AS ISO 9360.2—2003
ISO 9360-2:2001

Australian Standard™

Anaesthetic and respiratory equipment—Heat and moisture exchangers (HMEs) for humidifying respired gases in humans

Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml

Standards Australia

This Australian Standard was prepared by Committee HE-019, Anaesthetic and Breathing Equipment. It was approved on behalf of the Council of Standards Australia on 21 May 2003 and published on 30 June 2003.

The following are represented on Committee HE-019:

Australasian Society of Anaesthesia Paramedical Officers

Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

Australian Industry Group

Australian and New Zealand College of Anaesthetists

Australian and New Zealand Intensive Care Society

Australian Society of Anaesthetists

College of Biomedical Engineering Institution of Engineers Australia

Commonwealth Department of Health and Ageing

Department of Human Services (South Australia)

Health Department of Western Australia

Medical Industry Association of Australia Inc

NSW Health Department

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committee HE-019, Anaesthetic and Breathing Equipment. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/ New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 9360-2:2001, *Anaesthetic and respiratory equipment—Heat and moisture exchangers (HMEs) for humidifying respired gases in humans—Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml.*

The objective of this Standard is to specify certain requirements and test methods for heat and moisture exchangers without machine connector ports, including those incorporating breathing system filters. These devices are intended for the humidification of respired gases for tracheostomized patients having a tidal volume of 250 ml or greater.

The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

As this Standard is reproduced from an international Standard, the following applies:

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

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
9360	Anaesthetic and respiratory equipment—Heat and moisture exchangers (HMEs) for humidifying respired gases in humans	9360	Anaesthetic and respiratory equipment—Heat and moisture exchangers (HMEs) for humidifying respired gases in humans
9360-1	Part 1: HMEs for use with minimum tidal volumes of 250 ml	9360.1	Part 1: HMEs for use with minimum tidal volumes of 250 ml

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AUSTRALIAN STANDARD

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1 Scope

This part of ISO 9360 is based on ISO 9360-1:2000 and specifies certain requirements and test methods for heat and moisture exchangers (HMEs) without machine connector ports, including those incorporating breathing system filters. These devices are intended for the humidification of respired gases for tracheostomized patients having a tidal volume of 250 ml or greater.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 9360. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 9360 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 ISO and IEC maintain registers of currently valid International Standards.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*.

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis.*

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

ISO 11607, *Packaging for terminally sterilized medical devices*.

3 Terms and definitions

For the purposes of this part of ISO 9360, the terms and definitions given in ISO 4135 and ISO 9360-1 apply, except as follows.

3.1 (new)
HME internal volume
volume contained within the HME, when not pressurized, consisting of the internal surface of the impermeable material of the HME and a hypothetical boundary surface which consists of the minimum surface area which encloses the active element of the HME, minus the volume of all solid elements within the HME, minus the volume inside all the female connectors