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Australian STANDARD®

STANDARDS Australia

# Small-bore connectors for liquids and gases in healthcare applications

## Part 5: Connectors for limb cuff inflation applications



# AS IEC 80369.5:2026

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Australian Healthcare and Hospitals Association
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Engineers Australia
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## Part 5: Connectors for limb cuff inflation applications

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**Requirements**

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

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(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 dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections in limb cuff inflation applications of medical devices and accessories. Limb cuff inflation applications include connections between a sphygmomanometer and its cuff.

This document does not specify requirements for the medical devices or accessories that use these connectors.

This document does not specify requirements for pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive medical devices in place.

This document is identical to, and has been reproduced from, IEC 80369-5:2016, *Small-bore connectors for liquids and gases in healthcare applications – Part 5: Connectors for limb cuff inflation applications* and its Corrigendum No. 1 (2017) and Corrigendum No 2 (2021), which have been incorporated into the source text.

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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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 80369–5 has been prepared by a Joint Working Group of subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice, ISO technical committee 210, Quality management and corresponding general aspects for medical devices and CEN/CENELEC TC3/WG 2, Small-bore connectors.

The text of this standard is based on the following documents:

| FDIS | Report on voting |
|---|---|
| 62D/1306/FDIS | 62D/1329/RVD |

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Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 23 P members out of 23 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the International Standard 80369 series, published under the general title *Small-bore connectors for liquids and gases in healthcare applications*, can be found on the IEC and ISO websites.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

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

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

NOTE The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The contents of the corrigenda 1 (2017) and 2 (2021) have been included in this copy.

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# INTRODUCTION

This International Standard was developed because of several incidents, with catastrophic consequences, resultant from inappropriate medication, liquid nutritional formula or air being administered intravenously. Many incidents have been reported, leading to international recognition of the importance of these issues, and a need has been identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver fluids in other APPLICATIONS.

The International Standard 80369 series was developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. Part 1 specifies the requirements necessary to verify the designs and dimensions of SMALL-BORE CONNECTORS to ensure that:

a) they do not misconnect with other SMALL-BORE CONNECTORS; and

b) they safely and securely connect with their mating half.

Part 20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS. The other parts specify the designs of SMALL-BORE CONNECTORS for the various APPLICATIONS.

This part of International Standard 80369 specifies the design and the dimensions and drawings of SMALL-BORE CONNECTORS intended for use in limb cuff inflation APPLICATIONS. The informative Annex D through Annex G describe the methods by which this design has been assessed. Other parts of International Standard 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this International Standard are therefore dimensionally incompatible with the SMALL-BORE CONNECTORS used in other APPLICATIONS specified by the standards in this series, unless otherwise indicated. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS should be able to prevent air being delivered intravenously. CONNECTORS manufactured to the dimensions specified in this standard are also NON-INTERCONNECTABLE with any of the other CONNECTORS identified in the International Standard 80369 series of standards for SMALL-BORE CONNECTORS, unless otherwise indicated.

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# Australian Standard®

# Small-bore connectors for liquids and gases in healthcare applications

## Part 5: Connectors for limb cuff inflation applications

## 1 * Scope

This part of International Standard 80369 specifies dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in limb cuff inflation APPLICATIONS of MEDICAL DEVICES and ACCESSORIES. Limb cuff inflation APPLICATIONS include CONNECTIONS between a sphygmomanometer and its cuff. [3][7][1]

This part of International Standard 80369 does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

This part of International Standard 80369 does not specify requirements for pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive MEDICAL DEVICES in place.

NOTE 1 MANUFACTURERS are encouraged to incorporate the SMALL-BORECONNECTORS specified in this part of International Standard 80369 into MEDICAL DEVICES, medical systems or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for SMALL-BORE CONNECTORS, as specified in this part of International Standard 80369, will be included.

NOTE 2 The requirements for SMALL-BORE CONNECTORS intended to be used with neonatal PATIENTS to connect a cuff to a sphygmomanometer are intended to be added to this standard by an amendment or new edition. IEC 80601–2–30[7] defines the age range for neonatal mode usage of sphygmomanometers.

NOTE 3 The requirements for SMALL-BORE CONNECTORS intended to be used to connect a tourniquet to its inflating equipment are intended to be added to this standard by an amendment or new edition.

NOTE 4 ISO 80369–1:2010, 5.8, specifies alternative methods of compliance with ISO 80369–1:2010, for SMALL-BORE CONNECTORS intended for limb cuff inflation APPLICATIONS of MEDICAL DEVICES or ACCESSORIES which do not comply with this part of ISO 80369.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography on page 40.

ISO 5356–1:2004, *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

ISO 5356–1:2015, [2] *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

ISO 5356–2:2006, [3] *Anaesthetic and respiratory equipment – Conical connectors – Part 2: Screw-threaded weight-bearing connectors*

1 Figures in square brackets refer to the Bibliography.

2 Both the current and previous versions of this standard are normatively referenced.

3 Both the current and previous versions of this standard are normatively referenced.

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