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Australian STANDARD®

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Small-bore connectors for liquids and gases in healthcare applications

Part 1: General requirements



AS ISO 80369.1:2026

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- AusBiotech
- Australian & New Zealand College of Anaesthetists
- Australian Dental Industry Association
- Australian Digital Health Agency
- Australian Healthcare and Hospitals Association
- Australian Society of Anaesthetists
- Engineers Australia
- Federation of Sterilizing Research and Advisory Council of Australia
- Joint Accreditation System of Australia & New Zealand
- Medical Technology Association of Australia
- Queensland Health
- Therapeutic Goods Administration (TGA)

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

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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 general interface requirements for small-bore connectors that form part of a medical device or accessory that conveys liquids or gases to a patient.

This document also identifies the applications for which these small-bore connectors are intended to be used, which include, but are not limited to —

(a) respiratory;

(b) enteral;

(c) limb cuff inflation;

(d) neural;

(e) intravascular or hypodermic; and

(f) other use cases utilizing an ISO 80369-7 small-bore connector.

This document provides the methodology to assess non-interconnectable characteristics of small-bore connectors based on their inherent design in order to reduce the risk of misconnections between medical devices or between accessories for different applications as specified in this document, as well as those that can be developed under future parts of the ISO and IEC 80369 series.

This document is identical to, and has been reproduced from, ISO 80369-1:2025, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*.

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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 third edition cancels and replaces the second edition (ISO 80369-1:2018), which has been technically revised.

The main changes are as follows:

— update of normative references;

— update of the document according to ISO/IEC Directives, Part 2;

— addition of respiratory *applications*;

— addition of *interference test part*, *misconnection* and *unintended connection* definitions;

— deletion of Clause 4 for materials requirements, as those requirements are or will be placed in the individual *connector* parts of the series and normative Annex B describes the analysis and testing processes for determining *non-interconnectable* characteristics;

— revision of Annex B by summarising process description and adding figure, editorial changes and adding the dimensional analysis case “potential misconnection”;

— deletion of the original Annex C, replaced with normative reference to parts of ISO 20417;

— addition of Annex E summarizing the design assessments of the *application* parts of this series of documents;

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— replacement of contents of Annex F by referencing the relevant essential principles and labelling guidance of the International Regulators Forum (IMDRF);

— extension of the use of the ISO 80369-7 *connector* to *medical devices* and *accessories* beyond intravascular and hypodermic *applications* where the *risk* is acceptable.

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 the 1990s, concern grew regarding the proliferation of *medical devices* fitted with *Luer connectors* as specified in the ISO 594 series[1] and the reports of *patient* death or injury arising from *unintended connections* that resulted in the inappropriate delivery of fluids and gases via incorrect routes. In addition to clinical and workplace protocols and warnings, attention was turned to engineering solutions to reduce the probability of wrong route administration of liquids and gases.

Concerns regarding the use of *Luer connectors* with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN Bureau Technique (CEN/BT) and the European Commission. In November 1997, the newly created CEN Healthcare Forum (CHeF) steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report, CEN/CR 13825,[9] in which they concluded that there is a problem arising from the use of a single *connector* design to several different *applications*. In a coronary care unit, there could be as many as 40 *Luer connectors* on the *medical devices* used with a single *patient* until the use of *connectors* defined in the ISO and IEC 80369 documents started to be established. Therefore, it is not surprising that *unintended connections* were made.

Medical devices have, for many years, followed the established principle of "safety under single fault conditions." Simply stated, this means that a single fault should not result in an unacceptable *risk*. This principle is embodied in the requirements of numerous *medical device* standards.[6] Extending this principle to the use of *Luer connectors* (i.e. that an *unintended connection* should not result in an unacceptable *risk* to a *patient*) the FTG recommended that the *Luer connector* should be restricted to *medical devices* intended to be connected to the vascular system or a hypodermic syringe. In addition, the FTG recommended that new designs of *small-bore connectors* should be developed for other *applications*, and these should be *non-interconnectable* with *Luer connectors* and each other.

International medical device regulators forum (IMDRF), GRRP N47:2024,[10] Essential Principle 5.1.3, addresses this type of problem:

> Risk control measures adopted by manufacturers for the design and manufacture of the medical device and IVD medical device should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, manufacturers should control risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers should, in the following order of priority:
>
> a) eliminate or appropriately reduce risks through safe design and manufacture;
>
> b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated;
>
> c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

It is understood that *small-bore connector* systems cannot be designed to overcome all chances of *unintended connections* with the potential for wrong route administration or to eliminate deliberate misuse. With these *application*-specific *connectors* now available, the *risk* of unintended connections and wrong route administration is greatly reduced thereby improving *patient* safety. Introduction of *medical devices* and *accessories* utilizing these *small-bore connectors* is progressing albeit slowly.

The *risks* associated with *unintended connections* and subsequent wrong route administration of liquids and gases cannot be fully assessed until these *small-bore connectors* are part of a *medical device* or *accessory*. Therefore, the intended *applications* specified are recommendations. It is expected that particular *medical device* standards will reference the *connectors* from the relevant parts of the ISO and IEC 80369 series if considered appropriate.

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This document contains the general requirements to reduce *connections* between *small-bore connectors* used in different *applications* as well as specifying those *applications*.

It specifies the general requirements and *test methods* for assessing the *non-interconnectable* characteristics of *small-bore connectors* within the ISO and IEC 80369 series.

The *Luer connector* as originally defined in the withdrawn ISO 594 series has been widely used on many *medical devices* and *accessories* and in a wide range of clinical *applications* for many years. The clinical *applications* that present the highest *risk* to a *patient* from wrong route administration of liquids and gases have been identified and are those included in the *application* parts of the ISO and IEC 80369 series. ISO 80369-7, which replaces the ISO 594 series (i.e. the *Luer connector*), is intended for use with intravascular or hypodermic *applications.*

However, there are currently *medical devices* and *accessories* which incorporate a *Luer connector*, but do not fall into any of the *applications* specified by the ISO and IEC 80369 series. There are also some *medical devices* and *accessories* within the *applications* of the ISO and IEC 80369 series *applications* that incorporate a *Luer connector*. Those that present no unacceptable *risk* to the *patient* from an *unintended connection* to a *medical device* or *accessory* within intravascular or hypodermic *application* are suitable for consideration for the use of the *Luer connector* as specified in ISO 80369-7.

ISO 80369-20 specifies the common *test methods* for assessing the basic performance requirements specified in ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 for *small-bore connectors*.

ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 specify the material requirements, dimensional requirements for the interfaces of the *connectors* and the specific performance requirements for assessing the interconnectability of the mating connectors.

The designs and dimensions of *small-bore connectors* specified in ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 have been successfully assessed according to the requirements of this document (i.e. have been proven to be acceptable with regard to the *risk* of *misconnection* with the other *connectors* of this series).

The *risks* of changing to these new *small-bore connectors* should be assessed before these *small-bore connectors* are incorporated into *medical devices* as they will when the relevant particular *medical device* standards are revised.

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 italics in this document is given in Annex G.

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 1: General requirements

1 Scope

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

This document specifies general interface requirements for *small-bore connectors* that form part of a *medical device* or *accessory* that conveys liquids or gases to a *patient*.

This document also identifies the *applications* for which these *small-bore connectors* are intended to be used, which include, but are not limited to:

— respiratory;

— enteral;

— limb cuff inflation;

— neural;

— intravascular or hypodermic;

— other use cases utilizing an ISO 80369-7 *small-bore connector*.

This document provides the methodology to assess *non-interconnectable* characteristics of *small-bore connectors* based on their inherent design in order to reduce the *risk* of *misconnections* between *medical devices* or between *accessories* for different *applications* as specified in this document as well as those that can be developed under future parts of the ISO and IEC 80369 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, *Medical devices — Application of risk management to medical devices*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 80369-2, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications*

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

IEC 80369-5, *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*

ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

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