

Australian Standard™

**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**

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
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This Standard was issued in draft form for comment as DR 03170.

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First published as AS ISO 9360.1—2003.

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Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5348 5

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 9360-1:2000, *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*.

The objective of this Standard is to specify certain requirements for heat and moisture exchangers, including those incorporating breathing system filters, intended for the humidification of respired gases for use primarily with patients with a tidal volume equal to or greater than 250 ml, and incorporating at least one machine port, and describes test methods for their evaluation.

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.

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

<i>Reference to International Standard</i>	<i>Australian Standard</i>
IEC	AS/NZS
60601 Medical electrical equipment	3200 Medical electrical equipment
60601-1 Part 1: General requirements for safety	3200.1 Part 1.0: General requirements for safety—Parent Standard

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INTRODUCTION

The gases generally available for medical use lack sufficient moisture to be physiologically acceptable to the respiratory tract of patients. Heat and moisture exchangers are used to raise the water content and the temperature of the gas delivered to the respiratory tract. They are primarily intended for use independently or as part of a breathing system.

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AUSTRALIAN STANDARD

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****1 Scope**

This part of ISO 9360 specifies certain requirements for heat and moisture exchangers (HMEs), including those incorporating breathing system filters, intended for the humidification of respired gases for use primarily with patients with a tidal volume equal to or greater than 250 ml, and incorporating at least one machine port, and describes test methods for their evaluation.

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, 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: 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 7000:1989, *Graphical symbols for use on equipment — Index and synopsis*.

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

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

3 Terms and definitions

For the purpose of this part of ISO 9360, the terms and definitions given in ISO 4135 and the following apply.

3.1 Heat and moisture exchanger

HME

device intended to retain a portion of the patient's expired moisture and heat, and return it to the respiratory tract during inspiration