IEC 80369-5

Edition 1.0 2016-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Small-bore connectors for liquids and gases in healthcare applications –
Part 5: Connectors for limb cuff inflation applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé –
Partie 5: Raccords destinés à des applications au gonflage de brassard

IEC 80369-5:2016-03(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.20

ISBN 978-2-8322-3211-8

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

SMALL-BORE CONNECTORS FOR LIQUIDS AND GASES IN HEALTHCARE APPLICATIONS –

Part 5: Connectors for limb cuff inflation applications

FOREWORD

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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

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 corrigendum of February 2017 have been included in this copy.

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.

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-BORE CONNECTORS 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*

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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.

ISO 5356-2:2012, *Anaesthetic and respiratory equipment – Conical connectors – Part 2: Screw-threaded weight-bearing connectors*

ISO 8185:2007, *Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements*

EN 13544-2:2002, *Respiratory therapy equipment – Part 2: Tubing and connectors*
EN 13544-2:2002:AMD 1:2009

ASTM D638-14, *Standard test method for tensile properties of plastics*

ASTM D790-10, *Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO 80369-1:2010, ISO 14971:2007 and the following apply.

NOTE For convenience, the sources of all defined terms used in this document are given in the Index of defined terms.

3.1
NORMAL USE
operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+IEC 60601-1:2005/AMD1:2012, definition 3.71, modified, replaced 'OPERATOR' with 'USER'.]

3.2
RATED <VALUE>
term referring to a value assigned by the MANUFACTURER for a specified operating condition

[SOURCE: IEC 60601-1:2005, definition 3.97]

3.3
TEST METHOD
definitive PROCEDURE for evaluating CONNECTORS that produces a test result

[SOURCE: ISO 80369-20:2015, definition 3.1]

3.4
TYPE TEST
test on a representative sample with the objective of determining if the CONNECTOR, as designed and manufactured, can meet the requirements of this standard

[SOURCE: IEC 60601-1:2005, definition 3.135, modified: replaced 'equipment' with 'CONNECTOR'.]

3.5
USER
person interacting with (i.e. operating or handling) the MEDICAL DEVICE

Note 1 to entry: There can be more than one USER of a MEDICAL DEVICE.

Note 2 to entry: Common USERS include clinicians, PATIENTS, cleaners and maintenance and service personnel.

[SOURCE: IEC 62366-1:2015, definition 3.24]

3.6
USER PROFILE
summary of the mental, physical and demographic traits of an intended USER group, as well as any special characteristics, such as occupational skills, job requirements and working conditions, which can have a bearing on design decisions

[SOURCE: IEC 62366-1:2015, definition 3.29]

4 General requirements

4.1 General requirements for the limb cuff inflation APPLICATION

SMALL-BORE CONNECTORS of MEDICAL DEVICES or ACCESSORIES intended for use in limb cuff inflation APPLICATIONS made in compliance with this standard shall comply with ISO 80369-1:2010 unless otherwise indicated in this standard.

Because the following CONNECTORS are inadequately specified, SMALL-BORE CONNECTORS for use in limb cuff inflation APPLICATIONS should not, but may connect with:

– the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356-2:2006 and ISO 5356-2:2012;
– the temperature sensor CONNECTOR and mating ports made in compliance with Annex DD of ISO 8185:2007; and
– the nipples of EN 13544-2:2002 and EN 13544-2:2002+EN 13544-2:2002/AMD1:2009.

The reference CONNECTORS for evaluation of the NON-INTERCONNECTABLE characteristics are described in Annex C.

Where the design of the SMALL-BORE CONNECTOR of this standard relies on dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics, the NON-INTERCONNECTABLE characteristics shall be VERIFIED.

Check compliance by applying the tests of ISO 80369-1:2010, 5.1, and ISO 80369-1:2010, Annex B. Compliance also may be shown by applying a computer aided design (CAD) analysis of the dimensions of all of the International Standard 80369 series SMALL-BORE CONNECTORS and the SMALL-BORE CONNECTOR under test, in conjunction with physical testing of the SMALL-BORE CONNECTOR per Annex B of ISO 80369-1:2010, where the CAD analysis does not demonstrate the NON-INTERCONNECTABLE characteristics. When necessary, the SMALL-BORE CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with the NON-INTERCONNECTABLE characteristics test requirements of ISO 80369-1:2010, Annex B.

NOTE 1 MEDICAL DEVICES using the SMALL-BORE CONNECTORS of this standard that do not rely on the dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics are presumed to comply with the NON-INTERCONNECTABLE characteristics test requirements of this standard.

NOTE 2 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in informative Annex D.

NOTE 3 The summary of the usability requirements for these SMALL-BORE CONNECTORS is provided in informative Annex E.

NOTE 4 The summary of these SMALL-BORE CONNECTORS criteria and requirements is provided in informative Annex F.

NOTE 5 The summary of assessment of the design of these SMALL-BORE CONNECTORS according to ISO 80369-1:2010, Clause 7, is contained in informative Annex G.

4.2 Materials used for SMALL-BORE CONNECTORS

In addition to the requirements of ISO 80369-1:2010, Clause 4, SMALL-BORE CONNECTORS for this APPLICATION shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 700 MPa.

Check compliance by applying the tests of ASTM D638-14 or ASTM D790-10.

4.3 TYPE TESTS

Compliance with the requirements of this International Standard shall be determined by TYPE TESTS.

5 Dimensional requirements for sphygmomanometer and cuff SMALL-BORE CONNECTORS

5.1 * Requirements for adult or paediatric PATIENT SMALL-BORE CONNECTORS (S1)

SMALL-BORE CONNECTORS intended to be used with adult or paediatric PATIENTS to connect a cuff to a sphygmomanometer shall comply with the relevant dimensions and tolerances as given in

– Figure B.1 and Table B.1 for the male S1 CONNECTOR.
– Figure B.2 and Table B.2 for the female S1 CONNECTOR.

The male CONNECTOR shall be used for the cuff CONNECTOR.

NOTE Annex H describes an obsolete CONNECTOR that has been used to connect a cuff and sphygmomanometer and that does not comply with this standard.

Check compliance by confirming the relevant dimensions and tolerances specified in Annex B.

5.2 Void

6 Performance requirements

6.1 Air leakage

The engaged SMALL-BORE CONNECTORS for limb cuff inflation APPLICATIONS shall be evaluated for air leakage. The leakage flowrate of paediatric and adult SMALL-BORE CONNECTORS for limb cuff inflation APPLICATIONS shall not exceed 80 Pa•cm^3/s (0,60 mmHg•cm^3/s) while being subjected to an applied pressure of between 50 kPa (375,0 mmHg) and 55 kPa (412,5 mmHg) for a hold period of 95 s to 100 s. MANUFACTURERS may use a greater applied pressure or a longer hold period.

Check compliance by applying the tests of Annex I, while using the leakage reference CONNECTOR specified in Annex C.

6.2 * Resistance to separation from axial load

SMALL-BORE CONNECTORS for limb cuff inflation APPLICATIONS shall be evaluated for separation from axial load. Paediatric and adult CONNECTORS shall not separate from the reference CONNECTOR over the hold period while being subjected to a disconnection applied axial force between 2 N and 3 N for use in the home healthcare environment or for a CONNECTOR on a sphygmomanometer and 32 N and 35 N, otherwise. MANUFACTURERS may use a greater disconnection applied axial force or a longer hold period.

Check compliance by applying the tests of Annex J, while using the separation from axial load reference CONNECTOR specified in Annex C.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This annex provides a rationale for some requirements of IEC 80369-5 and is intended for those who are familiar with the subject of IEC 80369-5 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of International Standard 80369 necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The clauses and subclauses in this annex have been numbered to correspond to the numbering of the clauses and subclauses of this document to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

In 2000, a task group of the European standards organisation CEN proposed a strategy to reduce incidents of accidental misconnection of PATIENT therapy tubing by the use of a series of NON-INTERCONNECTABLE CONNECTORS, differentiated by design, for use in different medical APPLICATIONS. The strategy reserves the use of LUER CONNECTORS solely for use in MEDICAL DEVICES used to access the vascular system or for hypodermic syringes so that they can achieve their intended function. [4][4]

MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in this part of International Standard 80369 to the Secretariat of ISO/TC 210, so that it can consider this feedback during the revision of the relevant part of this series of International Standards.

Subclause 5.1 Requirements for adult or paediatric PATIENT SMALL-BORE CONNECTORS (S1)

The SMALL-BORE CONNECTORS specified for use with adult and paediatric cuffs and sphygmomanometers are readily available from many sources.[5] These CONNECTORS fully meet all the technical requirements of this International Standard, are widely available throughout the world, have been accepted by the marketplace and are familiar to the USERS and MANUFACTURERS alike. These CONNECTORS are NON-INTERCONNECTABLE with all of the other CONNECTORS specified in the International Standard 80369 series, except as noted.

Details of the locking and closure mechanisms indicated in NOTE 2 of Figure B.2 are not specified, as there are several different, MANUFACTURER-specific, variations in the marketplace. As a result, fully-detailed engineering drawings of the locking and closure mechanisms are not available. It is possible that these unspecified dimensions could increase the RISK of misconnection with other CONNECTORS in this series.

Subclause 6.2 Resistance to separation from axial load

The CONNECTORS specified in this part of International Standard 80369 for CONNECTORS intended to be used for CONNECTIONS in limb cuff inflation APPLICATIONS utilize pressures that are required to be held for a period of time when used in healthcare facilities. As a result,

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4 Figures in square brackets refer to the Bibliography.

5 Compliant connectors are commercially available from sources including: the BC series from Colder Products, http://www.colder.com/; the 20KA series from Parker Rectus, http://www.rectus.de/; and the BPF series from Value Plastics, http://www.valueplastics.com/. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO or IEC of these products.

these CONNECTIONS are expected to have a means to ensure the security of the CONNECTION (i.e. more than just a force fit like the LUER SLIP CONNECTOR of ISO 594-1). The exception to this requirement is for home healthcare environment sphygmomanometers where the PATIENT is the USER. In this case, the locking groove is not needed.

Clause C.2 Sphygmomanometer and cuff S1 reference CONNECTORS

The specified reference CONNECTORS are the CONNECTOR designs originally used by MANUFACTURERS for S1 in this APPLICATION. As such, it is appropriate that all other S1 CONNECTORS are designed and tested to interoperate with them.

Clause I.2 Test conditions
and
Clause J.2 Test conditions

Each TEST METHOD includes preconditioning and environmental test requirements

Temperature and humidity preconditioning requirements from ISO 594-1 and ISO 594-2 also have been added in the TEST METHODS for hygroscopic materials, as these materials are known to absorb moisture from surrounding gases and liquids, which can alter physical characteristics, dimensions and performance of CONNECTORS.

The temperature range specified for testing is identical to that specified in ISO 594-1 and ISO 594-2.

Annex B
(normative)

SMALL-BORE CONNECTORS for the limb cuff inflation APPLICATION

Figures B.1 and B.2 illustrate a male cuff S1 SMALL-BORE CONNECTOR and a female sphygmomanometer S1 SMALL-BORE CONNECTOR respectively. Tables B.1 and B.2 indicate the respective dimensions of these CONNECTORS.

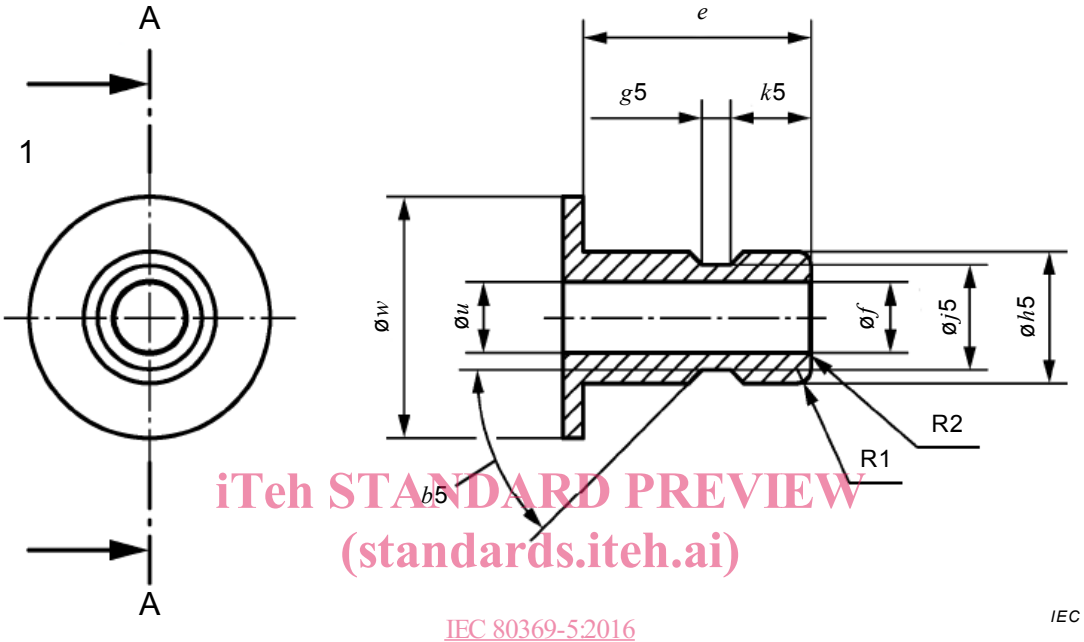

Table B.1 contains the dimensions for this figure.

The extent of the flange (Ø*w*) need not be round.

NOTE The sealing surface is represented by dimension Ø*h*5 of the male CONNECTOR that mates to the sealing surface of Ø*S*5 of the female CONNECTOR.

Figure B.1 – Male cuff S1 SMALL-BORE CONNECTOR