INTERNATIONAL STANDARD

ISO 80369-7

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

Part 7: Connectors for intravascular or hypodermic applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —
Partie 7: Raccords à 6 % (Luer) destinés aux applications intravasculaires ou hypodermiques

Reference number
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Foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80369-7 cancels and replaces ISO 594-1:1986 and ISO 594-2:1998, clauses, subclauses, tables, figures, and annexes of which have been consolidated and technically revised.

This part of ISO 80369 contains the following major technical revisions to ISO 594-1 and ISO 594-2.

a) New terms and definitions have been added to this part of ISO 80369 to more clearly define the various types of LUER CONNECTORS included in the scope of this part of ISO 80369. This part of ISO 80369 more broadly describes the requirements for the CONNECTORS used for intravascular or hypodermic APPLICATIONS, unlike ISO 594-1 and ISO 594-2 that are replaced by this part of ISO 80369, which only described the requirements for the fittings (intended CONNECTION surfaces) of these CONNECTORS. This distinction is important to define here because the previous International Standards do not contain the terms CONNECTOR or CONNECTION and ISO 80369- series does not use the term fitting.

b) Requirements for certain dimensions not previously identified in ISO 594-1 and ISO 594-2 are added to this part of ISO 80369 to reduce the RISK of misconnections between MEDICAL DEVICES or ACCESSORIES for different APPLICATIONS with the SMALL-BORE CONNECTORS that are being developed under other parts of the ISO 80369- series. These new dimensions were selected to represent the current design and dimensions of LUER CONNECTORS in clinical use at the time this part of ISO 80369 was developed. The term "6 % (Luer) taper" used throughout the previous standards has also been clarified to the more commonly used equivalent specified diameters separated by a specified distance on a common axis.

c) Requirements for gauging of LUER CONNECTORS made from SEMI-RIGID MATERIALS using plug and ring test gauges have been replaced by dimensional requirements, which are more precise and essential for reducing the RISK of misconnection with the other CONNECTORS identified in ISO 80369-1.

d) Separate requirements for LUER CONNECTORS made from SEMI-RIGID MATERIALS and RIGID MATERIALS have been eliminated and combined as one common set of dimensions and requirements. This consolidation of requirements was made to further reduce the RISK of misconnection with other SMALL-BORE CONNECTORS.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

— *Part 1: General requirements*

— *Part 3: Connectors for enteral applications*

— *Part 5: Connectors for limb cuff inflation applications*

— *Part 6: Connectors for neuraxial applications*

— *Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*

— *Part 20: Common test methods*

Additional parts on connectors for urethral and urinary applications and for respiratory applications are planned.

Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting 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 ISO 80369- series was developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 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.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 specifies the design and the dimensions and the drawings of SMALL-BORE CONNECTORS intended to be used as conical fittings with a 6 % (Luer) taper for CONNECTIONS in intravascular or hypodermic APPLICATIONS. Annex D to Annex G describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this part of ISO 80369 are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369- series of standards for SMALL-BORE CONNECTORS, except as indicated in Annex G. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS should reduce the RISK of air, non-vascular medication and liquid nutritional formula being delivered through an alternative route, such as intravenously or through an airway device.

In this part of ISO 80369, 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 or as noted: SMALL CAPITALS.

In this part of ISO 80369, 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 part of ISO 80369 conform to usage described in the ISO/IEC Directives, Part 2, Annex H. For the purposes of this part of ISO 80369, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80369;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80369;

— “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.

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

Part 7: Connectors for intravascular or hypodermic applications

1 * Scope

This part of ISO 80369 specifies dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections in intravascular applications or hypodermic connections in hypodermic applications of medical devices and accessories.

EXAMPLES Hypodermic syringes and needles or intravascular (IV) cannulae with male and female luer slip connectors and luer lock connectors.

NOTE 1 Hypodermic use includes percutaneous infusion and injection as well as pressurizing and depressurizing the retention mechanisms (e.g. balloon) used to hold invasive medical devices in place and endoscopic devices.

NOTE 2 The luer connector was originally designed for use at pressures up to 300 kPa.

This part of ISO 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 ISO 80369 does not specify requirements for the following small-bore connectors, which are specified in other International Standards:

— haemodialyser, haemodiafilter and haemofilter blood compartment ports (ISO 8637 and applicable portion of ISO 8638 referencing blood compartment ports);

— haemodialysis, haemodiafiltration and haemofiltration equipment connectors (ISO 8637);

— infusion system closure piercing connectors (ISO 8536-4).

NOTE 3 Manufacturers are encouraged to incorporate the small-bore connectors specified in this part of ISO 80369 into medical devices 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 ISO 80369, will be included.

NOTE 4 ISO 80369-1:2010, 5.8, specifies alternative methods of compliance with ISO 80369-1:2010, for small-bore connectors intended for use with intravascular applications or hypodermic application 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.

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*

ISO 80369-6:2016, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

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

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

ASTM D790-15e2, *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 80369-20:2015, ISO 14971:2007 and the following apply.

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

3.1
*** LUER CONNECTOR**
SMALL-BORE CONNECTOR that contains a conical mating surface with a 6 % (Luer) taper intended for use in intravascular or hypodermic APPLICATIONS of MEDICAL DEVICES and related ACCESSORIES

Note 1 to entry: A LUER CONNECTOR can be either a LUER SLIP CONNECTOR or a LUER LOCK CONNECTOR.

3.2
*** LUER SLIP CONNECTOR**
LUER CONNECTOR without a lock

Note 1 to entry: The LUER SLIP CONNECTOR is indicated by the abbreviation L1.

3.3
*** LUER LOCK CONNECTOR**
LUER CONNECTOR that contains a locking mechanism

Note 1 to entry: The LUER LOCK CONNECTOR is indicated by the abbreviation L2.

3.4
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, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.71, modified — replaced "OPERATOR" with "USER".]

3.5
RATED (value)
term referring to a value assigned by the MANUFACTURER for a specified operating condition

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

3.6
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, maintenance and service personnel.

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

3.7
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 and job requirements and working conditions, which can have a bearing on design decisions

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

4 General requirements

4.1 General requirements for LUER CONNECTORS

LUER CONNECTORS made in compliance with this part of ISO 80369 comply with the general requirements of ISO 80369-1:2010, unless otherwise indicated in this part of ISO 80369.

In some tolerance combinations, the inside diameter of the fluid lumen of male LUER CONNECTOR may contact the sealing surfaces of the N1 male CONNECTOR (N1), as specified in ISO 80369-6, in LMC conditions and thereby these CONNECTORS mutually fail when evaluating the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B. Additional information is provided in ISO 80369-1:2010, G.2.2.

Because the following CONNECTORS are inadequately specified, LUER CONNECTORS 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 CONNECTORS and mating ports made in compliance with ISO 8185:2007, Annex DD, and

— the nipples of EN 13544-2:2002 and 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 a LUER CONNECTOR of this part of ISO 80369 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 may be shown by applying a computer aided design (CAD) analysis of the dimensions of all of the ISO 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 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 LUER CONNECTORS of this part of ISO 80369 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 part of ISO 80369.

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

NOTE 3 The summary of the usability requirements for LUER CONNECTORS is provided in Annex E.

NOTE 4 The summary of LUER CONNECTORS criteria and requirements is provided in Annex F.

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

4.2 Material used for LUER CONNECTORS

In addition to the requirements of ISO 80369-1:2010, Clause 4, LUER CONNECTORS 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 D790-15e2.

4.3 Type tests

Compliance with the requirements of this part of ISO 80369 shall be determined by TYPE TESTS.

5 * Dimensional requirements for LUER CONNECTORS

LUER CONNECTORS shall comply with the dimensions and tolerances as given in

— Figure B.1 and Table B.1 for a male LUER SLIP CONNECTOR (L1),

— Figure B.2 and Table B.2 for a female LUER SLIP CONNECTOR (L1),

— Figure B.3 and Table B.3 for a male LUER LOCK CONNECTOR (L2), with fixed collar,

— Figure B.4 and Table B.4 for a male LUER LOCK CONNECTOR (L2), with floating or rotatable collar,

— Figure B.5 and Table B.5 for a female LUER LOCK CONNECTOR (L2),

— Figure B.6 and Table B.6 for a female LUER LOCK CONNECTOR (L2), with lugs at right angle to axis, variant A,

— Figure B.7 and Table B.7 for a female LUER LOCK CONNECTOR (L2), with lugs at right angle to axis, variant B, and

— Figure B.8 and Table B.8 for a female LUER LOCK CONNECTOR (L2), with lugs at right angle to axis, variant C.

Check compliance by confirming the dimensions and tolerances specified in Annex B, as appropriate.

6 Performance requirements

6.1 Fluid leakage

6.1.1 Fluid leakage requirement

LUER CONNECTORS shall be evaluated for leakage using either the leakage by pressure decay TEST METHOD or the positive pressure liquid leakage TEST METHOD.

6.1.2 Leakage by pressure decay

LUER CONNECTORS evaluated for fluid leakage performance with the leakage by pressure decay TEST METHOD shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied pressure of between 300 kPa and 330 kPa over a hold period between 15 s and 20 s using air as the medium. MANUFACTURERS may use a greater applied pressure.

Check compliance by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference CONNECTOR specified in Annex C.

6.1.3 Positive pressure liquid leakage

LUER CONNECTORS evaluated for fluid leakage performance with the positive pressure liquid leakage TEST METHOD shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 300 kPa and 330 kPa. MANUFACTURERS may use a greater applied pressure.

Check compliance by applying the tests of ISO 80369-20:2015, Annex C, while using the leakage reference CONNECTOR specified in Annex C.

6.2 Sub-atmospheric pressure air leakage

LUER CONNECTORS shall be evaluated for sub-atmospheric pressure air leakage. LUER CONNECTORS shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied sub-atmospheric pressure of between 80,0 kPa and 88,0 kPa over a hold period of between 15 s and 20 s. MANUFACTURERS may use a greater applied sub-atmospheric pressure.

Check compliance by applying the tests of ISO 80369-20:2015, Annex D, while using the leakage reference CONNECTOR specified in Annex C.

6.3 Stress cracking

LUER CONNECTORS shall be evaluated for stress cracking. LUER CONNECTORS shall meet the requirements of 6.1.1 after being subjected to stresses of ISO 80369-20:2015, Annex E.

Check compliance by applying the tests of ISO 80369-20:2015, Annex E, while using the stress cracking reference CONNECTOR specified in Annex C.

6.4 Resistance to separation from axial load

LUER CONNECTORS shall be evaluated for separation from axial load. LUER CONNECTORS shall not separate from the reference CONNECTOR over a hold period between 10 s and 15 s while being subjected to a disconnection applied axial force between

a) 23 N and 25 N for LUER SLIP CONNECTORS, and

b) 32 N and 35 N for LUER LOCK CONNECTORS.

MANUFACTURERS may use a greater disconnection applied axial force or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex F, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.5 Resistance to separation from unscrewing

LUER LOCK CONNECTORS shall be evaluated for separation from unscrewing. LUER LOCK CONNECTORS shall not separate from the reference CONNECTOR for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,019 8 N·m to 0,020 0 N·m. MANUFACTURERS may use a greater applied unscrewing torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex G, while using the resistance to separation from unscrewing reference CONNECTOR specified in Annex C.

6.6 Resistance to overriding

LUER LOCK CONNECTORS shall be evaluated for resistance to overriding. LUER LOCK CONNECTORS shall not override the threads or lugs of the reference CONNECTOR while being subjected to an applied torque of between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s. MANUFACTURERS may use a greater applied torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex G, while using the resistance to overriding 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 part of ISO 80369 and is intended for those who are familiar with the subject of part of ISO 80369 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper use. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 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 part of ISO 80369 to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

The scope includes the fittings described previously in ISO 594-1 and ISO 594-2.

In 2000, a Task Group of the European standards organization CEN proposed a strategy to reduce incidents of accidental misconnection of PATIENT therapy lines 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 applications so that they can achieve their intended function[13].

During the development of this part of ISO 80369, the committee frequently debated how LUER CONNECTOR activated MEDICAL DEVICES (LADs) should be interpreted. In context of this part of ISO 80369, "LADs" are considered to be a "component" of the MEDICAL DEVICE and are typically a female valve designed to interconnect with male LUER CONNECTOR. The following guidance relates specifically to the LAD (or female valve end) component only and does not include the rest of a MEDICAL DEVICE.

A LAD typically includes a valve that opens and permits access to the fluid conduit when a standard male LUER CONNECTOR is inserted into it. By design, it forms one-half of the CONNECTION that establishes a fluid conduit with a male LUER CONNECTOR. However, such LADs typically do not comply with this part of ISO 80369. Specifically, they often do not conform to 4.2 regarding materials (since their mating surfaces often include elastomeric materials) nor do they fully conform dimensionally to Clause 5. Thus, a typical LAD is not a LUER CONNECTOR. As such, they are not within the scope of this part of ISO 80369.

The committee, however, felt compelled to provide some guidance on the LAD due to the obvious similarities of intended use with LUER CONNECTORS. It is advisable that MANUFACTURERS of LADs utilize the features providing NON-INTERCONNECTABLE characteristics of this part of ISO 80369, wherever possible, to address the RISK of misconnections to their MEDICAL DEVICES. These elements can include the appropriate combinations of the following:

— materials conformance (i.e. ≥700 MPa) for interference features;

— dimensional conformance (i.e. dimensions *H*, *J*, *D*, and *G* from Annex B);

— dimensional and/or CAD analysis showing interference features;

— NON-INTERCONNECTABLE characteristics testing per ISO 80369-1:2010, Annex B;

— usability testing demonstrating NON-INTERCONNECTABLE characteristics.

Additionally, the functional performance requirements of Clause 6 should also be considered for the LAD component.

In this way, the LADs can be evaluated for both NON-INTERCONNECTABLE characteristics and performance characteristics associated with the ISO 80369- series.

The LADs by definition continue to not be considered a "conforming" LUER CONNECTOR (i.e. not complying with this part of ISO 80369), however they can be considered 'compatible with' a MEDICAL DEVICE utilizing a male LUER CONNECTOR (by way of functional performance).

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

Definition 3.1 LUER CONNECTOR

Definition 3.2 LUER SLIP CONNECTOR

Definition 3.3 LUER LOCK CONNECTOR

For clarity, the new terms LUER CONNECTOR, LUER SLIP CONNECTOR, and LUER LOCK CONNECTOR replace conflicting and confusing terms used in ISO 594-1 and ISO 594-2. The new terms align and harmonize this part of ISO 80369 with ISO 80369-1, which does not utilize the legacy terms fitting, conical, or taper. The new terms are equivalent to those now generically used to describe the SMALL-BORE CONNECTORS commonly named after their inventor, 19th century German medical instrument maker Hermann Wülfing Lüer.

Clause 5 Dimensional requirements for LUER CONNECTORS

The separate set of dimensions previously identified for SEMI-RIGID MATERIALS and RIGID MATERIALS are now merged into one set of dimensions. With modern test equipment and TEST METHODS, it is now practicable to define the dimensions with greater precision, thereby eliminating the need for gauging for the purposes of a TYPE TEST.

Legacy Luer gauges cannot be used to verify the performance of CONNECTORS that are intended to prevent misconnection because they lack the dimensions for surfaces not intended to form CONNECTIONS with LUER CONNECTORS. Maintenance of production quality (i.e. using gauges) is outside the scope of this part of ISO 80369. The dimensional requirements in Annex B are a more precise description of the design and performance characteristics for both intended CONNECTIONS and avoidance of misconnections.

Dimensions and tolerances not previously identified in ISO 594-1 and ISO 594-2 are added to this part of ISO 80369 to reduce the RISK of misconnections between MEDICAL DEVICES or between ACCESSORIES for different APPLICATIONS with non-LUER CONNECTORS that are being developed under other parts of the ISO 80369- series. These new requirements were selected to represent the inherent design and dimensions of LUER CONNECTORS in clinical use at the time this part of ISO 80369 was developed.

Since the configurations of the CONNECTORS proposed within ISO 80369-7 are SMALL-BORE CONNECTORS with or without a threaded collar, the requirements and parameters from ISO 594-1 and ISO 594-2 have been used where applicable.

The maximum inside diameter at the tip of the male taper (through bore), *Øf*, of 2,900 mm was chosen to describe the majority of LUER CONNECTORS available to USERS at the time of publication of this part of ISO 80369. The committee considered the clinical needs of high flow rate intravascular MEDICAL DEVICES and determined that the incremental increase in flow if *Øf* is increased to a theoretical sharp edge of 3,50 mm was not warranted in view of the increased RISK of misconnection with smaller male SMALL-BORE CONNECTORS in the ISO 80369- series.

Commercially developed glass prefilled syringes routinely mate with LUER CONNECTOR equipped MEDICAL DEVICES in order to effectively administer the medication stored within the syringe. Examples: disposable needles, needleless ports and other forms of Luer access. Current state-of-technology syringe

tip glass forming technology for manufacturing glass-prefilled syringes cannot conform completely to either previous Luer fitting standard, ISO 594 or this part of ISO 80369. Both the previous standard and this part of ISO 80369 have been developed using ground glass, metal and injection moulded technology and plastic resins as the baseline for compliance and capabilities.

The minimum inside diameter at the tip of the male taper (through bore), *Øf*, is not defined to accommodate the very small bore of glass syringes.

The committee acknowledges the differences in the manufacturing methodologies and the need for expanded tolerances in the glass forming manufacturing PROCESS. The baseline specifications of the tapered tip need to remain similar. However to accommodate the glass forming manufacturing PROCESS, there needs to be expanded dimensional tolerances. While these tolerances are outside of the range of this part of ISO 80369 with respect to some of the dimensions, a glass formed tip does successfully mate with the injection moulded female LUER CONNECTORS. Refer to ISO 11040-4 for a listing of those critical dimensions, their expanded corresponding tolerances and functional TEST METHODS that accommodate the formed tip manufacturing PROCESS.

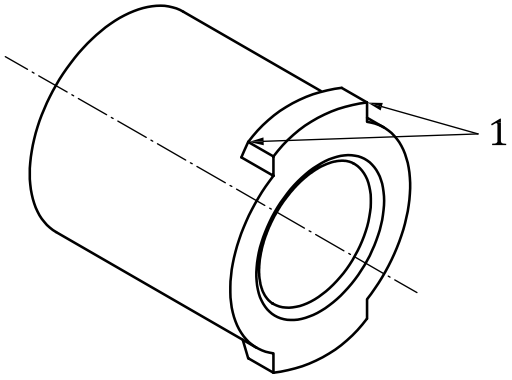
A dimensional analysis of the female LUER LOCK CONNECTOR (L2), variant A thread form was conducted during the development of this part of ISO 80369 to ensure both

— proper connection to other male LUER CONNECTORS, and

— prevention of misconnection to the other CONNECTORS of the ISO 80369- series.

The analysis demonstrated that in certain instances the thread form detailed in Figure B.6 and Table B.6 could, if taken to certain extremes, collide with non-sealing features of the mating male LUER CONNECTOR (i.e. Figure B.3 and Figure B.4) prior to a fluid tight seal being achieved. Specifically the diagonal distance between the corners of the right angle thread of the female LUER LOCK CONNECTOR of Figure B.6 could bind between adjacent threads of the mating male LUER CONNECTOR. Figure A.1 and Figure A.2 illustrate this possible interference. This can be worsened by the allowable variations in thread profile, thread pitch and thread lead, of the features of the mating male LUER CONNECTOR. This situation is unchanged from the legacy ISO 594-2, the same magnitude of interference was possible complying CONNECTORS.

Due to the proliferation of existing LUER CONNECTORS and general lack of data indicating a problem in use, the committee determined that the same level of interference would be permitted by this part of ISO 80369 (i.e. the permissible design is unchanged).



Key

1 corners that can interfere

Figure A.1 — Lug corners that can interfere