BS EN 80369-5:2016

BSI Standards Publication

Small-bore connectors for liquids and gases in healthcare applications

Part 5: Connectors for limb cuff inflation applications

bsi.

National foreword

This British Standard is the UK implementation of EN 80369-5:2016. It is identical to IEC 80369-5:2016.

The UK participation in its preparation was entrusted by Technical Committee CH/210, Quality management and corresponding general aspects for medical devices, to Subcommittee CH/210/5, Small Bore Connectors for Medical Devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EUROPEAN STANDARD

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English Version

Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications (IEC 80369-5:2016)

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)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 5: Verbindungsstücke für Anwendungen mit aufblasbaren Manschettensystemen für Gliedmaßen (IEC 80369-5:2016)

This European Standard was approved by CENELEC on 8 April 2016. CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of document 62D/1306/FDIS, future edition 1 of IEC 80369-5, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice", ISO/TC 210 "Quality management and corresponding general aspects for medical devices" and CEN/CENELEC TC 3/WG 2 "Smallbore connectors", was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80369-5:2016.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2017-05-04
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2019-11-04

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 80369-5:2016 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 3040:2009	NOTE	Harmonized as EN ISO 3040:2012 [1)] (not modified).
ISO 81060-1:2007	NOTE	Harmonized as EN ISO 81060-1:2012 (not modified).
IEC 60601-1-11:2015	NOTE	Harmonized as EN 60601-1-11:2015 (not modified).
IEC 60601-1-12:2014	NOTE	Harmonized as EN 60601-1-12:2015 (not modified).
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified).
IEC 80601-2-30:2009	NOTE	Harmonized as EN 80601-2-30:2010 (not modified).
IEC 80601-2-30:2009/A1:2013	NOTE	Harmonized as EN 80601-2-30:2010/A1:2015 (not modified).
ISO 80369-20:2015	NOTE	Harmonized as EN ISO 80369-20:2015 (not modified).
ISO 80369-6:2016	NOTE	Harmonized as EN ISO 80369-6:2016 (not modified).
ISO 80369-2 [2)]	NOTE	Harmonized as EN ISO 80369-2 [2)] (not modified).
ISO 80369-3:2016	NOTE	Harmonized as EN ISO 80369-3:2016 (not modified).

[1)] Superseded by EN ISO 3040:2016 (ISO 3040:2016).

[2)] At draft stage.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
-	-	Respiratory therapy equipment - Part 2: Tubing and connectors	EN 13544-2 +A1	2002 2009
ISO 5356-1	2004	Anaesthetic and respiratory equipment - Conical connectors - Part-1: Cones and sockets	EN ISO 5356-1	2004 [3)]
ISO 5356-1	2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets	EN ISO 5356-1	2015
ISO 5356-2	2006	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors	EN ISO 5356-2	2007 [4)]
ISO 5356-2	2012	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors	EN ISO 5356-2	2012
ISO 8185	2007	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems	EN ISO 8185	2009
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2012
ISO 80369-1	2010	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	EN ISO 80369-1	2010
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)] Superseded by EN ISO 5356-1:2015 (ISO 5356-1:2015).

[4)] Superseded by EN ISO 5356-2:2012 (ISO 5356-2:2012).

Annex ZZ
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/023[1] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZZ is based on normative references according to Annex ZA of this document.

NOTE 4 When an Essential Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.

Table ZZ.1 – Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
9.1	5, 6.2	ER 9.1 is met with respect to the connector dimensions and disconnection only.
12.7.4	6.3	ER 12.7.4 is met with respect to stress cracking only.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

[1] Replace with 'M/023 concerning the development of European standards related to medical devices' or with 'M/295 concerning the development of European standards related to medical devices', or with the reference number and title of any other standardization request as relevant.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 5: Connectors for limb cuff inflation applications

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

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.

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.

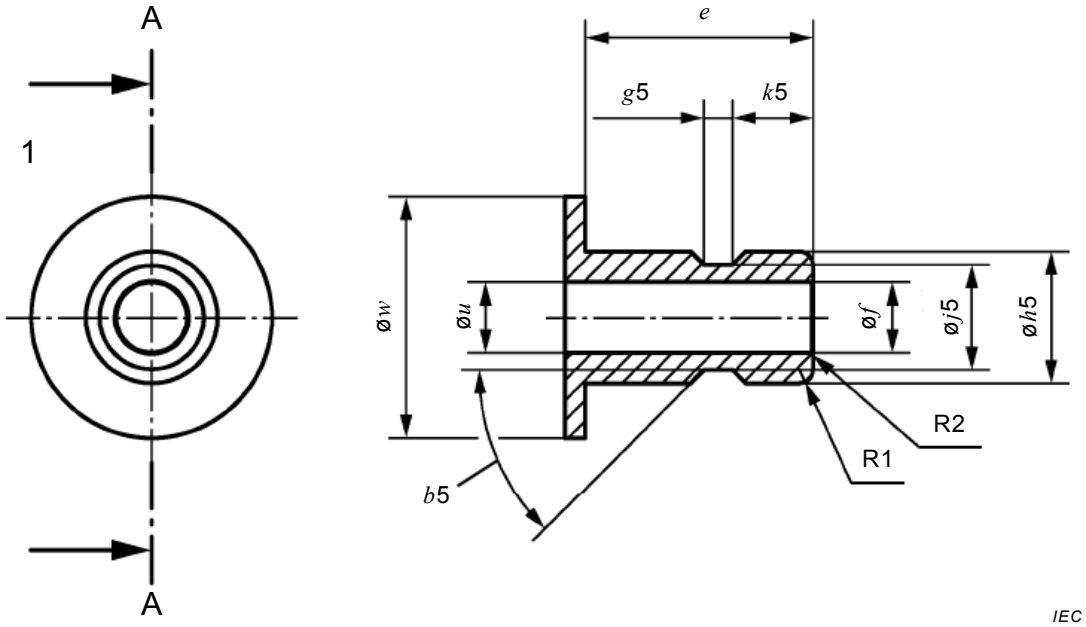

Table B.1 contains the dimensions for this figure.

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

Table B.1 – Male cuff S1 SMALL-BORE CONNECTOR dimensions

Dimensions in mm unless otherwise indicated

Male S1 SMALL-BORE CONNECTOR				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
$b5$ [a]	Angle of the latch groove side (degrees)	44,0°	45,0°	46,0°
e	Length of male bayonet	8,400	8,500	8,600
Øf	Inside diameter at the tip of the male bayonet	2,450	2,675	2,900
$g5$ [a]	Width of the latch groove base	0,910	1,060	1,210
Ø$h5$	Outside diameter of the male bayonet	4,880	4,930	4,980
Ø$j5$ [a]	Diameter of latch groove base	3,810	3,940	4,070
$k5$	Length from the male bayonet tip to latch groove	2,880	3,010	3,140
(L)	Length of engagement (reference) (see Figure B.3)	(1,510)	(1,610)	(1,710)
$r1$	Radius or chamfer at the outside tip of the male bayonet tip	0,200	0,510	0,820
$r2$	Radius or chamfer at the inside tip of the male bayonet tip	0,000	0,050	0,100
Øu	Inside diameter of the fluid lumen	2,450	2,675	—
Øw	Outside diameter of the minimum tangential circle of the male lock connector flange	6,400	9,000	11,600
[a] The locking groove detailed by $b5$, Ø$j5$ and $g5$ may be omitted.				

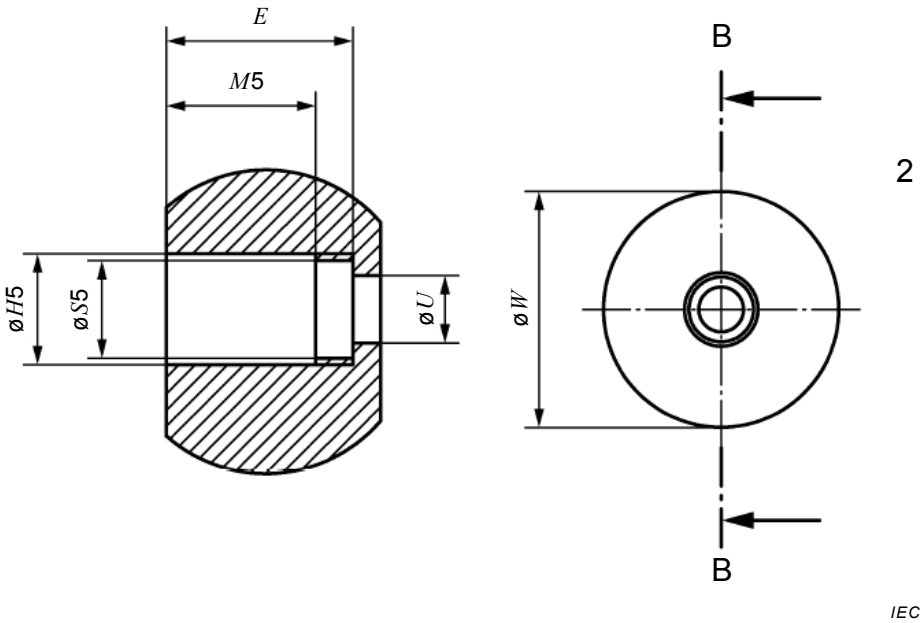

Table B.2 contains the dimensions for this figure.

The sealing surface of ØH of the female CONNECTOR need not comply with 4.2 (e.g. be elastomeric).

The outer diameter of the female CONNECTOR (ØW) need not be round.

NOTE 1 The sealing surface is represented by dimension Øh5 of the male CONNECTOR that mates to the sealing surface of ØS5 of the female CONNECTOR.

NOTE 2 The details of the locking mechanism using the groove of the male CONNECTOR are MANUFACTURER-specific.

Figure B.2 – Female sphygmomanometer S1 SMALL-BORE CONNECTOR

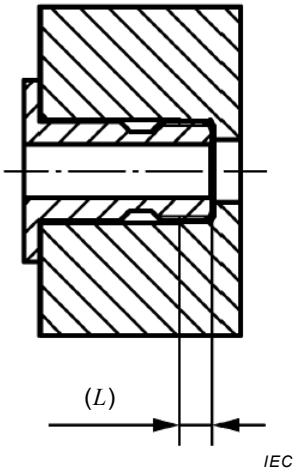

Table B.1 and Table B.2 contain the dimensions for this figure.

Figure B.3 – Sphygmomanometer and cuff SMALL-BORE CONNECTOR (S1) assembly

Table B.2 – Female sphygmomanometer S1 SMALL-BORE CONNECTOR dimensions

Dimensions in mm unless otherwise indicated

Female S1 SMALL-BORE CONNECTOR				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
E	Depth of female CONNECTOR (to fluid lumen)	8,600	8,600	—
Ø*H*5	Inside diameter of the female CONNECTOR	5,060	5,105	5,150
(*L*)	Length of engagement (reference) (see Figure B.3)	(1,510)	(1,610)	(1,710)
*M*5	Depth from face of female CONNECTOR to front of inner seal boundary	6,890	6,890	—
Ø*S*5	Inside diameter of the inner seal boundary	4,380	4,380	—
Ø*U*	Inside diameter of the fluid lumen	1,061 [a]	2,660	2,900
Ø*W*	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the CONNECTOR	10,060	16,280	22,500

[a] A minimum dimension of 0,0 mm is permitted for a plug (i.e. not intended to allow gas transfer).

Annex C
(normative)

Reference CONNECTORS

C.1 General requirements for reference CONNECTORS

The reference CONNECTORS for limb cuff inflation APPLICATION shall be manufactured from corrosion-resistant RIGID MATERIALS.

C.2 * Sphygmomanometer and cuff S1 reference CONNECTORS

The reference CONNECTORS for sphygmomanometer and cuff S1 for leakage, separation from axial load and NON-INTERCONNECTABLE characteristics shall be the standard commercially available CONNECTORS.[6]

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6 Compliant CONNECTORS are commercially available. The 20KA series from Parker Rectus, http://www.rectus.de/ is suitable. 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.

Annex D
(informative)

Assessment of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION

The requirements for CONNECTIONS for sphygmomanometers in limb cuff inflation are well understood, as sphygmomanometers have had product standards outlining those requirements for an extended period. These requirements are found in ISO 81060-1 and IEC 80601-2-30.

Annex E
(informative)

Summary of the usability requirements for SMALL-BORE CONNECTORS for limb cuff inflation APPLICATIONS

E.1 USER PROFILE

The USER PROFILE is a summary of the mental, physical and demographic traits of an intended USER population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements.

Sphygmomanometers (MEDICAL DEVICES intended to take or monitor non-invasive blood pressure) include nearly all PATIENT population types and age ranges as non-invasive estimation of blood pressure is one of the most common PATIENT parameters used in healthcare. As a result, the USER of a sphygmomanometer includes nearly every clinician in a healthcare facility or ambulance as well as most adults in the home healthcare environment. This profile does not cover the use of sphygmomanometers with neonatal PATIENTS as CONNECTORS for this PATIENT-population are not yet incorporated into this standard.

USERS of SMALL-BORE CONNECTORS for limb cuff inflation APPLICATION use are comprised of the PATIENTS themselves, family or friends helping the PATIENT and all levels of healthcare providers from volunteers to primary care providers and specialists. USERS are expected to perform an intended action in NORMAL USE.

USERS include:

a) PATIENTS, as the persons undergoing a medical, surgical or dental PROCEDURE who are also expected to perform an intended action.
b) clinical USERS, such as:
   - physicians, physician's assistants, all levels;
   - nurses, at all levels;
   - home-care providers, visiting nurses, PATIENTS and relatives; and
   - emergency medical technicians.

The USER PROFILE is summarized in Table E.1.

Table E.1 – USER PROFILE

	PATIENTS/primary caregivers	Professional clinical USERS
USER skills	No training [a] USERS can have a disability (e.g. impaired sight, inability to manipulate small CONNECTORS, inability to read and understand written instructions).	Clinical training at a variety of levels
PATIENT contact	Direct PATIENT contact	Direct PATIENT contact or limited PATIENT contact

[a] PATIENTS need to be able to connect or disconnect the cuff from the sphygmomanometer with little or no training.

E.2 Use scenarios

The CONNECTORS of many sphygmomanometers are not intended to be touched or manipulated in use. However there can be instances where disconnection is needed, such as individuals tampering with the CONNECTION based on the need to conduct tasks such as activities of daily living (changing clothes, needing to leave the area where continuous monitoring is taking place, etc.) or transportation, where it would be easier to disconnect the CONNECTOR rather than removing and replacing the cuff. Additionally, some home use

sphygmomanometers use the disconnection of the cuff as the emergency means to deflate the cuff.

E.3 Use environments and scenarios

Sphygmomanometers are utilized in virtually every environment where blood pressure screening or monitoring is needed. This can include, but is not limited to, commercial settings (pharmacies), home use, healthcare clinics, emergency and field medicine and hospital settings. In all settings there is the potential need for both single (screening) and continuous blood pressure monitoring. In these environments, the need for a secure CONNECTION and ability to disconnect is similar.

A sphygmomanometer is used whenever blood pressure screening or monitoring is necessary. Situations range from simple blood pressure screening to emergency use where multiple sphygmomanometers are being used during stressful events as well as the diagnostic determination of blood pressure. Locations include hospitals, surgery suites, PATIENT rooms, labour & delivery, intensive care units, doctors' offices, pain clinics, pharmacies, field hospitals, transport systems, infusion clinics, homes, assisted care units and emergency medical services.

The following temperature environments are expected for limb cuff inflation SMALL-BORE CONNECTORS:

a) ambient temperature, – 20 °C to + 50 °C (for field use in emergency medical services [5] and outdoor use by home healthcare PATIENTS [4]); and

b) body temperature, to 42 °C.

E.4 Generic USER needs

The generic USER needs for limb cuff inflation CONNECTIONS include the following:

a) The CONNECTORS of this APPLICATION should be easy to manipulate but they do not require the same force as the LUER CONNECTOR to connect or disconnect.

b) The CONNECTORS of this APPLICATION are not permitted to connect to other CONNECTORS in the environment of use.

c) The CONNECTORS of this APPLICATION are not permitted to leak under NORMAL USE to permit accurate blood pressure determinations to occur.

d) Security of CONNECTION should be evident by mechanical or cognitive means (visual, tactile and/or auditory confirmation of a CONNECTION).

e) The USER needs to be able to disconnect the CONNECTION when pressurized to permit the release of air pressure from the cuff and release of the PATIENT in sphygmomanometer failure.

f) The CONNECTORS for this APPLICATION need to be made from biocompatible materials suitable for skin contact.

g) Decontamination is needed. Sphygmomanometers and their cuffs are typically reusable and therefore it is necessary that they can be cleaned and, when appropriate, disinfected or sterilized.

Annex F contains the detailed requirements for CONNECTORS of this APPLICATION.

Annex F
(informative)

Summary of SMALL-BORE CONNECTOR design requirements for limb cuff inflation APPLICATIONS

Table F.1 is a summary of the design requirements for the adult or paediatric PATIENT sphygmomanometer and cuff S1 CONNECTOR.

Table F.1 – Adult or paediatric PATIENT sphygmomanometer and cuff S1 CONNECTOR-specific design requirements *(1 of 4)*

	Criteria	Requirements	Remarks
1	**Fluid type** a) Liquid b) Gas c) Both	 b)	
2	**Operating pressure range** maximum pressure minimum pressure subatmospheric? (yes/no)	 50 kPa (375 mmHg) atmospheric no	At least 10 % > than single fault condition pressure for a sphygmomanometer.
3	**RATED pressure range** minimum maximum	 0 55 kPa (412 mmHg)	
4	**Is there a need for a leak test?** a) No b) Yes reference for TEST METHOD	 b) ≤ 0,5 kPa/min (4 mmHg/min at 55 kPa (412 mmHg)	No more than 10 % of the permissible leakage of a sphygmomanometer and cuff (4 mmHg/min or 0,5 kPa/min).
5	**RATED flowrate range** minimum maximum	At least 15 l/min at 50 kPa (375 mmHg) Not applicable	The pneumatic system has to be capable of being deflated by the sphygmomanometer within 10 s.
6	**Internal diameter range** (through bore) tubing minimum maximum CONNECTOR minimum maximum	 3 mm 4 mm 1 mm 5,2 mm	
7	**RATED temperature range** minimum maximum	 – 0 °C + 50 °C	
8	**Minimum range of CONNECTOR mating diameters** minimum maximum	Not applicable	Incompatible with LUER CONNECTOR or other SMALL-BORE CONNECTORS of this series.

Table F.1 *(2 of 4)*

	Criteria	Requirements	Remarks
9	**General layout** a) Parallel-sided, O-ring seal b) Parallel-sided, other seal c) Conical d) Other (specify)	a) or b)	
10	**Method of keying** a) Collar b) Plug c) Other (specify)	Not applicable	
11	**Quick release?** a) No b) Yes i) single-handed operation ii) double-handed operation	b) i) or ii)	
12	**Positive locking/unlocking feature?** a) No b) Yes	a) or b)	
13	**Need for visual indication of locking status?** a) No b) Yes	a)	
14	**Need for indication of evidence of tampering?** a) No b) Yes	a)	
15	**Need for a syringe in the APPLICATION?** a) No b) Yes	a)	
16	**Need for an absence of sharp edges?** a) No b) Yes	b)	
17	**Minimum pull-apart force in NORMAL USE,** force Reference for TEST METHOD when locked force Reference for TEST METHOD	2 N, home use or CONNECTIONS on the sphygmomanometer 35 N, otherwise	
18	**Constructional materials** (excluding seals) a) RIGID MATERIAL i) metal ii) plastic b) SEMI-RIGID MATERIAL	a) i) or ii) b) > 700 MPa	

Table F.1 *(3 of 4)*

	Criteria	Requirements	Remarks
19	**Need for use of SEMI-RIGID MATERIAL?** a) No b) Yes, mating part of CONNECTOR (apart from seal)	 a) or b)	
20	**MRI compatibility?** a) No, with labelling b) No, without labelling c) Yes, with labelling d) Yes, without labelling	 b)	
21	**Stress-cracking resistance?** a) No b) Yes specify limits	No	Not applicable to this style CONNECTOR.
22	**Externally, how is CONNECTOR to be distinguishable from LUER CONNECTOR?** (describe)	Not a conical taper. Looks completely different.	
23	**Proposal for colour-coding?** a) No b) Yes reference standard	 a)	
24	**Labelling/symbols/marking?** (e.g. not for IV) a) No b) Yes	 a)	
25	**Other method for indicating INTENDED USE?** a) No b) Yes indicate method	 a)	
26	**Biocompatibility considered?** a) No b) Yes	 b)	
27	**Reuse variants** a) Multiple PATIENT use b) Single PATIENT use c) Single use d) Non-reusable (indicate method of auto-disabling)	 a), b), or c)	

Table F.1 *(4 of 4)*

	Criteria	Requirements	Remarks
28	**Decontamination needed?** a) No, single use only b) Yes, cleaning and disinfection indicate method c) Yes, cleaning and sterilization indicate method	b) At least one of: Quaternary ammonium, Glutaraldehyde, Ortho-phthaldehyde, Hydrogen peroxide, Glucoprotamine, Formaldehyde, Isopropanol, Sodium hypochlorite (bleach) 2,5 %, ethyl alcohol 75 %	Both the cuff and hose CONNECTORS should tolerate typical cleaning and disinfection agents.
29	**How is LUER CONNECTOR incompatibility achieved?** (ISO 594-1 and ISO 594-2) a) Dimensional b) Other indicate method	a)	
30	**How is ISO 80369-2 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	
31	**How is ISO 80369-3 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	
32	**How is ISO 80369-4 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	
33	**How is ISO 80369-5 incompatibility achieved?** a) Dimensional b) Other indicate method	This is the S1 CONNECTOR.	
34	**How is ISO 80369-6 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	

Table F.2 is a summary of the design requirements for the neonatal sphygmomanometer and cuff CONNECTOR.

Table F.2 – Neonatal sphygmomanometer and cuff CONNECTOR-specific design requirements *(1 of 4)*

	Criteria	Requirements	Remarks
1	**Fluid type** a) Liquid b) Gas c) Both	 b)	
2	**Operating pressure range** maximum pressure minimum pressure subatmospheric? (yes/no)	 25 kPa (187 mmHg) atmospheric no	At least 10 % > than SFC pressure for a neonatal sphygmomanometer (22 kPa or 165 mmHg).
3	**RATED pressure range** minimum maximum	 0 55 kPa (412 mmHg)	
4	**Is there a need for a leak test?** a) No b) Yes reference for TEST METHOD	 b) ≤ 0,25 kPa/min (2 mmHg/min) at 27 kPa (202 mmHg)	No more than 10 % of the permissible leakage of a sphygmomanometer and cuff (2 mHg/min or 0,25 kPa/min)..
5	**RATED flowrate range** minimum maximum	 At least 4,0 l/min at 25 kPa (187 mmHg) Not applicable	The pneumatic system has to be cable of being deflated by the sphygmomanometer within 10 s.
6	**Internal diameter range (through bore)** tubing minimum maximum CONNECTOR minimum maximum	 3 mm 4 mm 1 mm 5,2 mm	
7	**RATED temperature range** minimum maximum	 0 °C + 45 °C	Based on radiant warmer standard IEC 60601-2-21. Relative humidity can reach 100 %.
8	**Minimum range of CONNECTOR mating diameters** minimum maximum	Not applicable	Incompatible with LUER CONNECTOR or other SMALL-BORE CONNECTORS of this series.
9	**General layout** a) Parallel-sided, O-ring seal b) Parallel-sided, other seal c) Conical d) Other (specify)	 a), b) or d)	Conical should be avoided to ensure incompatibility with LUER CONNECTOR.

Table F.2 *(2 of 4)*

	Criteria	Requirements	Remarks
10	**Method of keying** a) Collar b) Plug c) Other (specify)	Not applicable	
11	**Quick release?** a) No b) Yes i) single-handed operation ii) double-handed operation	b) i) or ii)	
12	**Positive locking/unlocking feature?** a) No b) Yes	a) or b)	This should be reviewed in the usability testing.
13	**Need for visual indication of locking status?** a) No b) Yes	a)	This should be reviewed in the usability testing.
14	**Need for indication of evidence of tampering?** a) No b) Yes	a)	
15	**Need for a syringe in the APPLICATION?** a) No b) Yes	a)	
16	**Need for an absence of sharp edges?** a) No b) Yes	b)	
17	**Minimum pull-apart force in NORMAL USE,** force Reference for TEST METHOD when locked force Reference for TEST METHOD	10 N	
18	**Constructional materials** (excluding seals) a) RIGID MATERIAL i) metal ii) plastic b) SEMI-RIGID MATERIAL	a) i) or ii)	Metal could impact MRI compatibility, plastic is preferred.
19	**Need for use of SEMI-RIGID MATERIAL?** a) No b) Yes, mating part of CONNECTOR (apart from seal)	a) or b)	

Table F.2 *(3 of 4)*

	Criteria	Requirements	Remarks
20	**MRI compatibility?** a) No, with labelling b) No, without labelling c) Yes, with labelling d) Yes, without labelling	b) or d)	MRI compatibility is desirable.
21	**Stress-cracking resistance?** a) No b) Yes specify limits	no	Not applicable to this style CONNECTOR.
22	**Externally, how is CONNECTOR to be distinguishable from LUER CONNECTOR?** (describe)	Not a conical taper. Looks completely different.	
23	**Proposal for colour-coding?** a) No b) Yes reference standard	a)	
24	**Labelling/symbols/marking?** (e.g. not for IV) a) No b) Yes	a)	
25	**Other method for indicating INTENDED USE?** a) No b) Yes indicate method	a)	
26	**Biocompatibility considered?** a) No b) Yes	b)	
27	**Reuse variants** a) Multiple PATIENT use b) Single PATIENT use c) Single use d) Non-reusable (indicate method of auto-disabling)	a), b), c)	Hose CONNECTORS are (a), cuff CONNECTORS are (a), (b) or (c).
28	**Decontamination needed?** a) No, single use only b) Yes, cleaning and disinfection indicate method c) Yes, cleaning and sterilization indicate method	b) At least one of: Quaternary ammonium, Glutaraldehyde, Ortho-phthaldehyde, Hydrogen peroxide, Glucoprotamine, Formaldehyde, Isopropanol, Sodium hypochlorite (bleach) 2,5 %, ethyl alcohol 75 %	Both the cuff and hose CONNECTORS should tolerate typical cleaning and disinfection agents.

Table F.2 *(4 of 4)*

	Criteria	Requirements	Remarks
29	**How is LUER CONNECTOR incompatibility achieved?** (ISO 594-1 and ISO 594-2) a) Dimensional b) Other indicate method	a)	
30	**How is ISO 80369-2 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	
31	**How is ISO 80369-3 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	
32	**How is ISO 80369-4 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	
33	**How is ISO 80369-5 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	
34	**How is ISO 80369-6 incompatibility achieved?** a) Dimensional b) Other indicate method	a)	

Annex G
(informative)

Summary of assessment of the design of the CONNECTORS for limb cuff inflation APPLICATION

G.1 General

The S1 SMALL-BORE CONNECTORS specified in Annex B of this International Standard, which are intended for use with adult or paediatric PATIENTS to connect a cuff to a sphygmomanometer or its hose, have been in widespread use for this purpose for more than 20 years. USERS have found these CONNECTORS to be clinically acceptable and more importantly, they are NON-INTERCONNECTABLE with the 6 % female LUER CONNECTORS used in intravascular and hypodermic APPLICATIONS.

NOTE The summary of the assessment for SMALL-BORE CONNECTORS intended to be used with neonatal PATIENTS to connect a cuff to a sphygmomanometer or to connect a tourniquet to its inflating equipment is intended to be added to this annex by an amendment or new edition that introduces those CONNECTORS.

G.2 Summary of the engineering analysis of the design

G.2.1 NON-INTERCONNECTABLE analysis

A three-dimensional computer aided design (CAD) engineering analysis has been performed using computational analysis and 3D solid model constructs of all tolerances and material conditions for all CONNECTORS represented by this series of International standards. The SMALL-BORE CONNECTORS specified in this standard have been shown by engineering analysis to be NON-INTERCONNECTABLE with the other specified CONNECTORS of this series with the exception of the following. Table G.1 summarises the potential misconnections.

A technical report is planned to describe the PROCESS for the CAD engineering analysis more completely.

Table G.1 – Summary of possible misconnection from CAD analysis

S1	CONNECTOR of concern	Summary	Reference
Male	N1 male	Physical testing per ISO 80369-1:2010, Annex B, results in no CONNECTION	G.2.2
N1 from ISO 80369-6:2015			

G.2.2 S1 male to N1 male

Testing was performed according to the TEST METHOD of ISO 80369-1:2010, Annex B.

The test demonstrated that the CONNECTORS are NON-INTERCONNECTABLE.

G.3 Summary of the design VERIFICATION

Because of the long and successful history of widespread clinical use, the committee concluded that it was unnecessary to evaluate further these CONNECTOR systems according to PROCESSES and PROCEDURES of ISO 80369-1:2010, Clause 7.

S1 CONNECTORS of two configurations were tested:

a) nylon having a nominal modulus of elasticity (tensile) of 1 200 MPa, and

b) metal.

These are widely available in the marketplace. These materials meet the requirements of 4.2.

Performance testing was performed according to ISO 80369-20:2015 as required by Clause 6.

Conclusion:

The test results indicate the S1 design is compliant with the performance requirements specified in Clause 6 using the TEST METHODS defined in ISO 80369-20:2015.

G.4 Summary of the design validation

Because of the long and successful history of widespread clinical use, the committee concluded that it was unnecessary to further evaluate further these CONNECTOR systems according to PROCESSES and PROCEDURES of ISO 80369-1:2010, 7.3.4.

G.5 Summary of the design review

The S1 CONNECTORS reflect the specific designs that have been in use for decades.

Because of the long and successful history of widespread clinical use, the committee concluded that it was unnecessary to evaluate further the S1 CONNECTORS according to PROCESSES and PROCEDURES of ISO 80369-1:2010, Clause 7.4. The S1 CONNECTORS specified in Annex B have been shown to be NON-INTERCONNECTABLE with the other specified CONNECTORS of this series.

The committee reviewed the assessment of the design of the S1 CONNECTORS based on the results reported in this Annex G.

In summary, the design review concludes there is significant objective engineering, technical and clinical evidence supporting the S1 CONNECTOR for the intended APPLICATION.

Annex H
(informative)

Obsolete limb cuff inflation CONNECTOR

The CONNECTORS described in this annex have been used for decades for non-automated sphygmomanometers. These CONNECTORS have not been included in this standard for future use because they are known to fail the NON-INTERCONNECTABLE tests of ISO 80369-1:2010, Annex B.

However, there are a very large number of sphygmomanometers in current clinical use that utilize this CONNECTOR system. Because these sphygmomanometers have an expected service life of several decades, they will require a permanent adaptor to convert from this obsolete CONNECTOR to the S1 CONNECTORS specified in this standard.

The historical dimensions of the obsolete CONNECTOR are described in Figure H.1, Table H.1 and Table H.2 of this annex to assist in the development of permanent adaptors for the retrofit conversion of existing installed sphygmomanometers to the new CONNECTORS.

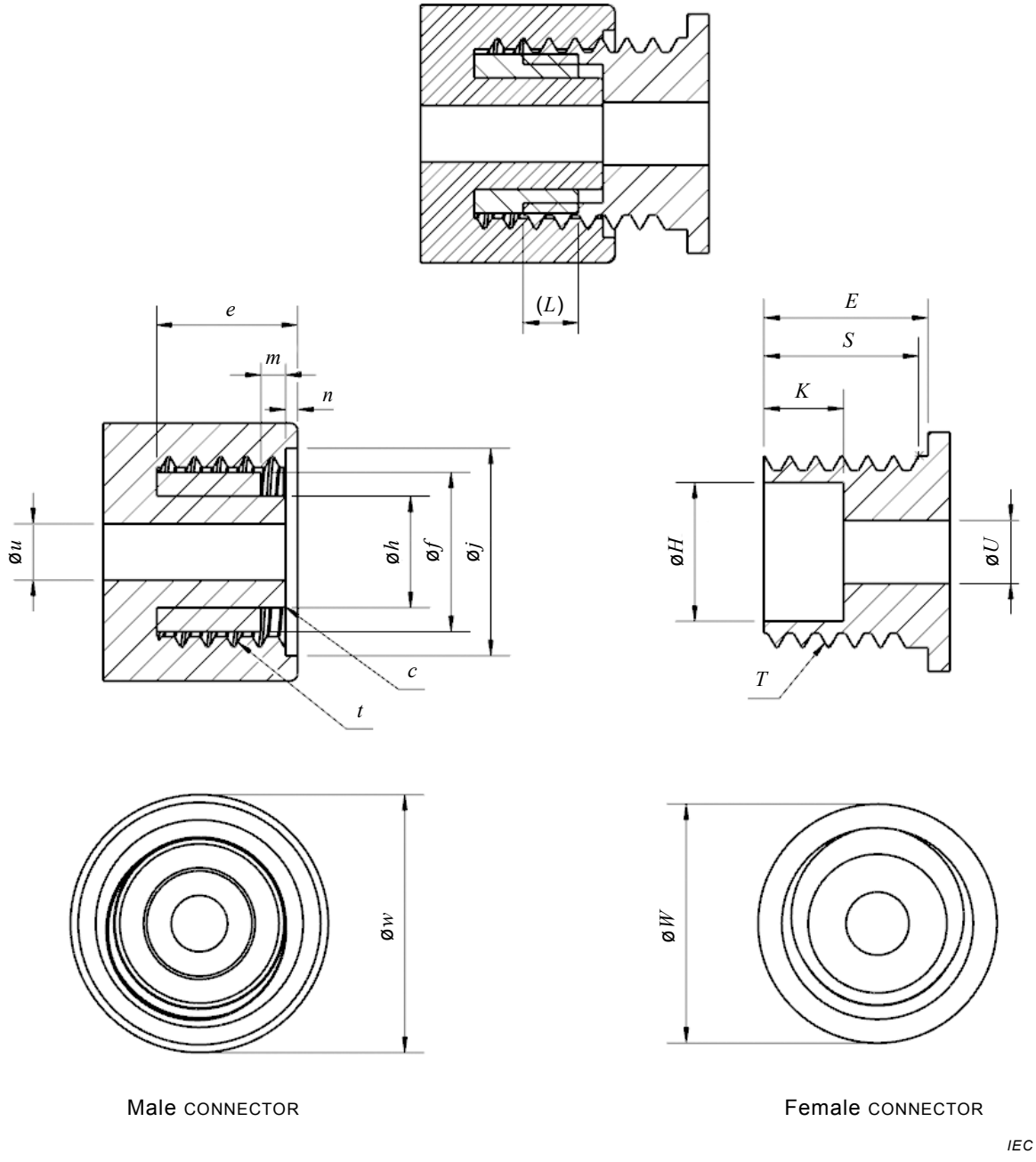

Table H.1 and Table H.2 contain the dimensions for this figure.

Figure H.1 – Obsolete sphygmomanometer and cuff SMALL-BORE CONNECTOR

Table H.1 – Obsolete male sphygmomanometer and cuff SMALL-BORE CONNECTOR dimensions

Dimensions in mm unless otherwise indicated

Male CONNECTOR				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
c	Outer face radius of the male tip	0,000	0,127	0,254
e	Length of the male protrusion	5,25	—	—
Ø*f*	Outer diameter of the outer seal boundary	—	—	6,500
Ø*h*	Outer diameter of the male protrusion	3,495	4,555	5,615
Ø*j*	Inner diameter of the male shroud	7,940	8,470	9,000
(*L*)	Length of seal engagement (reference)	(2,250)	—	—
m	Length from start of internal threads to the front of the outer seal boundary	1,000	—	—
n	Length to start of thread from shroud face	0,500	—	—
t	Thread designation	5/16-24 UNF-2A internal thread[a]		
Ø*u*	Inner diameter of the fluid lumen (recommended)	1,651	2,301	2,951
Ø*w*	Width of major projections (shroud/latching mechanism)	9,500	10,530	11,560
[a] Fine (UNF) of the Unified Thread Standard. Major diameter [9].				

Table H.2 – Obsolete female sphygmomanometer and cuff SMALL-BORE CONNECTOR dimensions

Dimensions in mm unless otherwise indicated

Female CONNECTOR				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
E	Length of protruding male CONNECTOR	6,700	—	—
Ø*H*	Inner diameter of the sealing surface of the female CONNECTOR	5,610	5,670	5,730
K	Inner diameter of the sealing surface of the female CONNECTOR	3,250	—	—
(*L*)	Length of seal engagement (reference)	(2,250)	—	—
S	Length of external thread	5,710	—	—
T	Thread designation	5/16-24 UNF-2A external thread [a]		
Ø*U*	Inner diameter of the fluid lumen (recommended)	2,200	2,580	2,960
Ø*W*	Width of major projections (lugs/latching mechanism)	7,910	9,760	11,610
[a] Fine (UNF) of the Unified Thread Standard. Major diameter [9].				

Annex I
(informative)

Air leakage by pressure decay TEST METHOD

I.1 Principle

The CONNECTOR under test is securely assembled to an appropriate reference CONNECTOR. The air is introduced into the CONNECTION and pressurized to the specified pressure. The leakage flowrate is then measured.

I.2 * Test conditions

I.2.1 Test sample preconditioning

Prior to testing, precondition the CONNECTOR under test at 20 °C ± 5 °C and 50 % ± 10 % relative humidity for not less than 24 h. Preconditioning need not be performed for a CONNECTOR made from non-hygroscopic materials.

I.2.2 Environmental test conditions

Perform tests at a temperature within the range of 15 °C to 30 °C and at a relative humidity between 25 % and 65 %.

I.3 Apparatus

The following items shall be utilized.

a) The male or female CONNECTOR under test.

b) The appropriate reference CONNECTOR, as specified in Annex C for the leakage TEST METHOD, to be assembled to the CONNECTOR under test.

c) A means to contain and pressurize air to the specified test pressure. Rigid fixtures and apparatus materials (such as metal) should be used to avoid inaccurate test results.

d) A device capable of measuring and displaying the elapsed time with an accuracy of ± 1 s.

e) A device capable of measuring and displaying the applied pressure with a minimum accuracy of 0,3 %.

Additional apparatus required for TEST METHOD 2:

f) A stop valve and hoses to connect parts of the test setup.

g) A graduated cylinder with at least 1,0 ml (1,0 cm^3) resolution.

An automated pressure decay leak test system may be substituted for any or all items c), d), e) and f).

I.4 PROCEDURE

Check compliance with either TEST METHOD 1 or TEST METHOD 2.

TEST METHOD 1 consists of the following.

a) Assemble the CONNECTOR under test to the appropriate male or female reference CONNECTOR, both CONNECTORS being dry. Fully engage the locking mechanism, if present.

b) Seal the outlet bore of the CONNECTOR under test.

c) Apply the air at the applied pressure specified for the specific CONNECTOR under test to the assembly through the bore and close the valve.

d) Record the test pressure and start the timing device.

e) Wait for the hold period and record the test pressure and time.

f) Calculate the change in test pressure.

g) Calculate the leakage rate, L on the basis of Equation I.1.

$$L = \frac{sp}{tp} \times v \times \frac{\Delta p}{\Delta t} \quad \text{(I.1)}$$

where

L = the leakage rate in Pa·cm^3/s,

sp = the lower limit of the specified test pressure in Pa,

tp = the actual test pressure at the start of the test in Pa,

v = the volume from the valve to the test specimen in cm^3,

Δp = the pressure change during the test period in Pa, and

Δt = the test period in s.

EXAMPLE At a specified pressure of 50 kPa, a test pressure of 55 kPa (gauge) and a total volume of 30 cm^3, a pressure drop of 350 Pa is established within a period of 100 min.

$$L = \frac{50 \times 10^3}{55 \times 10^3} \times 30 \times \frac{350}{100 \times 60} = 1,59\ Pa \cdot cm^3 / s$$

h) Confirm that the leakage rate does not exceed the value for the CONNECTOR under test.

TEST METHOD 2 consists of the following.

a) Assemble the CONNECTOR under test to the appropriate male or female reference CONNECTOR, both CONNECTORS being dry. Fully engage the locking mechanism, if present.

b) Seal the outlet bore of the CONNECTOR under test.

c) Submerge the engaged CONNECTORS in the water bath and place water filled graduated cylinder above.

d) Apply the air at the applied pressure specified for the specific CONNECTOR under test to the assembly through the bore and close the valve.

e) Start the timing device and wait 100 min.

f) Measure the volume of air in the graduated cylinder.

g) Divide the volume by 100, (i.e. calculate the leakage volume per minute).

h) Confirm that the leakage volume does not exceed 0,10 cm^3/min.

I.5 Test report

Prepare a test report that:

– specifies testing was performed according to IEC 80369-5:2016, Annex I, Air leakage by pressure decay TEST METHOD;

– identifies the CONNECTORS under test;

– identifies the number of CONNECTORS tested;

– identifies the applied pressure used;

– identifies the acceptance criterion;

– discloses the measured test pressure;

– discloses the volume of the test apparatus;

– discloses the pressure drop during the test period; and

– discloses the calculated leakage rate.

Annex J
(informative)

Resistance to separation from axial load TEST METHOD

J.1 Principle

The security of the CONNECTION to an axial pull is determined by applying an axial separation force between the assembled CONNECTOR under test and the appropriate reference CONNECTOR. Where locking mechanisms are present, they are engaged. The CONNECTION is expected to be maintained.

J.2 * Test conditions

J.2.1 Test sample preconditioning

Prior to testing, precondition the CONNECTOR under test at 20 °C ± 5 °C and 50 % ± 10 % relative humidity for not less than 24 h. Preconditioning need not be performed for a CONNECTOR made from non-hygroscopic materials.

J.2.2 Environmental test conditions

Perform tests at a temperature within the range of 15 °C to 30 °C and at a relative humidity between 25 % and 65 %.

J.3 Apparatus

The following items shall be utilized:

a) the male or female CONNECTOR under test;

b) the appropriate reference CONNECTOR, as specified in Annex C for the resistance to separation from axial load TEST METHOD, to be assembled to the CONNECTOR under test;

c) a means of measuring the specified axial force;

d) a device capable of measuring and displaying the elapsed time with an accuracy of ± 1 s.

J.4 PROCEDURE

Check compliance with the following test.

a) Assemble the CONNECTOR under test to the appropriate male or female reference CONNECTOR, both CONNECTORS being dry. Fully engage the locking mechanism, if present.

b) Apply an axial force in a direction away from the test fixture at a rate of approximately 2,5 N/s until the specified axial force is reached. Hold the axial force for a period between 10 s and 15 s.

c) Confirm by visual inspection that CONNECTORS remain engaged.

J.5 Test report

Prepare a test report that:

– specifies testing was performed according to IEC 80369-5:2016, Annex J, “Resistance to separation from axial load TEST METHOD”;

– identifies the CONNECTORS under test;

– identifies the number of CONNECTORS tested;

– identifies the applied separation force used;

– identifies the duration that force was applied;

– identifies the acceptance criterion; and

– identifies the presence or absence of separation.

Annex K
(informative)

Reference to the essential principles

This document has been prepared to support the essential principles of safety and performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in intravascular or hypodermic APPLICATIONS of MEDICAL DEVICES and related ACCESSORIES according to ISO/TR 16142:2006. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2006. Other means are possible. Table K.1 maps the clauses and subclauses of this document with the essential principles of ISO/TR 16142:2006.

Table K.1 – Correspondence between this document and the essential principles *(1 of 2)*

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
A.1	—	Not applicable
A.2	—	Not applicable
A.3	—	Not applicable
A.4	—	Not applicable
A.5	—	Not applicable
A.6	—	Not applicable
A.7.1	—	Not applicable
A.7.2	—	Not applicable
A.7.3	—	Not applicable
A.7.4	—	Not applicable
A.7.5	4, 5, 6	
A.7.6	4, 5, 6	
A.8.1	—	Not applicable
A.8.1.1	—	Not applicable
A.8.1.2	—	Not applicable
A.8.2	—	Not applicable
A.8.3	—	Not applicable
A.8.4	—	Not applicable
A.8.5	—	Not applicable
A.8.6	—	Not applicable
A.9.1	4, 5, 6	
A.9.2	—	Not applicable
A.9.3	—	Not applicable
A.10.1	—	Not applicable

Table K.1 *(2 of 2)*

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
A.10.2	—	Not applicable
A.10.3	—	Not applicable
A.11.1.1	—	Not applicable
A.11.2.1	—	Not applicable
A.11.2.2	—	Not applicable
A.11.3.1	—	Not applicable
A.11.4.1	—	Not applicable
A.11.5.1	—	Not applicable
A.11.5.2	—	Not applicable
A.11.5.3	—	Not applicable
A.12.1	—	Not applicable
A.12.2	—	Not applicable
A.12.3	—	Not applicable
A.12.4	—	Not applicable
A.12.5	—	Not applicable
A.12.6	—	Not applicable
A.12.7.1	—	Not applicable
A.12.7.2	—	Not applicable
A.12.7.3	—	Not applicable
A.12.7.4	4, 5, 6	
A.12.7.5	—	Not applicable
A.12.8.1	4, 5, 6	
A.12.8.2	—	Not applicable
A.12.8.3	—	Not applicable
A.13.1	—	Not applicable
A.14.1	—	Not applicable

Index of defined terms

NOTE The ISO Online Browsing Platform (OBP) provides access to terms and definitions. [7]

Term	Source
ACCESSORY	ISO 80369-1:2010, 3.1
APPLICATION	ISO 80369-1:2010, 3.2
CONNECTION	ISO 80369-1:2010, 3.4
CONNECTOR	ISO 80369-1:2010, 3.5
INTENDED USE	ISO 14971:2007, 2.5
LUER CONNECTOR	ISO 80369-7:2016, 3.1
LUER SLIP CONNECTOR	ISO 80369-7:2016, 3.2
MANUFACTURER	ISO 14971:2007, 2.8
MEDICAL DEVICE	ISO 14971:2007, 2.9
NON-INTERCONNECTABLE	ISO 80369-1:2010, 3.6
NORMAL USE	3.1
PATIENT	ISO 80369-1:2010, 3.7
PROCEDURE	ISO 14971:2007, 2.12
PROCESS	ISO 14971:2007, 2.13
RATED	3.2
RESPONSIBLE ORGANIZATION	ISO 80369-1:2010, 3.8
RIGID MATERIAL	ISO 80369-1:2010, 3.9
RISK	ISO 14971:2007, 2.16
RISK ASSESSMENT	ISO 14971:2007, 2.18
SEMI-RIGID MATERIAL	ISO 80369-1:2010, 3.10
SMALL-BORE	ISO 80369-1:2010, 3.11
TEST METHOD	3.3
TYPE TEST	3.4
USER	3.5
USER PROFILE	3.6
VERIFICATION	ISO 14971:2007, 2.28

7 Available at: https://www.iso.org/obp/ui/#home

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[1] ISO 594-1:1986, *Luer conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*

[2] ISO 3040:2009, *Geometrical product specifications (GPS) – Dimensioning and tolerancing – Cones*

[3] ISO 81060-1:2007, *Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type*

[4] IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

[5] IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

[6] IEC 62366-1:2015, *Medical devices – Application of usability engineering to medical devices*

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IEC 80601-2-30:2009/AMD1:2013

[8] CEN CR 13825, *Luer connectors – A report to CEN CHeF from the CEN forum task group "Luer fittings"*

[9] ASME/ANSI B1.1:2003, *Unified Inch Screw Threads (UN and UNR Thread Form)*

[10] ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods*

[11] ISO 80369-6:___[8], *Small-bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications*

[12] ISO 80369-2:___[9], *Small-bore connectors for liquids and gases in healthcare applications – Part 2: Connectors for breathing systems and driving gases applications*

[13] ISO 80369-3:___[10], *Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications*

[14] ISO 80369-4:___[11], *Small-bore connectors for liquids and gases in healthcare applications – Part 4: Connectors for enteral applications Connectors for urethral and urinary applications*

[15] ISO 594-2:1986, *Luer conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: Lock fittings*

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8 To be published.

9 To be published.

10 Under development.

11 Planned but not yet begun as of the date of publication.

[16] ISO TR 16142:2006, *Medical devices – Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

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