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

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

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**.

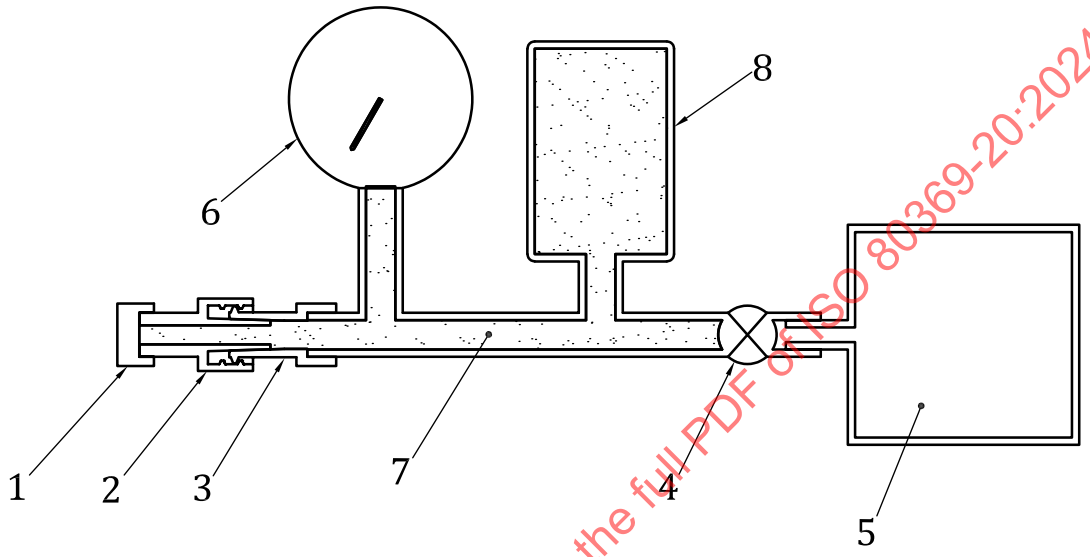
B.3.7 A **means** to achieve the test volume specified in the relevant *application* part of the ISO 80369 series and the ISO 18250 series.

NOTE The test volume is the total volume of the connected system under pressure or vacuum, including *small-bore connector* and measuring equipment. Potential methods to determine the test volume can be based on e.g. a dimensional calculation or a measurement of the amount of water that the connected system can hold or a combination of these.

B.3.8 A **stop valve**.

B.3.9 A **means** to seal the *connector* under test at its open end.

An automated pressure decay leak test system may be substituted for any or all items B.3.4, B.3.5, B.3.6, B.3.7, B.3.8.



Key

1 means to seal the *connector* under test
2 *connector* under test
3 appropriate reference *connector*
4 stop-valve
5 pressure source
6 pressure-measuring device, e.g. a manometer
7 test volume
8 means to achieve the test volume

Apparatus shall be made of a material that is sufficiently rigid to provide accurate and repeatable test results.

Figure B.1 — Example test apparatus for leakage by pressure decay

B.4 *Procedure*

a) Seal the through bore of the *connector* under test prior to step c).

b) Assemble the *connector* under test to the appropriate reference *connector*, both *connectors* being dry, as follows, unless otherwise specified in the relevant application part of the ISO and IEC 80369 series or ISO 18250 series.

   1) For a non-locking (slip) *connector*, assemble by applying an axial force of between 26,5 N and 27,5 N. Then, while continuing to apply the axial force, rotate the *connector* under test with a torque not exceeding 0,10 N·m to give a rotation not exceeding 90°. Hold the force and torque for 5 s to 6 s and then release.

2) For a locking *connector*, assemble by rotating the collar of the *connector* under test to a torque of between 0,08 N·m and 0,12 N·m. Then, while continuing to apply the torque, apply an axial force of between 26,5 N and 27,5 N. Hold the force and torque for 5 s to 6 s and then release.

c) Apply the pressure specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series and close the valve.

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

e) After the test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series, record the end pressure and the elapsed time.

f) Calculate the difference between end pressure and start pressure.

g) Determine whether the change in pressure as an absolute value exceeds the value specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

B.5 Test report

Prepare a test report that:

a) specifies testing was performed according to this document (i.e. ISO 80369-20:2024, Annex B);

b) identifies the date of the testing;

c) identifies the *connectors* under test;

d) identifies the number of *connectors* tested;

e) identifies the preconditioning and environmental test conditions;

f) identifies the reference *connector* used;

g) identifies the applied pressure used;

h) identifies the acceptance criterion;

i) identifies any deviations from the *procedure*;

j) identifies any unusual features observed;

k) identifies the test volume used as defined in Figure B.1;

l) discloses the test period;

m) discloses the pressure change during the test period according to Clause B.4, f);

n) discloses whether the acceptance criterion is met.

Annex C
(informative)

Falling drop positive-pressure liquid leakage *test method*

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

C.1 Principle

A *connector* is assembled to a reference *connector*. Water is introduced into the *connection* and pressurized for the test period to demonstrate that no water leaks from the *connection*.

C.2 Test conditions

C.2.1 Test sample preconditioning

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

C.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.

C.3 Apparatus

The following shall be used.

C.3.1 ***Connector,*** under test.

C.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.

C.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.

C.3.4 A **means** to contain pressurized water and maintain the specified test pressure.

C.3.5 A **means** of measuring the applied pressure with a minimum accuracy of ± 0,3 % of the applied pressure.

C.3.6 A **means** of measuring and displaying the elapsed time with an accuracy of ± 1 s.

C.3.7 **Distilled or potable water**. The water may be dyed with methylene blue.

C.4 *Procedure*

a) Assemble the *connector* under test to the appropriate *cone* or *socket* reference *connector*, both *connectors* being dry.

   1) For a non-locking (slip) *connector*, assemble by applying an axial force of between 26,5 N and 27,5 N. Then, while continuing to apply the axial force, rotate the *connector* under test with a torque not exceeding 0,10 N·m to give a rotation not exceeding 90°. Hold the force and torque for 5 s to 6 s and then release.

   2) For a locking *connector*, assemble by rotating the collar of the *connector* under test to a torque of between 0,08 N·m and 0,12 N·m. Then, while continuing to apply the torque, apply an axial force of between 26,5 N and 27,5 N. Hold the force and torque for 5 s to 6 s and then release.

b) Introduce water into the assembly to expel the air.

c) Ensure that the outside of the *connector* assembly is dry.

d) With the axis of assembled *connectors* horizontal, seal the assembly outlet and increase the internal water pressure to the applied pressure specified in the relevant *application* part of the ISO 80369 series and the ISO 18250 series.

e) Maintain the pressure for the test period specified in the relevant *application* part of the ISO 80369 series and the ISO 18250 series while maintaining the assembled *connectors* in the horizontal orientation.

f) Visually inspect for a falling drop of water from the *connection* during the specified test period.

C.5 Test report

Prepare a test report that:

a) specifies testing was performed according to this document (i.e. ISO 80369-20:2024, Annex C);

b) identifies the date of the testing;

c) identifies the *connectors* under test;

d) identifies the number of *connectors* tested;

e) identifies the preconditioning and environmental test conditions;

f) identifies the reference *connector* used;

g) identifies the acceptance criterion;

h) identifies any deviations from the *procedure*;

i) identifies any unusual features observed;

j) discloses the pressure range during the test period;

k) discloses the test period;

l) discloses the presence or absence of a falling drop of water within the specified test period according to Clause C.4, f).

Annex D
(informative)

Subatmospheric-pressure air leakage *test method*

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

D.1 Principle

Air leakage during aspiration in a *connector* assembly is tested by measuring the change in subatmospheric pressure over time after the vacuum pressure is applied to the bore of the *connector*. The relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series specifies the test conditions (e.g. the test volume, the test period, the start pressure and the acceptance criterion, i.e. the maximum pressure change).

D.2 Test conditions

D.2.1 Test sample preconditioning

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

D.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.

D.3 Apparatus

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

D.3.1 ***Connector,*** under test.

D.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.

D.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.

D.3.4 **Vacuum source**. Pressures specified in the *application* parts of the ISO and IEC 80369 series and the ISO 18250 series are gauge pressures. Rigid fixtures and apparatus materials (e.g. metal) should be used to achieve accurate and repeatable test results.

At high altitudes the specified subatmospheric pressure are not always achievable. In this case measures shall be taken to increase the ambient pressure around the *connector* under test.

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

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

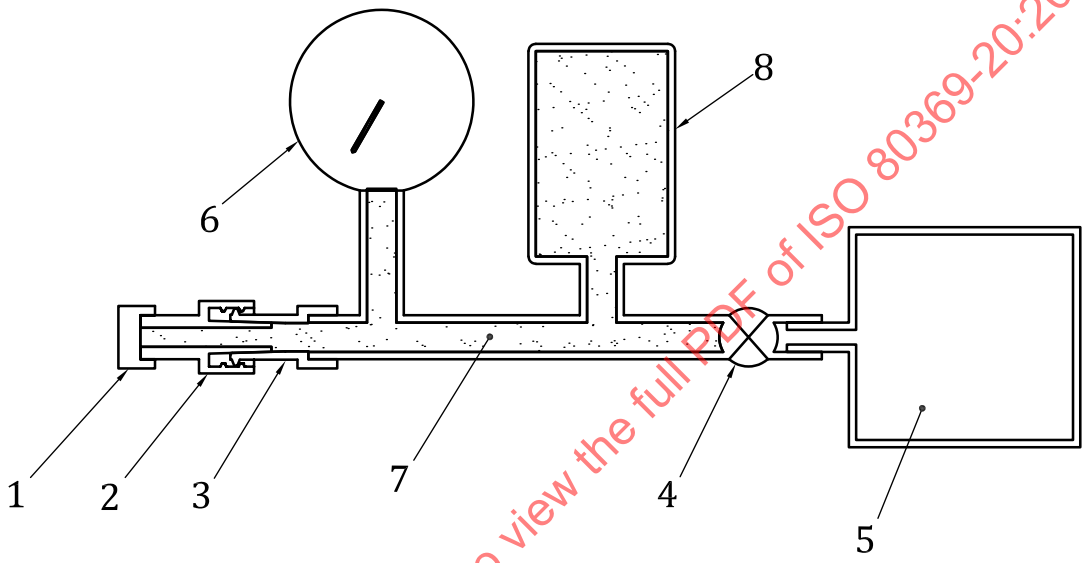
D.3.7 A **means** to achieve the test volume specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

NOTE The test volume is the total volume of the connected system under pressure or vacuum, including *small-bore connector* and measuring equipment. Potential methods to determine the test volume can be based on, e.g. a dimensional calculation or a measurement of the amount of water that the connected system can hold or a combination of these.

D.3.8 Stop valve.

D.3.9 A **means** to seal the *connector* under test at its open end.

An automated pressure decay leak test system may be substituted for any or all items D.3.4, D.3.5, D.3.6, D.3.7, D.3.8.



Key

1 means to seal the *connector* under test
2 *connector* under test
3 appropriate reference *connector*
4 stop-valve
5 vacuum source
6 pressure-measuring device, e.g. a manometer
7 test volume
8 means to achieve the test volume

Apparatus shall be made of a material that is sufficiently rigid to provide accurate and repeatable test results.

Figure D.1 — Example of test apparatus for subatmospheric-pressure air leakage

D.4 *Procedure*

a) Seal the through bore of the *connector* under test prior to step c).

b) Assemble the *connector* under test to the appropriate *cone* or *socket* reference *connector*, both *connectors* being dry.

   1) For a non-locking (slip) *connector*, assemble by applying an axial force of between 26,5 N and 27,5 N. Then, while continuing to apply the axial force, rotate the *connector* under test with a torque not

exceeding 0,10 N·m to give a rotation not exceeding 90°. Hold the force and torque for 5 s to 6 s and then release.

2) For a locking *connector*, assemble by rotating the collar of the *connector* under test to a torque of between 0,08 N·m and 0,12 N·m. Then, while continuing to apply the torque, apply an axial force of between 26,5 N and 27,5 N. Hold the force and torque for 5 s to 6 s and then release.

c) Apply the subatmospheric pressure specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series and close the valve.

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

e) After the test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series, record the end pressure and the elapsed time.

f) Calculate the difference between end pressure and start pressure.

g) Determine whether the change in pressure as an absolute value exceeds the value specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

D.5 Test report

Prepare a test report that:

a) specifies testing was performed according to this document (i.e. ISO 80369-20:2024 Annex D);

b) identifies the date of the testing;

c) identifies the *connectors* under test;

d) identifies the number of *connectors* tested;

e) identifies the preconditioning and environmental test conditions;

f) identifies the reference *connector* used;

g) identifies the acceptance criterion;

h) identifies any deviations from the *procedure*;

i) identifies any unusual features observed;

j) identifies the test volume as defined in Figure D.1;

k) discloses the test period;

l) discloses the pressure change during the test period according to Clause D.4, f);

m) discloses whether the acceptance criterion is met.

Annex E
(informative)

Stress cracking *test method*

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

E.1 Principle

A *connector* is securely assembled to an appropriate reference *connector* and the *connection* is evaluated for stress cracking by demonstrating that it properly seals utilizing a leakage test.

E.2 Test conditions

E.2.1 Test sample preconditioning

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

E.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.

E.3 Apparatus

The following shall be used.

E.3.1 ***Connector,*** under test.

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

E.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.

E.3.4 A **means** of measuring and displaying the elapsed time with an accuracy of ± 10 min for at least 48 h.

E.4 *Procedure*

a) Assemble the *connector* under test to the appropriate *cone* or *socket* reference *connector*, both *connectors* being dry.

   1) For a non-locking (slip) *connector*, assemble by applying an axial force of between 26,5 N and 27,5 N. Then, while continuing to apply the axial force, rotate the *connector* under test with a torque not exceeding 0,10 N·m to give a rotation not exceeding 90°. Hold the force and torque for 5 s to 6 s and then release.

2) For a locking *connector*, assemble by rotating the collar of the *connector* under test to a torque of between 0,08 N·m and 0,12 N·m. Then, while continuing to apply the torque, apply an axial force of between 26,5 N and 27,5 N. Hold the force and torque for 5 s to 6 s and then release.

b) Leave the *connector* under test and reference *connector* assembled for not less than 48 h unless otherwise specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

c) Confirm that the *connector* under test properly seals by performing a leakage test as specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series. The preconditioning process of the leakage test need not be performed.

E.5 Test report

Prepare a test report that:

a) specifies testing was performed according to this document (i.e. ISO 80369-20:2024, Annex E);

b) identifies the dates of the testing;

c) identifies the *connectors* under test;

d) identifies the number of *connectors* tested;

e) identifies the preconditioning and environmental test conditions;

f) identifies the reference *connector* used;

g) identifies any deviations from the *procedure*;

h) identifies any unusual features observed;

i) discloses the leakage test method used;

j) discloses the test period;

k) discloses the test report of the leakage test method used;

l) discloses the results of the leakage test performed according to Clause E.4, c).

Annex F
(informative)

Resistance to separation from axial load *test method*

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

F.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*. The *connection* is expected to be maintained.

F.2 Test conditions

F.2.1 Test sample preconditioning

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

F.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.

F.3 Apparatus

The following shall be used.

F.3.1 ***Connector,*** under test.

F.3.2 Appropriate **reference *connector***, as specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series for the resistance to separation from axial load *test method*, to be assembled to the *connector* under test.

F.3.3 A **means** to simultaneously apply an axial force of 35 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.

F.3.4 A **means** of measuring and displaying the elapsed time with an accuracy of ± 1 s.

F.3.5 A **means** of measuring the specified axial separation force.

F.4 *Procedure*

a) Assemble the *connector* under test to the appropriate *cone* or *socket* reference *connector*, both *connectors* being dry.

   1) For a non-locking (slip) *connector*, assemble by applying an axial force of between 26,5 N and 27,5 N. Then, while continuing to apply the axial force, rotate the *connector* under test with a torque not

exceeding 0,10 N·m to give a rotation not exceeding 90°. Hold the force and torque for 5 s to 6 s and then release.

2) For a locking *connector*, assemble by rotating the collar of the *connector* under test to a torque of between 0,08 N·m and 0,12 N·m. Then, while continuing to apply the torque, apply an axial force of between 26,5 N and 27,5 N. Hold the force and torque for 5 s to 6 s and then release.

b) Apply the specified axial pull force from the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series at a rate of approximately 10 N/s until the minimum specified force is reached. Hold the axial force for the test period from the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series. Do not apply any force in other directions. For *connectors* with floating collar apply the axial force to the body that includes the mating surfaces.

c) Confirm that the sealing interface of the *connectors* has not detached.

F.5 Test report

Prepare a test report that:

a) specifies testing was performed according to this document (i.e. ISO 80369-20:2024, Annex F);

b) identifies the date of the testing;

c) identifies the *connectors* under test;

d) identifies the number of *connectors* tested;

e) identifies the preconditioning and environmental test conditions;

f) identifies the reference *connector* used;

g) identifies any deviations from the *procedure*;

h) identifies any unusual features observed;

i) identifies the applied axial pull force;

j) discloses the presence or absence of the complete detachment of the sealing interface of the *connectors* according to Clause F.4, c).

Annex G
(informative)

Resistance to separation from unscrewing *test method*

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

G.1 Principle

The security of *connection* between *cone* and *socket* locking *connectors* is determined by inspecting the *connection* after applying specified unscrewing torque. The *connection* is expected to be maintained.

G.2 Test conditions

G.2.1 Test sample preconditioning

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

G.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.

G.3 Apparatus

The following shall be used.

G.3.1 ***Connector,*** under test.

G.3.2 Appropriate **reference *connector***, as specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series for the resistance to separation from unscrewing *test method*, to be assembled to the *connector* under test.

G.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.

G.3.4 A **means** of measuring and displaying the elapsed time with an accuracy of ± 1 s.

G.3.5 A **means** of measuring the specified unscrewing torque.

G.4 *Procedure*

a) Assemble the *connector* under test to the appropriate *cone* or *socket* reference *connector*, both components being dry.

   1) Assemble by rotating the collar of the *connector* under test to a torque of between 0,08 N·m and 0,12 N·m. Then, while continuing to apply the torque, apply an axial force of between 26,5 N and 27,5 N. Hold the force and torque for 5 s to 6 s and then release.

b) Apply an unscrewing torque to the collar as specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

c) Hold the torque at this value for the test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series. Do not apply any supplementary force in other directions.

d) Confirm that the *connectors* have not completely separated.

G.5 Test report

Prepare a test report that:

a) specifies testing was performed according to this document (i.e. ISO 80369-20:2024, Annex G);

b) identifies the date of the testing;

c) identifies the *connectors* under test;

d) identifies the number of *connectors* tested;

e) identifies the preconditioning and environmental test conditions;

f) identifies the reference *connector* used;

g) identifies any deviations from the *procedure*;

h) identifies any unusual features observed;

i) identifies the applied unscrewing torque;

j) discloses the test period;

k) discloses the presence or absence of the complete detachment of the *connectors* according to Clause G.4, d).

Annex H
(informative)

Resistance to overriding *test method*

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

H.1 Principle

The resistance to overriding of *cone* and *socket* locking *connectors* is determined by observing the thread or lugs of the *connector* under test after applying the specified torque.

H.2 Test conditions

H.2.1 Test sample preconditioning

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

H.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.

H.3 Apparatus

The following shall be used.

H.3.1 ***Connector,*** under test.

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

H.3.3 A **means** to simultaneously apply an axial force of 27,5 N and torque as specified by the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

H.3.4 A **means** of measuring and displaying the elapsed time with an accuracy of ± 1 s.

H.3.5 A **means** of measuring the specified overriding torque.

H.4 *Procedure*

a) Assemble the *connector* under test to the appropriate *cone* or *socket* reference *connector*, both *connectors* being dry.

   1) Assemble by rotating the collar of the *connector* under test to a torque of between 0,08 N·m and 0,12 N·m. Then, while continuing to apply the torque, apply an axial force of between 26,5 N and 27,5 N. Hold the force and torque for 5 s to 6 s and then release.

b) Apply the torque specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series to the *connector* under test, applying the unscrewing torque to the collar for *connectors* with a floating or rotatable collar.

c) Hold the torque at this value for the test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series. Do not apply any supplementary force or torque in other directions.

d) Confirm that the threads or lugs of the reference *connector* have not completely extended past the threads or lugs of the *connector* under test and that there is no cocking of the *connectors*.

H.5 Test report

Prepare a test report that:

a) specifies testing was performed according to this document (i.e. ISO 80369-20:2024, Annex H);

b) identifies the date of the testing;

c) identifies the *connectors* under test;

d) identifies the number of *connectors* tested;

e) identifies the preconditioning and environmental test conditions;

f) identifies the reference *connector* used;

g) identifies any deviations from the *procedure*;

h) identifies any unusual features observed;

i) identifies the applied torque;

j) discloses the test period;

k) discloses the presence or absence of the threads or lugs of the reference *connector* completely overriding the threads or lugs of the *connector* under test according to Clause H.4 d);

l) discloses the presence or absence of cocking of the *connectors* such that they are not axially aligned according to Clause H.4 d).

Annex I
(informative)

Disconnection by unscrewing *test method*

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

I.1 Principle

The ability to disconnect the *connection* using a twist of *cone* and *socket connectors* is determined by inspecting the *connection* after applying the specified torque. The *connection* is expected to disconnect.

I.2 Test conditions

I.2.1 Test sample preconditioning

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

I.3 Apparatus

The following shall be used.

I.3.1 ***Connector,*** under test.

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

I.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.

I.3.4 A **means** to measure an unscrewing torque of at least 0,24 N·m, or more if required by the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

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

I.4 *Procedure*

a) Assemble the *connector* under test to the appropriate *cone* or *socket* reference *connector*, both *connectors* being dry.

   1) For a non-locking (slip) *connector*, assemble by applying an axial force of between 26,5 N and 27,5 N. Then, while continuing to apply the axial force, rotate the *connector* under test with a torque not

exceeding 0,10 N·m to give a rotation not exceeding 90°. Hold the force and torque for 5 s to 6 s and then release.

2) For a locking *connector*, assemble by rotating the collar of the *connector* under test to a torque of between 0,08 N·m and 0,12 N·m. Then, while continuing to apply the torque, apply an axial force of between 26,5 N and 27,5 N. Hold the force and torque for 5 s to 6 s and then release.

b) Let the assembled *connectors* sit for a time between 10 min and 15 min.

c) Apply and measure an increasing unscrewing torque to the *connector* under test until the *connection* separates. Do not apply any supplementary force in other directions.

d) Record the peak torque at which the *connector* under test completely begins to loosen from the reference *connector* and confirm that the torque does not exceed the value specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

e) The sampling frequency of the means to measure the unscrewing torque shall be appropriate in order to capture peak torque value caused by static friction.

I.5 Test report

Prepare a test report that:

a) specifies testing was performed according to this document (i.e. ISO 80369-20:2024, Annex I);

b) identifies the date of the testing;

c) identifies the *connectors* under test;

d) identifies the number of *connectors* tested;

e) identifies the preconditioning and environmental test conditions;

f) identifies the reference *connector* used;

g) identifies the acceptance criterion;

h) identifies any deviations from the *procedure*;

i) identifies any unusual features observed;

j) discloses the peak unscrewing torque according to Clause I.4 d);

k) discloses whether the acceptance criterion is met.

Annex J
(informative)

Modification of the *test methods* to generate variable data for statistical analysis

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

J.1 Principle

This Annex provides variations to *test methods* of this document that create variable test data for those *manufacturers* who wish to perform variable testing. Statistical methods for the analysis of the variable test data are also provided.

J.2 *Test method* variations

J.2.1 Leakage by pressure decay *test method*

Use the *test method* for leakage by pressure decay described in Annex B.

Determine the upper tolerance limit of the pressure change from the test results and confirm that it does not exceed the value specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

J.2.2 Falling drop positive-pressure liquid leakage *test method*

The *test method* for liquid leakage in Annex C specifies pressurizing the *connection* with liquid for a minimum of 30 s at a specific minimum pressure and inspecting for a falling drop. Then the test is stopped.

a) To acquire variable data, do not stop the test after 30 s. After 30 s, gradually increase the pressure until a drop forms and falls or the test sample bursts.

b) Record the pressure at which the drop falls or the sample fails.

c) Determine the lower tolerance limit from the test results and confirm that it exceeds the specification limit.

Testing to failure of *connectors* manufactured from certain materials such as metal is not recommended due to possible damage to the reference *connector*.

J.2.3 Subatmospheric-pressure air leakage *test method*

Use the *test method* for subatmospheric pressure air leakage described in Annex D.

Determine the upper tolerance limit of the pressure change from the test results and confirm that it does not exceed the value specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

J.2.4 Resistance to separation from axial load *test method*

The *test method* for separation force described in Annex F specifies that the load on the samples is increased at a rate of approximately 10 N/s for the test period specified in the relevant *application* part of the ISO and

IEC 80369 series and the ISO 18250 series, limiting the axial load to the specification limit. Then the test is stopped.

a) To acquire variable data, do not stop the test after the test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series. After the test period, continue increasing the load at approximately 10 N/s until the *connectors* separate.

b) Determine the lower tolerance limit for the separation force from the test results and confirm that it exceeds the specification limit specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

Testing to failure of *connectors* manufactured from certain materials such as metal is not recommended due to possible damage to the reference *connector*.

J.2.5 Resistance to separation from unscrewing *test method*

The *test method* for unscrewing torque of Annex G specifies that the unscrewing torque as specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series is applied for the test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series, limiting the torque to the specification limit. Then the test is stopped.

a) To acquire variable data, do not stop the test after the test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series. After the test period, gradually increase the unscrewing torque until the *connectors* separate.

b) Determine the lower tolerance limit for unscrewing torque from the test results and confirm that it exceeds the limit specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

J.2.6 Resistance to overriding *test method*

The *test method* for resistance to overriding of Annex H specifies that the unscrewing torque is applied for test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series. Then the test is stopped.

a) To acquire variable data, do not stop the test after the test period specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series. After the test period, gradually increase the torque and hold for the specified test period, repeating until the *connectors* override.

b) Determine the lower tolerance limit from the test results and confirm that it exceeds the limit specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

Testing to failure of *connectors* manufactured from certain materials such as metal is not recommended due to possible damage to the reference *connector*.

J.2.7 Disconnection by unscrewing *test method*

Use the *test method* for disconnection by unscrewing in Annex I.

Determine the upper tolerance limit of the torque from the test results and confirm that it does not exceed the value specified in the relevant *application* part of the ISO and IEC 80369 series and the ISO 18250 series.

J.3 Statistical analysis of variable data

J.3.1 Test for normality

a) The test data should be analysed for normality per ISO 5479.

b) If the data departs from the normal distribution, then the data should be transformed if possible using one of many available transforms such as a logarithmic, exponential, Box-Cox, or Johnson transform.

c) If transformation does not produce normally distributed data, then distribution-free methods should be used to determine the tolerance limits.

d) Most modern statistical software packages have incorporated tests for normality as well as multiple transformations for normalizing non-normal data. The use of one of these software packages for analysis of the test results is recommended.

J.3.2 Tolerance limit calculation

a) Calculate the one-sided upper tolerance limit (UTL) or lower tolerance limit (LTL) per the methods detailed in ISO 16269-6:2014. A brief summary of the method is described here.

b) A statistical lower tolerance limit is in the form ($\mu - k\sigma$), where we are ($1 - \alpha$) confident that at least (p) of the distribution is above ($\mu - k\sigma$). If this lower tolerance interval limit is above the lower specification limit, then the specification passes. The same logic holds for the upper specification criterion as well as for a two-sided specification, simply changing the "-" to "+" or "±".

c) The confidence level ($1 - \alpha$) and proportion (p) of the population used to calculate the tolerance limits should be determined per the *manufacturer's* standard operating *procedures*. ($1 - \alpha$) and (p) are typically determined by the *risk* associated with failure of the *connector* in the intended *application*.

d) Using the appropriate table from Annex C or Annex D in ISO 16269-6:2014, determine k from the sample size (n), ($1 - \alpha$), and (p). Separate k factors are presented depending on the characteristic having a one or two-sided specification.

e) Calculate the sample mean ($\bar{x}$) and sample standard deviation (s).

f) The upper or lower tolerance limit is determined from the formula $\bar{x} \pm k \cdot s$.

g) Most modern statistical software packages have incorporated the calculation of tolerance limits. The use of one of these software packages for analysis of the test results is recommended.

NOTE Tabled k factors are calculated using the inverse cumulative distribution function for the non-central t distribution and therefore assume that the data are normally distributed. Violations of this assumption can give biased results.