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Australian STANDARD®

STANDARDS Australia

Small-bore connectors for liquids and gases in healthcare applications

Part 20: Common test methods



AS ISO 80369.20:2026

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This page explains the meaning of the language and structure of this Standard.

Refer to Standards Australia's Standardisation Guide 006 for more details about drafting rules.

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Requirements

To conform to a Standard, all requirements in the Standard need to be met.

A requirement is any statement in the Standard which uses the word "shall".

Recommendations, permissions and possibilities

The following words are commonly used in Standards, but statements using them do not have to be followed to conform to the Standard:

(a) "should" means that something is recommended.

(b) "may" means that something is permitted.

(c) "can" means that something is possible.

Structure of Standards

A Standard always has the following parts:

(i) The Preface states who developed the Standard, what the Standard is aiming to do, and how it relates to other documents.

(ii) The Scope states what the Standard is about, what it covers and what it does not cover.

(iii) The Normative references clause lists other documents that are referenced in the Standard as part of requirements.

(iv) The Terms and definitions clause defines important terms to help with understanding the Standard.

A Standard may also include other parts, such as the following:

(1) A normative appendix sets additional requirements that need to be conformed to.

(2) An informative appendix provides additional information or guidance. They usually do not contain requirements. If an informative appendix does contain requirements, the Standard will explain when those requirements apply.

(3) A Bibliography lists documents referenced in the Standard but not as part of requirements.

Many Standards include notes. Notes provide recommendations and/or guidance only. They never contain requirements.

Preface

This Standard was prepared by the Standards Australia Committee HE-028, Quality Management and Corresponding General Aspects for Medical Devices.

The objective of this document is to specify the common test methods to evaluate the performance requirements for small-bore connectors specified in the AS ISO 80369 series and IEC 80369 series as well as the ISO 18250 series.

This document is identical to, and has been reproduced from, ISO 80369-20:2024, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*.

As this document has been reproduced from an international document, a comma is to be read as a full point when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/SC 62D, *Particular medical equipment, software, and systems,* and with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80369-20:2015), which has been technically revised.

The main changes are as follows:

— clarification that these test methods are also used by the ISO 18250 series;

— major technical revision of the *test methods* described in Annex B “Leakage by pressure decay test method” and Annex D “Subatmospheric-pressure air leakage test method” (replacement of leakage rate by the pressure change as acceptance criterion; definition of three defined mandatory test conditions; more information about this change is included in Annex A);

— introduction of a new attributive *test method* “Air leakage during aspiration” as Annex K;

— editorial revision of the assembling *procedures* of a *connector* under test, affecting all annexes with *test methods*;

— editorial update according to ISO/IEC Directives, Part 2;

— replacement of the terms “male” by “*cone*” and “female” by “*socket*” in the description of a *connector*;

— update of dated normative references;

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— definition for *type test* has been updated;

— expansion of the range of environmental test conditions for relative humidity;

— extension of requirements for test reports;

— clarification that all tests are intended to be *type tests*.

A list of all parts in the ISO and IEC 80369 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

In this document, the following verbal forms are used.

— “Shall” indicates requirements.

— “Should” indicates recommendations.

— “May” indicates permissions.

— “Can” indicates possibility or capability.

This document uses italic type to distinguish defined terms from the rest of the text. It is important for the correct understanding of this document that those defined terms are identifiable throughout the text of this document. A list of the defined terms used in this document (in italics) is given in Annex M.

Requirements in this document have been broken down so that each requirement is clearly delineated and listed individually. This has been done to support the common practice of automatic tracking of requirements and automatic verification of the requirements of this document.

Annex A contains guidance and rationale on specific subclauses in this document.

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Small-bore connectors for liquids and gases in healthcare applications

Part 20: Common test methods

1 Scope

NOTE Clause A.2 contains guidance or rationale for this clause.

This document specifies the common *test methods* to evaluate the performance requirements for *small-bore connectors* specified in the ISO and IEC 80369 series as well as the ISO 18250 series.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:—,[1] *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 80369-1:—,[1)] ISO 14971:2019, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

NOTE For convenience, the sources of all defined terms that appear in italics in this document are given in Annex M.

3.1
type test
test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this document

[SOURCE: IEC 60601-1:2005, 3.135, modified — replaced “standard” with “document.”]

4 *Test methods* for *small-bore connectors*

Table 1 contains the list of *test methods* and their corresponding Annex included in this document. For statistical analysis, *test methods* may be modified according to Annex J. The tests to evaluate the performance requirements for *small-bore connectors* specified in the ISO and IEC 80369 series and the *connectors* specified in the ISO 18250 series described in this document are intended be performed as *type tests*.

[1] Third edition under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2024. The previous edition is ISO 80369-1:2018.

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