies.

## 57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57 applies.

## 58 Protective earthing — Terminals and connections

IEC 60601-1:1988, Clause 58 applies.

## 59 Construction and layout

IEC 60601-1:1988, Clause 59 applies.

## 101 Additional requirements for AVDDs

### 101.1 Connectors

If conical connectors are used at the inlet and outlet of an operator-detachable **AVDD**, they shall be of size 23 mm in accordance with ISO 5356-1. The connector at the inlet shall be male and that at the outlet shall be female. All other systems of connectors for **AVDDs** shall ensure that the devices can only be fitted so that the gas flow through them is in the intended direction.

*Compliance is checked by visual inspection and functional testing.*

### 101.2 Controls

A control to adjust the vapour concentration shall be provided. A scale or indicator shall be provided for the calibrated range of the **AVDD**. It shall not be possible to set the control above the calibrated range. Means shall be provided to prevent the unintentional operation of the **AVDD** control. [See also 6.3 aa).]

*Compliance is checked by visual inspection and functional testing.*

### 101.3 Rotary control

If a rotary control is provided, the anaesthetic vapour concentration shall increase when the control is turned anti-clockwise.

*Compliance is checked by visual inspection and functional testing.*

NOTE Attention is drawn to the fact that the requirement in this subclause is contrary to the convention for direction of rotation for electronic controls.

### 101.4 Contamination

Means shall be provided to prevent contamination of the contents of one **AVDD** with another volatile anaesthetic agent.

*Compliance is checked by visual inspection and functional testing.*

### 101.5 Agent-specific keyed filling systems

If an agent-specific rectangular keyed filling system is used, it shall comply with ISO 5360.

*Compliance is checked by visual inspection.*

### 101.6 Overfilling

When operated in accordance with the manufacturer's instructions, it shall not be possible to overfill the **AVDD** such that

a) its performance is affected, or

b) the fluid level is no longer visible, or indicated.

*Compliance is checked by visual inspection and functional testing.*

## 102 Appendices of IEC 60601-1:1988

The Appendices of IEC 60601-1:1988 apply.

*Addition:* The subsequent annexes form an additional element of this part of ISO 8835.

# Annex AA
(informative)

# Rationale

This annex provides a rationale for some requirements of this part of ISO 8835, and is intended for those who are familiar with the subject of this part of ISO 8835 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 part of ISO 8835 necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 8835. The numbering is, therefore, not consecutive.

## AA.43 Fire prevention

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

The risk of fire is fundamentally determined by the three elements which 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;

— an oxidant.

Therefore, following the basic safety concepts of IEC 60601-1, 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 can occur, provided it is self-limiting so that no safety hazard is created (e.g. a fuse or a resistor within a sealed compartment).

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although normally only in ambient air and 100 % oxygen environments. The minimum ignition temperature can be critically dependent upon the concentration of the oxidant present. If ignition temperatures for other materials or 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 which 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, whilst 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 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. If the potential spark power dissipation deviates from well-established safe practice, therefore, specific spark tests should be conducted simulating the most unfavourable environment which 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, which is given in the American NFPA publication 53M[1] as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit for medical equipment in 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, values have been adopted from accepted working practices or from tests performed in other environments. Simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these values can be either over-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 therefore now generally accepted that there are no single or universally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances whilst not being unduly restrictive. Ultimately, electrical energy is only significant in respect of 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 with 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 single fault conditions.

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 single fault conditions.

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.51.103 Vapour output during and after oxygen flush

There are hazards that can arise from interaction between conventional AVDDs and the oxygen flush on an anaesthetic system. For example:

— if the AVDD is mounted downstream of the oxygen flush, the high flowrate (75 l/min) during a flush can cause the mass output from the AVDD to increase. In some cases this could cause liquid anaesthetic agent to be forced out of the AVDD during a flush;

— if the anaesthetic system piping has a high resistance to flow, the pressure at the AVDD during a flush can be high enough to cause a so-called “pumping effect” which may increase the output concentration of the AVDD.

The first edition of ISO 5358 (ISO 5358:1980) had requirements to meet these hazards in that 19.4 required the flow of gas from the oxygen flush to be delivered to the fresh gas outlet without passing through any AVDD. It also required that the pressure at the AVDD should not be greater than 10 kPa during a flush. This 10 kPa helped determine the safety of an AVDD, in that 15.10 required the AVDD to be tested with a pressure fluctuation of 10 kPa without the output changing by more than 20 %.