AS/NZS 3200.2.13:2005
IEC 60601-2-13:2003

AS/NZS 3200.2.13:2005

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.13: Particular requirements for safety—Anaesthetic systems

STANDARDS AUSTRALIA

STANDARDS NEW ZEALAND
Paerewa Aotearoa

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 20 January 2005 and on behalf of the Council of Standards New Zealand on 28 January 2005.
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The following are represented on Committee HE-003:

Australian College of Physical Scientists and Engineers in Medicine
Australian Society for Ultrasound in Medicine
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

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Australian/New Zealand Standard™

Medical electrical equipment

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS 3200.2.13:1999, *Medical electrical equipment,* Part 2.13: *Particular requirements for safety—Anaesthetic workstations.*

This Particular Standard has been reproduced from, and is identical to, IEC 60601-2-13:2003, *Medical electrical equipment,* Part 2-13: *Particular requirements for the safety and essential performance of anaesthetic systems*, and supplements the corresponding Clauses of IEC 60601-1:1998, *Medical electrical equipment,* Part 1: *General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998, *Medical electrical equipment,* Part 1.0: *General requirements for safety—Parent Standard* and is hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

The General Standard details electrical safety requirements for all types of medical electrical equipment. A Particular Standard details additional safety requirements for a related group of medical electrical devices. A Collateral Standard details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

In the text of this Standard, the following print types are used:

(a) Requirements, compliance with which can be tested and definitions ..... in large roman type

(b) Explanations, advice, introductions, general statements, exceptions and references ..... in smaller roman type

(c) Headings of sub-clauses and text specifications.....*in italic type*

(d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index.....IN SMALL CAPITALS

Some pages of the original, which relate to IEC administrative matters, are also omitted from this edition.

As this publication has been reproduced from an international Standard, the following modifications apply:

(i) Its number does not appear on each page of text and its identity is shown on the cover and title page.

(ii) The substitution of a full point for a comma where it appears as a decimal marker.

(iii) The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60079	Electrical apparatus for explosive gas atmospheres	60079	Electrical apparatus for explosive gas atmospheres
60079-4	Part 4: Method of test for ignition temperature	60079.4	Part 4: Method of test for ignition temperature
60079-11	Part 11: Intrinsic safety	60079.11	Part 11: Intrinsic safety ‘i’
ISO		AS	
32	Gas cylinders for medical use—Marking for identification of content	—	

ISO		AS	
407	Small medical gas cylinders—Pin-index yoke-type valve connections	—	
3746	Acoustics—Determination of sound power levels of noise sources using sound pressure—Survey method using an enveloping measurement surface over a reflecting plane	—	
4135	Anaesthetic and respiratory equipment—Vocabulary	—	
5145	Cylinder valve outlets for gases and gas mixtures—Selection and dimensioning	—	
5359	Low-pressure hose assemblies for use with medical gases	2902	Medical gas systems—Low-pressure flexible connecting assemblies (hose assemblies)
5362	Anaesthetic reservoir bags	—	
7396	Medical gas pipeline systems		
7396.1	Part 1: Pipelines for compressed medical gases and vacuum	2896	Medical gas systems—Installation and testing of non-flammable medical gas pipeline systems
7767	Oxygen monitors for monitoring patient breathing mixtures—Safety requirements	—	
8835	Inhalational anaesthesia systems		
8835-2	Part 2: Anaesthetic breathing systems for adults	—	
8835-3	Part 3: Anaesthetic gas scavenging systems—Transfer and receiving systems	—	
8835-4	Part 4: Anaesthetic vapour delivery devices	—	
8835-5	Part 5: Requirements for anaesthetic ventilators	—	
9170	Terminal units for medical gas pipeline systems	—	
9170-1	Part 1: Terminal units for use with compressed medical gases and vacuum	—	
9703	Anaesthesia and respiratory care alarm signals	2901	Medical devices—Characteristics of audible and visible alarm signals
9703-1	Part 1: Visual alarm signals		
9703-2	Part 2: Auditory alarm signals		
9703-3	Part 3: Guidance on application of alarms	—	

ISO		AS	
9918	Capnometers for use with humans—Requirements	—	
10524	Pressure regulators and pressure regulators with flow-metering devices for medical gas systems	3840 3840.1	Pressure regulators for use with medical gasses Part 1: Pressure regulators and pressure regulators with flow-metering devices
11196	Anaesthetic gas monitors	—	
15223	Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied	—	
		AS/NZS	
5356	Anaesthetic and respiratory equipment—Conical connectors	2496	Breathing attachments for anaesthetic purposes for humans
5356-1	Part 1: Cones and sockets		
5356-2	Part 2: Screw-threaded, weight-bearing connectors		

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SECTION 101 – ADDITIONAL CLAUSES SPECIFIC TO ANAESTHETIC GAS DELIVERY SYSTEMS

INTRODUCTION

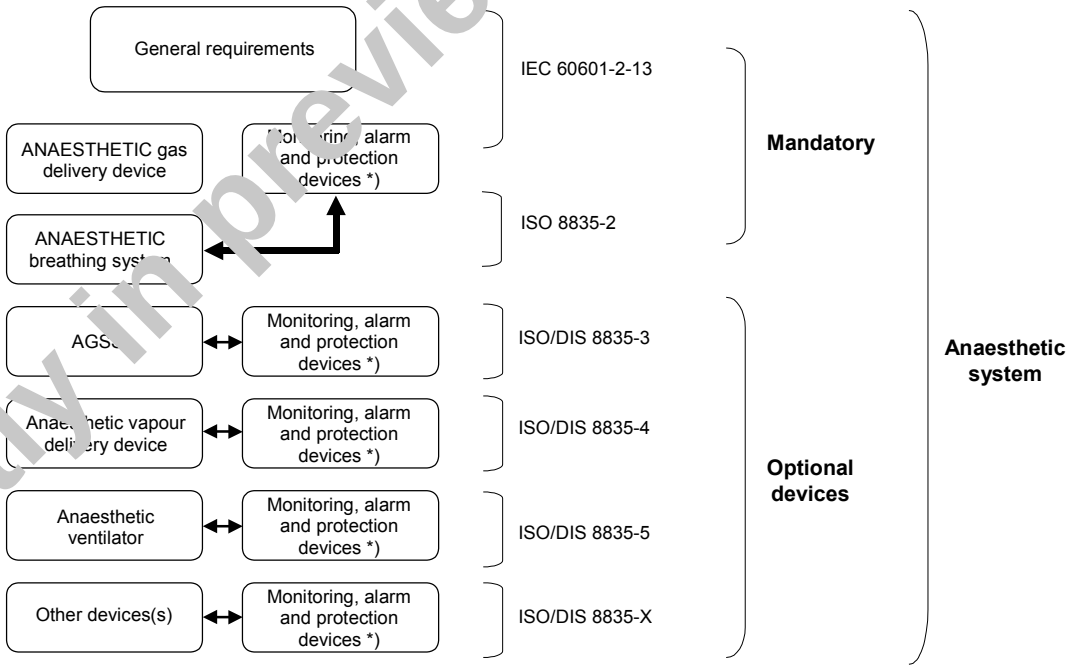
In response to requests for harmonization between the current European and International standards for anaesthetic workstations this standard has been developed by the IEC/ISO Joint Working Group to specify requirements for ANAESTHETIC SYSTEMS supplied complete, as well as requirements for individual devices which are intended to be part of an ANAESTHETIC SYSTEM. It applies in conjunction with IEC 60601-1:1988 (Including all amendments) hereafter referred to as the General Standard. As stated in 1.3 of IEC 60601-1-1988, the requirements in this standard take priority over those of the General Standard.

This standard has been structured to allow USERS to configure an ANAESTHETIC SYSTEM in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, the standard identifies particular requirements pertinent to specific devices, and to their associated MONITORING DEVICE(S), ALARM SYSTEM(s) and PROTECTION DEVICE(S), and defines the interfaces. This standard also specifies requirements for optional devices, together with their respective MONITORING DEVICE(S), ALARM SYSTEM(S) and PROTECTION DEVICE(S).

The indicated requirements are followed by specifications for the relevant tests. An asterisk (*) denotes clauses for which there is a rationale comment in Annex AA. It is considered that knowledge of the reasons for these requirements will facilitate the proper application of the standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

NOTE The decimal separator for all numeric values is "," (comma).

The following graphic representation of the structure of this standard is being provided for informational purposes only.



NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.13:
Particular requirements for safety—Anaesthetic systems

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 safety and essential performance requirements for an ANAESTHETIC SYSTEM (as defined in 2.101.7) as well as individual devices designed for use in an ANAESTHETIC SYSTEM.

This Particular Standard does not apply to:

– ANAESTHETIC SYSTEM(S) intended for use with flammable anaesthetic agents, as determined by Annex DD,
– portable ANAESTHETIC SYSTEM(S) for use in remote sites, open fields for rescue operations or in disaster areas,
– dental analgesia apparatus.

1.2 Object

Replacement:

The object of this Particular Standard is to specify particular safety and essential performance requirements for individual devices designed for use in an ANAESTHETIC SYSTEM as well as specific requirements for the ANAESTHETIC GAS DELIVERY SYSTEM. This standard specifies requirements and defines interfaces for:

– individual devices designed for use in an ANAESTHETIC SYSTEM(S), and
– integrated ANAESTHETIC SYSTEMS.

1.3 Particular Standards

This Particular Standard amends and supplements a set of IEC publications consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendment 1 (1991) and amendment 2 (1995), hereinafter referred to as the “General Standard”.

The General Standard takes into account IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems* and IEC 60601-1-2 2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.*