

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
एनेस्थेटिक और श्वसन उपकरण
चिकित्सा गैसों के उपयोग के लिए लौ-प्रेसर होस असेंबली

Draft Indian Standard
Anaesthetic and Respiratory Equipment
Low-Pressure Hose Assemblies for Use with Medical Gases

ICS 11.040.10, 83.140.40

Anaesthetic, Resuscitation and Allied
Equipment Sectional Committee, MHD 11

Last date for comments 10 May 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

This Indian Standard is an identical adoption of ISO 5359: 2014 “Anaesthetic and respiratory equipment Low-pressure hose assemblies for use with medical gases”.

Amendment 1 published in 2017 to ISO 5359:2014 is given at the end of this publication.

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 Standard</i>	<i>Indian</i>	<i>Degree of Equivalence</i>
ISO 1307:2006, Rubber and plastics hoses — Hose sizes, minimum and maximum inside diameters, and tolerances on cut-to-length hoses	IS 15933: 2011/ ISO 1307: 2006, Rubber and Plastics Hoses — Hose Sizes, Minimum and Maximum Inside Diameters, and Tolerances on Cut-To-Length Hoses		Identical
ISO 1402:2021, Rubber and plastics hoses and hose assemblies — Hydrostatic testing	IS 443 (Part 3): 2023/ ISO 1402: 2021, Methods of Test for Rubber and Plastics — Tubing, Hoses and Hose Assemblies Part 3 Rubber and Plastics Hoses and Hose Assemblies — Hydrostatic Testing (<i>Fourth Revision</i>)		Identical
ISO 8033:2016, Rubber and plastics hoses — Determination of adhesion between components	IS 443 (Part 7): 2022/ ISO 8033: 2016, Methods of Test for Rubber and Plastics — Tubing, Hoses and Hose Assemblies Part 7 Rubber and Plastics Hoses — Determination of Adhesion Between Components		Identical
ISO 9170-1:2017, Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum	IS 17812 (Part 1): 2022/ ISO 9170-1:2017, Terminal Units for Medical Gas Pipeline Systems: Part 1 Terminal Units for use with Compressed Medical Gases and Vacuum (<i>First Revision</i>)		Identical
ISO 14155:2020, Clinical investigation of medical devices for human subjects — Good clinical practice	IS/ISO 14155: 2020, Clinical investigation of medical devices for human subjects - Good clinical practice		Identical
ISO 14971: 2019, Medical devices — Application of risk management to medical devices	IS/ISO 14971: 2019, Medical devices - Application of risk management to medical devices (<i>First Revision</i>)		Identical
ISO 15001:2010, Anaesthetic and respiratory equipment — Compatibility with oxygen	IS/ISO 15001: 2010, Anaesthetic and respiratory equipment - Compatibility with oxygen (<i>First Revision</i>)		Identical

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 5359:2014 + AMD 1:2017** or kindly contact:

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Abstract

ISO 5359:2014 specifies requirements for low-pressure hose assemblies intended for use with the following medical gases: oxygen, nitrous oxide, medical air, helium, carbon dioxide, xenon, specified mixtures of the gases listed above, oxygen-enriched air, air for driving surgical tools, nitrogen for driving surgical tools, and for use with vacuum. It applies to hose assemblies operating at pressures up to 1400 kPa and for vacuum systems at pressures not greater than 60 kPa absolute. It does not specify the dimensions and allocation of the gas-specific inlet and outlet connectors for the hose assemblies. It does not specify requirements for coaxial hoses used for the supply and removal of air for driving surgical tools. Nor does it specify the intended uses of hose assemblies.

Introduction

This International Standard has been prepared in response to the need for a safe method of connecting medical equipment to a fixed medical gas pipeline system or other medical gas supply system such that hose assemblies carrying different gases, or the same gas at different pressures, cannot be interchanged. Fixed medical gas pipelines, once installed, are rarely disturbed and are subjected to commissioning procedures to avoid the possibility of cross-connections or contamination of the medical gas conveyed. However, hose assemblies are subjected to wear and tear, misuse and abuse throughout their relatively short service life and are frequently connected to, and disconnected from, the medical equipment and the fixed pipeline.

While recognizing that no system is absolutely safe, this International Standard includes those requirements considered necessary to prevent foreseeable hazards arising from the use of hose assemblies. Operators should be continually alert to the possibility of damage being caused by external factors. Therefore, regular inspection and repair should be undertaken to ensure that hose assemblies continue to meet the requirements of this International Standard.

This International Standard pays particular attention to

- — suitability of materials,
- — gas specificity,
- — prevention of cross-connections,
- — cleanliness,
- — testing,
- — identification, and
- — information supplied.

Requirements on respiratory therapy tubing are covered by ISO 17256, which refers to ISO 80369-2 on small bore connectors for breathing systems and driving gases.

While the desirability of achieving agreement on a single International Standard for screw-threaded connectors has never been in doubt, the present pattern of usage has made such agreement impossible.

Nevertheless, fears that proliferation of individual national standards or practices will eventually result in potentially dangerous cross-connection between components for different gases have led to the choice of three screw-threaded connector systems, and one gas-specific

quick connector system for use on low pressure hose assemblies. The three systems of non-interchangeable screw-threaded connectors are the diameter index safety system (DISS), the non-interchangeable screw-threaded (NIST) system and the sleeve indexed system (SIS). Dimensions and allocation of these connectors to medical gases are not specified in this International Standard.

Rationales for some of the requirements of this International Standard are given in Annex A. Such requirements are indicated by the asterisk (*) after the clause number in the main text.

1 Scope

1.1 This International Standard specifies requirements for low-pressure hose assemblies intended for use with the following medical gases:

- — oxygen,
- — nitrous oxide,
- — medical air,
- — helium,
- — carbon dioxide,
- — xenon,
- — specified mixtures of the gases listed above,
- — oxygen-enriched air,
- — air for driving surgical tools,
- — nitrogen for driving surgical tools,

and for use with vacuum.

1.2 *It applies to hose assemblies operating at pressures up to 1400 kPa and for vacuum systems at pressures not greater than 60 kPa absolute.

1.3 This International Standard does not specify the dimensions and allocation of the gas-specific inlet and outlet connectors for the hose assemblies.

NOTE 1 Specifications for the dimensions and allocation of diameter index safety system (DISS) connectors are specified in CGA V-5.

NOTE 2 Specifications for the dimensions and allocation of sleeve indexed system (SIS) connectors are specified in AS 2896.

NOTE 3 Dimensions and allocation of non-interchangeable screw-threaded (NIST) connectors are specified in ISO 18082 .

NOTE 4 Terminal units designed for quick connectors are specified in ISO 9170-1.

1.4 This International Standard does not specify requirements for coaxial hoses used for the supply and removal of air for driving surgical tools.

1.5 This International Standard does not specify the intended uses of hose assemblies.

NOTE Environmental aspects are dealt with in Annex B.