International Standard

ISO 80369-20

Second edition
2024-11

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 80369-20:2024(en)

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Published in Switzerland

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Foreword

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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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/SC 62D, *Particular medical equipment, software, and systems,* and with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80369-20:2015), which has been technically revised.

The main changes are as follows:

— clarification that these test methods are also used by the ISO 18250 series;

— major technical revision of the *test methods* described in Annex B “Leakage by pressure decay test method” and Annex D “Subatmospheric-pressure air leakage test method” (replacement of leakage rate by the pressure change as acceptance criterion; definition of three defined mandatory test conditions; more information about this change is included in Annex A);

— introduction of a new attributive *test method* “Air leakage during aspiration” as Annex K;

— editorial revision of the assembling *procedures* of a *connector* under test, affecting all annexes with *test methods*;

— editorial update according to ISO/IEC Directives, Part 2;

— replacement of the terms “male” by “*cone*” and “female” by “*socket*” in the description of a *connector*;

— update of dated normative references;

— definition for *type test* has been updated;

— expansion of the range of environmental test conditions for relative humidity;

— extension of requirements for test reports;

— clarification that all tests are intended to be *type tests*.

A list of all parts in the ISO and IEC 80369 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

In this document, the following verbal forms are used.

— “Shall” indicates requirements.

— “Should” indicates recommendations.

— “May” indicates permissions.

— “Can” indicates possibility or capability.

This document uses italic type to distinguish defined terms from the rest of the text. It is important for the correct understanding of this document that those defined terms are identifiable throughout the text of this document. A list of the defined terms used in this document (in italics) is given in Annex M.

Requirements in this document have been broken down so that each requirement is clearly delineated and listed individually. This has been done to support the common practice of automatic tracking of requirements and automatic verification of the requirements of this document.

Annex A contains guidance and rationale on specific subclauses in this document.

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

Part 20: Common test methods

1 Scope

NOTE Clause A.2 contains guidance or rationale for this clause.

This document specifies the common *test methods* to evaluate the performance requirements for *small-bore connectors* specified in the ISO and IEC 80369 series as well as the ISO 18250 series.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:—[1)], *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:—,[1)] ISO 14971:2019, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

NOTE For convenience, the sources of all defined terms that appear in italics in this document are given in Annex M.

3.1
type test
test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this document

[SOURCE: IEC 60601-1:2005, 3.135, modified — replaced “standard” with “document.”]

4 *Test methods* for *small-bore connectors*

Table 1 contains the list of *test methods* and their corresponding Annex included in this document. For statistical analysis, *test methods* may be modified according to Annex J. The tests to evaluate the performance

1) Third edition under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2024. The previous edition is ISO 80369-1:2018.

requirements for *small-bore connectors* specified in the ISO and IEC 80369 series and the *connectors* specified in the ISO 18250 series described in this document are intended be performed as *type tests*.

NOTE 1 The *application* parts of the ISO and IEC 80369 series and the ISO 18250 series specify which tests given in Table 1 are required as well as their acceptance criterion.

NOTE 2 This document has been prepared to address the relevant essential principles guidance[8] of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex L.

Table 1 — *Test methods* and corresponding Annex in this document

Test method	Annex in this document
Leakage by pressure decay	Annex B
Falling drop 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
Air leakage during aspiration	Annex K

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document, but who have not participated in its development. An understanding of the rationales underlying these requirements is considered 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 document necessitated by those developments.

An attempt was made to harmonize the functional *test methods* for the *connectors* of each *application* in this document. The *test method* annexes in this document describe a specific test *procedure* but allow for modification to specific test conditions or acceptance criterion as necessary for each *application.*

Many of the *test methods* in this document were extracted from the withdrawn ISO 594 series of documents[2)]. An attempt was made 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 the withdrawn 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.

A.2 Rationale for particular clauses and subclauses

A.2.1 General

The numbering of the following rationales corresponds to the numbering of the clauses and subclauses of this document. The numbering is, therefore, not consecutive.

A.2.2 Clause 1: Scope

The ease of assembly *test method* that was part of the withdrawn ISO 594 series has been removed as a requirement from the *application* parts of the ISO and IEC 80369 series and is not present in this document. The acceptance criterion of the withdrawn 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 the ISO and IEC 80369 series. Therefore, the ease of assembly *test method* has been omitted from the ISO and IEC 80369 series.

A.2.3 Clauses B.2, C.2, D.2, E.2, F.2, G.2, H.2, I.2, K.2: Test conditions

Clause 2 in each *test method* includes preconditioning and environmental test requirements.

Temperature and humidity preconditioning requirements from the withdrawn ISO 594-1 and ISO 594-2 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 impact of humidity and temperature for materials can be evaluated using manufacturing data, material technical data or comparative study.

2) Withdrawn and replaced by ISO 80369-7.

The temperature range specified for testing is identical to that specified in the withdrawn ISO 594-1 and ISO 594-2. However, it is permitted to utilize different ranges if specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series, to evaluate the performance of *connectors* exposed to heated solutions and outdoor conditions.

A.2.4 Annex B: Leakage by pressure decay *test method*

This pressure decay *test method* is based upon the informative liquid leakage *test method* of the withdrawn ISO 594-1:1986, Annex A[3)]. The *test method* of the withdrawn ISO 594-1:1986, Annex A used an applied pressure on the inside of the *connection* and the change of this pressure over time to describe a leak. To describe the size of a leak, the leakage rate was calculated by the leakage rate formula. In the development of this document, it was seen that the leakage rate formula is only applicable under very specific test conditions. Some of the factors are the geometrical shape of the leak which is unknown and the type of gas flow which can change during the test. In order to overcome the difficulty related to the test conditions, the evaluation within the *test method* was modified. The leakage rate and the calculation of the leakage rate were taken out of the *test method* and the pressure change itself is used as the acceptance criterion. This modification allows to use the *test method* in a wider range of test conditions.

The test conditions specified include:

— start pressure;

— test period;

— test volume.

Values for these test conditions are not specified in Annex B. These values are individual for each *connector* depending on their use case and the pressure change threshold. The documents referencing the *test method* of Annex B state the values for these test conditions for each specified pressure change threshold.

A.2.5 Annex C: Falling drop positive-pressure liquid leakage *test method*

This liquid leakage *test method* is performed in the same manner as in the now withdrawn ISO 594-1:1986 and ISO 594-2:1998.

A.2.6 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 withdrawn ISO 594 series.

This *test method* is similar to the *test method* of Annex B. The difference is that the *test method* of Annex D applies a subatmospheric pressure inside the *connector* while the *test method* of Annex B pressurizes the inside of the *connector*. Allowing for this difference, the rationale for Annex B is also applicable for Annex D.

A.2.7 Annex E: Stress cracking *test method*

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

A.2.8 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 withdrawn ISO 594 series. The title and principle have been elaborated to describe the intent of the test.

A.2.9 Annex G: Resistance to separation from unscrewing *test method*

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

3) Withdrawn and replaced by ISO 80369-7.

A.2.10 Annex H: Resistance to overriding *test method*

This resistance to overriding *test method* is performed in the same manner as in the withdrawn ISO 594 series.

A.2.11 Annex I: Disconnection by unscrewing *test method*

This *test method* is intended to ensure that *connectors*, which can be connected and disconnected multiple times per day, can be successfully disconnected by the *user*.

A.2.12 Annex J: Alternate *test methods* to generate variable data for statistical analysis

Multiple *test methods* in this document 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 change in pressure. 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.

A.2.13 Annex K: Air leakage during aspiration *test method*

This air leakage during aspiration *test method* is based on a *test method* in the withdrawn ISO 594 series. It is based on visually detecting bubbles of leaking air passing through water. This *test method* was refined to overcome some shortcomings of the *test method* in the withdrawn ISO 594 series.

The *test method* of Annex D is not suitable to cover the requirements for all *connector* use cases. When the intent of the *connection* is to convey liquids, whatever is the nature of the liquid, the *test method* of Annex K can be a better and more suitable *test method* than the subatmospheric pressure air leakage *test method*.

Annex B
(informative)

Leakage by pressure decay *test method*

NOTE Clause A.2 contains guidance and rationale for this Annex.

B.1 Principle

The *connector* under test is assembled to an appropriate reference *connector*. Air is introduced into the *connection* and pressurized for the test period to demonstrate that the pressure loss is not exceeded.

B.2 Test conditions

B.2.1 Test sample preconditioning

Prior to testing, precondition the *connector* under test at (20 ± 5) °C and (50 ± 10) % relative humidity (RH) 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 RH between 10 % and 70 %, unless other ranges are specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

B.3 Apparatus

The following shall be used (see Figure B.1).

B.3.1 ***Connector***, under test.

B.3.2 Appropriate **reference *connector***, as specified in the relevant *application* part of the ISO 80369 series and the ISO 18250 series for the leakage *test method*, to be assembled to the *connector* under test.

B.3.3 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 the ISO and IEC 80369 series and the ISO 18250 series.

B.3.4 A **means** to contain and pressurize air to the specified test pressure. Pressures specified in the *application* parts of the ISO and IEC 80369 series and the ISO 18250 series are gauge pressures.

B.3.5 A **means** of measuring and displaying the elapsed time with an accuracy of ± 1 s.

B.3.6 A **means** of measuring the applied gauge pressure with an accuracy of ± 0,3 % of the applied **pressure**.

B.3.7 A **means** to achieve the test volume specified in the relevant *application* part of the ISO 80369 series and the ISO 18250 series.