INTERNATIONAL STANDARD

ISO 80369-7

First edition
2016-10-15

Corrected version
2016-12-01

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
ISO 80369-7:2016(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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.

This corrected version of ISO 80369-7:2016 incorporates the following corrections:

— in the Scope, NOTE 1 has been removed and the other notes renumbered accordingly;

— in the second paragraph of 6.6, the reference to the annex has been changed;

— the lower-case greek letter "β" has been changed into a capital greek letter "*B*" in the notes of Tables B.5 and B.6;

— the representation of the angle *B* has been updated in Figure B.7;

— values and angles have been corrected in Figures C.1, C.2, C.3, C.4 and C.6.

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 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 2 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 3 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]

