

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा

**संवेदनाहारी और श्वसन उपकरण — मनुष्यों में श्वसन गैसों को नम
करने के लिए ताप और नमी एक्सचेंजर्स (एचएमई) — भाग 1: 250
मिलीलीटर की न्यूनतम ज्वारीय मात्रा के साथ उपयोग के लिए एचएमई
[ISO 9360-1:2000, संशोधित]**

Draft Indian 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
[ISO 9360-1:2000, MOD]**

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied
Equipment Sectional Committee, MHD-11

Last date for comments 10 August 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 4135, Anaesthesiology — Vocabulary.	IS 13200: 2023/ ISO 4135:2022, Anaesthetic and Respiratory Equipment Vocabulary (<i>Second Revision</i>)	Identical
ISO 5356-1:1996, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.	IS/ISO 5356-1: 2015, Anaesthetic and respiratory equipment - Conical connectors: Part 1 cones and sockets (<i>First Revision</i>)	Identical
ISO 5356-2:1987, Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weightbearing connectors.	IS/ISO 5356-2: 2012, Anaesthetic and respiratory equipment - Conical connectors: Part 2 screw - Threaded weight - Bearing connectors	Identical
ISO 7000:1989, Graphical symbols for use on equipment — Index and synopsis.	IS 16450 : 2023/ ISO 7000:2019, Graphical Symbols for Use on Equipment Registered Symbols	Identical
ISO 11607, Packaging for terminally sterilized medical devices.	IS/ISO 11607 : 2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems (<i>First Revision</i>)	Identical
	IS/ISO 11607 : 2019, Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (<i>First Revision</i>)	
IEC 60601-1:1988, Medical electrical equipment — Part 1: General requirements for safety.	MHD/15/22648/ IS 13450 (Part 1) : 2024, Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (IEC 60601-1 : 2020, MOD) (<i>Third Revision</i>)	Modified

The references Standard ISO 11607, into two parts i.e. IS/ISO 11607 : 2019 and IS/ISO 11607 : 2019

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (*revised*)'.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to **ISO 9360-1:2000** or kindly contact:

Head
Medical Equipment and Hospital Planning Department
Bureau of Indian Standards
9 Bahadur Shah Zafar Marg
New Delhi-110002
Email: mhd@bis.gov.in; hmhd@bis.gov.in

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.

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.