INTERNATIONAL STANDARD

ISO 80369-20

First edition
2015-05-15

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

Part 20: Common test methods

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 20: Méthodes d'essai communes

Reference number
ISO 80369-20:2015(E)

COPYRIGHT PROTECTED DOCUMENT

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.

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*

The following parts are under preparation:

— *Part 2: Connectors for breathing systems and driving gases applications*

An additional part on Connectors for urethral and urinary applications is planned.

Introduction

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 ISO 80369-1 and Clause 3: 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 International Standard conform to usage described in 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, and

— "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.

The following paragraph is directed to authorities with jurisdiction and is not intended to address clinical implementation.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations might 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 committee that the content of this publication be adopted for implementation nationally not earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

This part of ISO 80369 describes the common TEST METHODS for evaluating the performance requirements of the SMALL-BORE CONNECTORS specified in this series.

During the development of the ISO 80369- series, it became evident that many of the TEST METHODS were very similar for each of the APPLICATIONS. It was therefore decided to standardize all the TEST METHODS into a separate part of the series to prevent unnecessary duplication and minor differences. It is also recognized that not all CONNECTORS can be evaluated using each TEST METHOD in this part. The TEST METHODS applicable to each CONNECTOR are specified in the respective part of the ISO 80369- series.

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

Part 20:
Common test methods

1 *Scope

This part of ISO 80369 specifies the TEST METHODS to evaluate the performance requirements for SMALL-BORE CONNECTORS specified in the ISO 80369- series.

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.

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*

3 Terms and definitions

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

3.1
TEST METHOD
definitive PROCEDURE for evaluating CONNECTORS that produces a test result

3.2
TYPE TEST
test on a representative

[SOURCE: IEC 60601-1:2005, definition 3.135]

4 TEST METHODS for SMALL-BORE CONNECTORS

Table 1 contains the list of TEST METHODS and their corresponding Annex included in this part of ISO 80369.

Table 1 — TEST METHODS and corresponding Annex of this part of ISO 80369

Test method	Annex
Leakage by pressure decay	Annex B
Positive pressure liquid leakage	Annex C
Subatmospheric-pressure air leakage	Annex D
Stress cracking	Annex E
Resistance to separation from axial load	Annex F
Resistance to separation from unscrewing	Annex G
Resistance to overriding	Annex H
Disconnection by unscrewing	Annex I
Modification of the TEST METHODS to generate variable data for statistical analysis	Annex J
NOTE MANUFACTURERS can use the modified TEST METHODS of Annex J.	

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This annex provides a rationale for some requirements of this part of ISO 80369 and is intended for those who are familiar with the subject of this 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 application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this part of ISO 80369 necessitated by those developments.

The committee attempted to harmonize the functional TEST METHODS for the CONNECTORS of each APPLICATION in this part of ISO 80369. The TEST METHOD annexes in this part of ISO 80369 describe a specific test PROCEDURE for a TYPE TEST, but allow for modification to specific test conditions or acceptance criteria as necessary for each APPLICATION.

Many of the TEST METHODS in this part of ISO 80369 were extracted from the ISO 594- series of standards. The committee attempted to minimize changes to these TEST METHODS. However, changes were made to TEST METHODS which contained subjective acceptance criteria.

The assembly PROCEDURE in each Annex mimics the assembly PROCEDURE that was extracted from ISO 594. An additional clarification was made for CONNECTORS with a floating or rotatable locking collar. Test sample preconditioning and environmental test condition requirements were added to each Annex.

NOTE Manufacturer should also consider performing functional performance testing using a representative sample of the SMALL BORE CONNECTOR being evaluated with a representative sample of appropriate mating connectors.

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 ease of assembly TEST METHOD that was part of the ISO 594- series has been removed as a requirement from the APPLICATION parts of ISO 80369 and is not present in this part of ISO 80369. The acceptance criterion of the ISO 594- series for ease of assembly was subjective. It was underdefined for a standardized TEST METHOD, i.e. “a satisfactory fit” is not repeatable. Furthermore, the intent of the ease of assembly test was to ensure that the USER can complete the CONNECTION using the mating halves of the CONNECTOR. This requirement is satisfied by the requirement for usability validation for all new connectors being added to ISO 80369. Therefore, the ease of assembly TEST METHOD has been omitted from the ISO 80369- series of standards.

This part was given the –20 designation to leave space for CONNECTORS in new APPLICATIONS that might be developed in the future using the numbers ISO 80369-8 through ISO 80369-19.

Subclause B.2, C.2, D.2, E.2, F.2, G.2, H.2, I.2 Test conditions

Subclause 2 in 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. However, it is permitted to utilize different ranges if specified in the relevant application part of these series of standards, to evaluate the performance of CONNECTORS exposed to heated solutions and outdoor conditions.

Annex B Leakage by pressure decay TEST METHOD

This pressure decay TEST METHOD is a new TEST METHOD that was not part of the former ISO 594- series. However, it is based upon the informative liquid leakage TEST METHOD of ISO 594-1:1986, Annex A.

Formula B.1

Formula B.1 utilized in this TEST METHOD is derived from ISO 594-1:1986, Annex A. The following paragraphs are a discussion of the derivation of Formula B.1 and practicalities of the usage of this formula.

Formula B.1 yields a leakage index as opposed to a more traditional leak rate (mass or volume over time). In a common leak test, the leak rate is proportional to the applied pressure, requiring the initial applied pressure to be tightly specified in order to compare results from one test to another. To eliminate this discrepancy, Formula B.1 includes a term ($1/t_p$) which normalizes the results, making all results comparable to the requirement regardless of different initial applied pressures.

The results from Formula B.1 are approximated from a linear pressure versus time law instead of the exact exponential relationship that occurs for a compressible fluid and rigid container. Because of this derivation, the error between the exact and approximated pressure versus time equations is less than 4 % when the recorded pressure decay does not exceed 22 % of the starting pressure.

Formula B.1 neglects a temperature correction. Within the specified range of test condition temperatures, 15°C to 25°C, the error is less than ± 1 %, which is noticeably less than the expected variability range for a common product, as well as the effects of the linear approximation for pressure decay.

In this TEST METHOD the use of a compressible fluid, usually air or other gases, is preferable to liquids because the test, when performed with fluids that are considered incompressible, is strongly biased by the artifact of the elastic compliance of the components of the connection under test. In this case, the true effect of the leaking orifice cannot be detected.

Annex C Falling drop positive-pressure liquid leakage TEST METHOD

This liquid leakage TEST METHOD is performed in the same manner as in the ISO 594- series.

Annex D Subatmospheric-pressure air leakage TEST METHOD

This subatmospheric-pressure air leakage TEST METHOD is a new TEST METHOD that was not part of the former ISO 594- series. The ISO 594- series TEST METHOD for subatmospheric-pressure (ISO 594-1, 5.3 and ISO 594-2, 5.3) creates an unspecified subatmospheric test pressure and asks the observer to look for continued formation of bubbles of an unspecified size. The TEST METHOD included in this part of ISO 80369 was developed during the committee drafts of ISO 80369-2 and ISO 80369-6.

Formula D.1

See also rationale for Formula B.1.

Annex E Stress cracking TEST METHOD

This stress cracking TEST METHOD is performed in the same manner as in the ISO 594- series. The acceptance criteria have been changed to require passing a functional leak test after the stress cracking test has been performed.

Annex F Resistance to separation from axial load TEST METHOD

This resistance to separation from axial load TEST METHOD is performed in the same manner as in the ISO 594- series. The title and principle have been elaborated to describe the intent of the test.

Annex G Resistance to separation from unscrewing TEST METHOD

This resistance to separation from unscrewing TEST METHOD is performed in the same manner as the ISO 594- series. The title and principle have been elaborated to describe the intent of the test.

Annex H Resistance to overriding TEST METHOD

This resistance to overriding TEST METHOD is performed in the same manner as the ISO 594- series.

Annex I Disconnection by unscrewing TEST METHOD

This disconnection by unscrewing TEST METHOD replaces the TEST METHOD described in the ISO 594- series to account for locking, non-locking (slip) and rotating-collar connectors. It is intended to ensure that CONNECTORS, which can be connected and disconnected multiple times per day, can be successfully disconnected by the USER.

Annex J Alternate TEST METHODS to generate variable data for statistical analysis

Multiple TEST METHODS in this part of ISO 80369 are written as attribute data TEST METHODS that can be modified to become variable data TEST METHODS.

Attribute data tests are more commonly known as pass/fail tests. Attribute data tests can only determine if the specification is met. They provide no indication of how the CONNECTOR fails and typically require a large sample size to have the same statistical power as an equivalent variable data test.

Variable data tests are those tests that produce a quantifiable result such as the force required to separate the CONNECTORS or the actual leak rate. Variable data test results determine the value at which the CONNECTOR fails, provide a numerical result that can be statistically analysed, and typically require a smaller sample size to have the same statistical power as equivalent attribute data test results.

Annex B
(normative)

*Leakage by pressure decay TEST METHOD

B.1 Principle

The CONNECTOR under test is assembled to an appropriate reference CONNECTOR. The medium, as specified in the relevant APPLICATION part of this series, is introduced into the CONNECTION and pressurized to the specified pressure.

B.2 *Test conditions

B.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.

B.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 %, unless other ranges are specified in the relevant APPLICATION part of ISO 80369.

B.3 Apparatus

a) the male or female CONNECTOR under test;

b) the appropriate reference CONNECTOR, as specified in the relevant APPLICATION part of ISO 80369 for the leakage TEST METHOD, to be assembled to the CONNECTOR under test;

c) a means to simultaneously apply an axial force of 27,5 N and torque of 0,12 N·m, or more if required by the relevant APPLICATION part of ISO 80369;

d) a means to contain and pressurize the medium to the specified test pressure. Rigid fixtures and apparatus materials (such as metal) should be used to avoid inaccurate test results;

e) a means of measuring and displaying the elapsed time with an accuracy of ± 1 s;

f) a means of measuring the applied pressure with a minimum accuracy of 0,3 %;

g) a stop valve;

h) a leak-proof plug.

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

B.4 Procedure

a) Assemble the CONNECTOR under test to the appropriate male or female reference CONNECTOR, both CONNECTORS being dry.