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Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 1: General requirements and common test methods

Dispositifs médicaux — Connecteurs pour systèmes de livraison de réservoir pour des applications de soins de santé —

Partie 1: Exigences générales et méthodes d'essai courantes

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Foreword

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

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

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

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

For an explanation 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 medical devices*.

A list of all the parts in the ISO 18250 series can be found on the ISO website. The numbering of the parts follows in parallel the clinical applications listed in ISO 80369-1:2018 where applicable. Other parts are expected to be added in the future for applications not yet covered.

In this document, 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;

— compliance checks: *italic type*;

— TERMS DEFINED IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

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.

For the purposes of this document, the following verbal forms are used:

— "shall" indicates that compliance with a requirement or a test is mandatory for compliance with this document,

— "should" indicates that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document, 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.

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

During the development of the ISO 80369 series of standards for small-bore CONNECTORS, it became evident that equally important were the CONNECTIONS between MEDICAL DEVICES and fluid RESERVOIRS. It was agreed that such CONNECTORS should be developed in parallel with the small-bore CONNECTORS specified in the ISO 80369 series of standards and comply with analogous safety and interoperability requirements.

ISO 16142-1:2016, Clause 4 addresses this type of problem.

The solutions adopted by the MANUFACTURER for the design and manufacture of the MEDICAL DEVICE should conform to safety principles, taking into account the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:

a) identify known or foreseeable HAZARDS and estimate the associated RISKS arising from the INTENDED USE and foreseeable misuse;

b) eliminate RISKS as far as reasonably practicable through inherently safe design and manufacture;

c) reduce as far as reasonably practicable the remaining RISKS by taking adequate protection measures, including alarms or information for safety;

d) inform users of any residual RISK.

It was soon realized that many of the RESERVOIRS that contain liquids for administering to PATIENTS for different APPLICATIONS all utilized the same ubiquitous spike as the CONNECTOR between the giving set and the RESERVOIR leading to wrong drug administration. The ISO 18250 series endeavours to provide unique designs for each of the APPLICATIONS specified to reduce the RISK of administering the wrong drug. It is understood that RESERVOIR CONNECTOR systems cannot be designed to overcome all chances of MISCONNECTION or to eliminate deliberate misuse. However, a number of steps that would improve the current situation and lead to greater PATIENT safety can be taken. This will only be achieved through a long-term commitment involving industry, healthcare professionals, MEDICAL DEVICE purchasers and MEDICAL DEVICE regulatory authorities.

The ISO 18250 series specifies the requirements to prevent MISCONNECTION between RESERVOIR CONNECTORS used in different APPLICATIONS. This document specifies the general requirements and TEST METHODS common to all RESERVOIR CONNECTORS in this series. TEST METHODS that are specific to a particular RESERVOIR CONNECTOR will be included in that APPLICATION part. The ISO 18250 series specifies the requirements to prevent MISCONNECTIONS or reduce their occurrence to acceptable levels between RESERVOIR CONNECTORS used in different APPLICATIONS.

Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 1: General requirements and common test methods

1 *Scope

This document specifies general requirements for RESERVOIR CONNECTORS, which convey fluids in healthcare APPLICATIONS. These RESERVOIR CONNECTORS are used in MEDICAL DEVICES or ACCESSORIES intended for use with a PATIENT.

This document also specifies the healthcare fields in which these RESERVOIR CONNECTORS are intended to be used.

These healthcare fields of use include, but are not limited to, APPLICATIONS for

— respiratory,

— enteral,

— neural,

— intravascular,

— citrate-based anticoagulant solution, and

— irrigation.

RESERVOIR CONNECTORS as specified in this document are NON-INTERCONNECTABLE with:

— the RESERVOIR CONNECTORS of every other APPLICATION specified in the ISO 18250 series;

— removable temperature sensor port specified in Annex EE of ISO 80601-2-74:2017;

— the nipples specified in Annex B of ISO 17256[1)];

unless otherwise specified in the ISO 18250 series.

APPLICATION parts of the ISO 18250 series can specify additional CONNECTORS with which RESERVOIR CONNECTORS (as specified in those APPLICATION parts) are to be NON-INTERCONNECTABLE.

This document provides the methodology to assess NON-INTERCONNECTABLE characteristics of RESERVOIR CONNECTORS based on their inherent design and dimensions in order to reduce the RISK of MISCONNECTIONS between MEDICAL DEVICES or between ACCESSORIES for different APPLICATIONS.

This document does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these RESERVOIR CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 1 MANUFACTURERS are encouraged to incorporate the RESERVOIR CONNECTORS specified in the ISO 18250 series into MEDICAL DEVICES, medical systems or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for RESERVOIR CONNECTORS as specified in the series of standards will be included.

1) Under preparation. Stage at the time of publication: ISO/DIS 17256:2017.

NOTE 2 The ISO 18250 series does not apply to screw and crown cork caps and necks as they are not CONNECTORS specific for MEDICAL DEVICES. Examples of screw caps and necks are defined in DIN 55525, ASTM D2911/D2911M, DIN 6063-1, DIN 6063-2, DIN 168-1. Examples of crown cork caps and necks are defined in DIN 6094, ISO 12821, EN 14635.

This document also specifies the TEST METHODS to verify the common performance requirements for RESERVOIR CONNECTORS. The performance requirements for these common TEST METHODS are specified in the APPLICATION parts and not in the general part.

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 527-1, *Plastics — Determination of tensile properties — Part 1: General principles*

ISO 527-2, *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics*

ISO 178, *Plastics — Determination of flexural properties*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 17256[2)], *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*

ISO 18250-3, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications*

ISO 18250-6[3)], *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 6: Neural applications*

ISO 18250-7[4)], *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 7: Intravascular applications*

ISO 18250-8, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 8: Citrate-based anticoagulant solution for apheresis applications*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971, IEC 62366-1, and the following apply.

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

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

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

2) Under preparation. Stage at the time of publication: ISO/DIS 17256:2017.

3) Under preparation. Stage at the time of publication: ISO/DIS 18250-6:2018.

4) Under preparation. Stage at the time of publication: ISO/FDIS 18250-7:2018.

3.1
ACCESSORY
additional part(s) for use with MEDICAL DEVICE in order to:

— achieve the INTENDED USE,

— adapt it to some special use,

— facilitate its use,

— enhance its performance, or

— enable its functions to be integrated with those of other MEDICAL DEVICES

[SOURCE: IEC 60601-1:2005, definition 3.3, modified — "equipment" has been replaced with MEDICAL DEVICE]

3.2
APPLICATION
specific healthcare field in which a RESERVOIR CONNECTOR is intended to be used

[SOURCE: ISO 80369-1:2018, 3.2, modified — "SMALL-BORE CONNECTOR" has been replaced with "RESERVOIR CONNECTOR"]

Note 1 to entry: Annex K lists RESERVOIR CONNECTOR APPLICATIONS and gives examples of the MEDICAL DEVICES used within that healthcare field.

3.3
CONNECTION
union or joining of mating halves of a CONNECTOR

[SOURCE: ISO 80369-1:2018, 3.3]

3.4
CONNECTOR
mechanical device, consisting of one of two mating halves and designed to join a conduit to convey liquids or gases

[SOURCE: ISO 80369-1:2018, 3.4]

Note 1 to entry: This term refers to both mating halves of the CONNECTION and applies to both the mechanical devices on the RESERVOIR side and PATIENT side.

3.5
MISCONNECTION
CONNECTION between CONNECTORS intended for different APPLICATIONS or from different designs within the same APPLICATION and not intended to connect

3.6
NON-INTERCONNECTABLE
having characteristics which incorporate geometries or other characteristics that prevent different CONNECTORS from making a CONNECTION

[SOURCE: ISO 80369-1:2018, 3.10]

3.7
PATIENT
person undergoing a medical, surgical or dental PROCEDURE

[SOURCE: IEC 60601-1:2005, definition 3.76, modified — "person or animal" has been replaced by "person"]

3.8
RESERVOIR
fluid container within MEDICAL DEVICE field

3.9
TEST METHOD
PROCEDURE that produces a test result

4 Materials used for RESERVOIR CONNECTORS

4.1 *General

To verify the MISCONNECTION requirements specified in this document, RESERVOIR CONNECTORS shall be made of materials with a modulus of elasticity either in tension or in flexure of at least 700 MPa, unless otherwise specified in specific APPLICATION parts of the ISO 18250 series.

Check compliance in accordance with ISO 527-1 and ISO 527-2 or ISO 178 at (23 ± 2) °C temperature and (50 ± 5) % relative humidity.

Non-rigid materials are allowed in order to provide sealing surfaces or other performance characteristics whereas they do not affect NON-INTERCONNECTABLE characteristics, or unless otherwise specified in specific APPLICATION parts of the ISO 18250 series.

MANUFACTURERS shall demonstrate that, when non-rigid materials are introduced in the design, the NON-INTERCONNECTABLE characteristics are not affected.

NOTE The TEST METHODS listed in Annex L are considered acceptable alternatives to ISO 527-1 and ISO 527-2, and ISO 178.

4.2 Alternative TEST METHODS

MANUFACTURERS may use alternative TEST METHODS to those listed in Annex L if it can be demonstrated that they are technically equivalent to ISO 527-1 and ISO 527-2 or ISO 178 within the typical uncertainty range of the mechanical properties of the plastics used.

In cases of dispute, the TEST METHODS listed in this document shall be identified as the reference TEST METHODS.

Check compliance by inspection of the technical file.

5 *Requirements for RESERVOIR CONNECTORS for specific APPLICATIONS

5.1 *RESERVOIR CONNECTOR incompatibility

RESERVOIR CONNECTORS for APPLICATIONS specified in this document shall be NON-INTERCONNECTABLE with:

— the RESERVOIR CONNECTORS of every other APPLICATION specified in the ISO 18250 series;

— the defined surfaces of nipples of ISO 17256;

— the defined surfaces of temperature sensors and mating ports made in compliance with Annex EE of ISO 80601-2-74:2017;

unless otherwise indicated in this document or the APPLICATION parts of the ISO 18250 series.

Check compliance by confirming that OBJECTIVE EVIDENCE verifies that RISKS have been reduced to acceptable levels for the acceptability criteria specified in Annex B.

5.2 Enteral APPLICATIONS

RESERVOIR CONNECTORS intended to be used for CONNECTIONS in enteral APPLICATIONS shall comply with ISO 18250-3, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE.

5.3 Neural APPLICATIONS

RESERVOIR CONNECTORS intended to be used for CONNECTIONS in neural APPLICATIONS shall comply with ISO 18250-6, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE.

5.4 Intravascular APPLICATIONS

RESERVOIR CONNECTORS intended to be used for CONNECTIONS in intravascular APPLICATIONS shall comply with ISO 18250-7, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE.

5.5 Citrate-based anticoagulant solution for apheresis APPLICATIONS

RESERVOIR CONNECTORS intended to be used for CONNECTIONS in citrate-based anticoagulant solution for apheresis APPLICATIONS shall comply with ISO 18250-8, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE.

6 *RESERVOIR CONNECTORS for APPLICATIONS not already covered in the ISO 18250 series

RESERVOIR CONNECTORS for APPLICATIONS other than those specified in 5.2, 5.3, 5.4 and 5.5 shall:

a) comply with Clause 4, 5.1 and Clause 7;

b) not create an unacceptable RISK for a specific MEDICAL DEVICE or ACCESSORY; and

c) be evaluated in accordance with Annex B.

Check compliance by confirming that OBJECTIVE EVIDENCE verifies that RISKS have been reduced to acceptable levels for the acceptability criteria specified in Annex B and other acceptability criteria established by the MANUFACTURER for NON-INTERCONNECTABLE characteristics.

CONNECTORS that satisfy the requirements of this clause are identified as compliant with “Clause 6 of ISO 18250-1:2018” only. They may or may not comply with ISO 18250-1 as a whole, nor necessarily with any of the APPLICATION parts of the ISO 18250 series.

7 *Performance requirements

7.1 Leakage

7.1.1 Positive-pressure liquid leakage

There shall be no leakage from the RESERVOIR CONNECTOR sufficient to form a falling drop when subjected to a pressure of (50 ± 10) kPa within a period of 30 s.

Check compliance using the test method specified in Annex C.

7.1.2 Sub atmospheric pressure air leakage

There shall be no leakage of air through the RESERVOIR CONNECTOR at a sub-atmospheric pressure of (40 ± 0,1) kPa.

Check compliance using the test method specified in Annex D.

7.2 Stress-cracking

RESERVOIR CONNECTORS shall show no signs of stress-cracking when subjected to an axial connection force of (27,5 ± 1) N at a torque of (0,12 ± 0,02) N·m, an axial disconnection force of (35 ± 1) N and an internal pressure of (50 ± 1) kPa.

Check compliance using the test method specified in Annex E.

7.3 Resistance to separation from axial load

RESERVOIR CONNECTORS shall not separate when subjected to an axial disconnection force of less than 35 N.

Check compliance using the test method specified in Annex F.

7.4 Resistance to separation from unscrewing

RESERVOIR CONNECTORS shall not separate when subjected to a disconnection torque of less than 0,12 N·m.

Check compliance using the test method specified in Annex G.

7.5 Resistance to overriding

RESERVOIR CONNECTORS shall not override any threads or locking features when subjected to an applied torque of 35 N·m.

Check compliance using the test method specified in Annex H.

7.6 Disconnection by unscrewing for floating or rotating screw-thread locking CONNECTORS and locking CONNECTORS with fixed threads

RESERVOIR CONNECTORS shall become detached when an unscrewing torque of 0,25 N·m is applied.

Check compliance using the test method specified in Annex I.

The TEST METHODS may be referenced fully, in part, or not at all in the individual APPLICATION parts of the ISO 18250 series.

Annex A
(informative)

Rationale and guidance

A.1 General

This annex provides rationale for the important 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 reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The clauses and subclauses in this annex have been numbered to correspond to the numbering of the clauses and subclauses of this document to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

Advances in modern medicine have led to a significant rise in the number of MEDICAL DEVICES attached to PATIENTS. Many of these MEDICAL DEVICES fall into the categories of monitoring devices, diagnostic devices and drug delivery devices.

Such MEDICAL DEVICES perform a variety of similar, but not interchangeable, functions. Examples include: intravenous and neural fluid delivery, and enteral feeding. Despite the varied nature of the functions performed, many of these MEDICAL DEVICES use a universal system of RESERVOIR CONNECTORS based on the closure-piercing device defined in ISO 1135-4 and ISO 8536-4.

The universal nature of the CONNECTORS used, and the proximity of several different CONNECTORS around a single PATIENT, makes accidental MISCONNECTIONS inevitable. The consequences of such MISCONNECTIONS vary but a significant number is actually or potentially fatal.

Serious and usually fatal MISCONNECTIONS include intravenous injection of enteral feeds and intrathecal administration of e.g. vincristine. Less disastrous MISCONNECTIONS such as enteral administration of intravenous fluids might not directly HARM the PATIENT but cause a failure of the intended treatment.

Introducing the ISO 18250 series of standards for RESERVOIR CONNECTORS alongside the ISO 80369 series of small bore CONNECTORS will help to reduce the likelihood of MISCONNECTIONS and incorrect administration of fluids leading to a direct improvement in PATIENT safety.

Subclause 4.1 General

The modulus of elasticity (MoE) of 700 MPa was chosen as the minimum as this is considered to be the worst-case scenario for the sort of materials likely to be used for RESERVOIR CONNECTORS. If the CONNECTORS comply with the MISCONNECTION and the performance requirements specified in this document using material with this MoE, then devices made from more rigid materials are also expected to comply with the requirements and reduce the possibility of forcing, beyond a reasonable detection threshold, a fit between RESERVOIR CONNECTORS from different APPLICATIONS made from flexible materials.

Non-rigid materials can be used for components such as gaskets as long as they do not affect the NON-INTERCONNECTABILITY characteristics of the RESERVOIR CONNECTOR. In addition, it provides the possibility for rubber portions in CONNECTORS like the closures for intravascular infusion bottles in case these CONNECTORS will be included in the framework of the ISO 18250 series.

The definition of material stiffness is based upon the value of the Young's modulus. As many standard and non-standard TEST METHODS have been developed in order to estimate this value, it was decided to refer to the mechanical TEST METHODS given in ISO 527-1, ISO 527-2 and ISO 178, while allowing the use of different methods considered to be technically equivalent. Annex L provides a list of these equivalent TEST METHODS that may be used providing results applicable for the purpose of this document within the typical uncertainties on the mechanical properties of plastics.

The different values obtained from these various tests are considered to fall within acceptable limits for the model approximations and raw material variability. Since the standard TEST METHODS refer to standard specimen that cannot represent the effective behaviour of the material after processing, 4.2 allows the MANUFACTURERS to set specific TEST METHODS for the estimate of the effective Young's modulus, provided that MANUFACTURERS can produce OBJECTIVE EVIDENCE of the reliability of the methods.

The adoption of rigid materials is regarded as a minimal necessary condition for reduction of MISCONNECTIONS. First, because it is not sufficient for a final assessment as it cannot univocally describe the mechanical behaviour of plastic materials even in a rough approximation of the linear elastic range. Second, because the model approximations that underlie the standard TEST METHODS are often not accurate, neglecting phenomena like plastic and viscoelastic behaviour that may occur in reality during a MISCONNECTION attempt.

Different TEST METHODS can be used to estimate the Young's modulus of these materials and may produce slightly different values. Thus materials whose modulus is close to 700 MPa may be reported as above or below that threshold depending on the method used. For the purposes of this document, as long as one of the referenced methods provides a result above the threshold, that will be taken as sufficient evidence to assess compliance with the appropriate clause. This can be considered acceptable provided that the adoption of rigid materials is regarded as a minimal necessary condition for reduction of MISCONNECTIONS.

Clause 5 Requirements for RESERVOIR CONNECTORS for specific APPLICATIONS

National regulatory bodies, hospital accreditation organizations, and independent public health organizations recognize MISCONNECTIONS as a persistent problem with potentially fatal consequences. Warnings have been issued and strategies offered for healthcare organizations to reduce RISKS and MANUFACTURERS to redesign CONNECTORS to prevent MISCONNECTIONS. The ability of CONNECTORS used to interconnect is identified as a root cause of MISCONNECTIONS.

Reference [5] identifies the problem of unintended CONNECTION, with sometimes fatal consequences, when using the same CONNECTOR on devices used for different APPLICATIONS and recommended restricting the use of Luer CONNECTORS to hypodermic and vascular APPLICATIONS. The ISO 80369 series has addressed this problem. RESERVOIR CONNECTORS have a similar issue in that the spike has become ubiquitous and has led to unintended CONNECTIONS to the wrong RESERVOIR with fatal consequences for the patient. This document, by developing unique RESERVOIR CONNECTORS for each of the identified APPLICATIONS, attempts to address this problem.

Clause 5 provides the requirements for RESERVOIR CONNECTORS based upon the APPLICATION categories specified in 5.2 to 5.5. Minimal requirements including verifiable acceptability criteria are established to reduce the RISK of MISCONNECTION. The purpose is to make the RISK of MISCONNECTION acceptably low by ensuring that halves of incompatible CONNECTORS are NON-INTERCONNECTABLE. OBJECTIVE EVIDENCE is required that the criteria are met for the RISK of MISCONNECTION for these criteria to be acceptable.

The requirements are not comprehensive. Additional requirements and criteria for other NON-INTERCONNECTABLE characteristics may be needed to reduce the RISK of incompatible MISCONNECTIONS to acceptable levels. This circumstance is acknowledged in this document by requiring that all RISK acceptability criteria applicable to NON-INTERCONNECTABLE characteristics be met.

The adoption of CONNECTORS different from the ones defined by the APPLICATION parts of the ISO 18250 series for APPLICATIONS already covered by this series of standards is not allowed within the conceptual framework of the ISO 18250 series of standards.

Subclause 5.1 RESERVOIR CONNECTOR incompatibility

The respiratory therapy tubing connectors specified in ISO 17256 are restricted to an elastomeric funnel inlet that is compatible with the fir-tree/nipple and an outlet that complies with the dimensions of an R2 respiratory small-bore connector to be included in the future ISO 80369-2. Previously this tubing had elastomeric funnel connectors at both ends. As these are still of common use, allowing CONNECTION of a RESERVOIR to a gas supply device such as a flow meter, oxygen concentrator or nebulizer air compressor, it was therefore considered to be a RISK that needed to be addressed, hence the inclusion of the nipple as a connector that should be considered when assessing possible MISCONNECTIONS.

The temperature sensor ports used on humidifiers specified in ISO 80601-2-74 were also considered to be a risk of MISCONNECTION that should be avoided.

Clause 6 RESERVOIR CONNECTORS for APPLICATIONS not already covered in the ISO 18250 series

Clause 6 provides the requirements for RESERVOIR CONNECTORS for APPLICATIONS not yet identified within the APPLICATION parts of the ISO 18250 series to be added to the ISO 18250 series.

Clause 6 has purposely been restricted to RESERVOIR CONNECTORS for APPLICATIONS that are not already specified. Manufacturers of proprietary CONNECTORS cannot therefore claim compliance with this document.

MANUFACTURERS may wish to design a proprietary CONNECTOR for their devices but, as the details of these would be unknown to the committee, there is no guarantee that proprietary CONNECTORS from different MANUFACTURERS, for different APPLICATIONS, will not interconnect thereby putting PATIENTS' lives at RISK.

Clause 7 Performance requirements

These performance requirements and compliance TEST METHODS have been adopted from the ISO 80369 series as they are considered to be synonymous, with the exception of the high-pressure requirements which are not needed. Many of the TEST METHODS in this document were extracted from ISO 80369-20:2015 which used the ISO 594 series[5)] as a basis for TEST METHOD development. Minimal changes were made to these TEST METHODS, except when the TEST METHODS contained subjective acceptance criteria.

Due to the specific design characteristics of some of the CONNECTORS, some TEST METHOD steps will specify alternate methods or PROCESSES. When this occurs, the method will reference the changes for the CONNECTOR TEST METHOD in question. If a CONNECTOR is not mentioned in the body of the method, then it can be presumed that the TEST METHOD applies to the unnamed CONNECTOR.

The assembly PROCEDURE in each annex mimics the assembly PROCEDURE that was extracted from the ISO 594 series. Test sample preconditioning and environmental test condition requirements were added to each annex.

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 the ISO 18250 series and is not present in this document. 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 the ISO 18250 series. Therefore, the ease of assembly TEST METHOD has been omitted from this document.

5) ISO 594-1 and ISO 594-2, now withdrawn and superseded by ISO 80369-7.

Any modifications to these common test methods or reservoir connector specific test methods will be included in the application part.

Subclause B.2.3 Identification of potential connectable or contactable surface diameters and features

In addition to designs defined in the ISO 18250 series, the non-interconnectable requirements listed in Clause 5 refer to the defined surfaces of several connectors not included in the ISO 18250 series, but whose presence in the same clinical environment may cause a potential unacceptable risk if misconnections are not prevented.

Usually the connectors whose standards were initially intended for interoperability and performance purposes, not including non-interconnectable characteristics, result in geometrically underdefined connectors or allow a broad, although defined, variation range for particular dimensions. See e.g. the ISO 5356 series.

During dimensional analysis test methods, the potential for misconnection, involving undefined or partially defined dimensions, may be evaluated if deemed necessary.

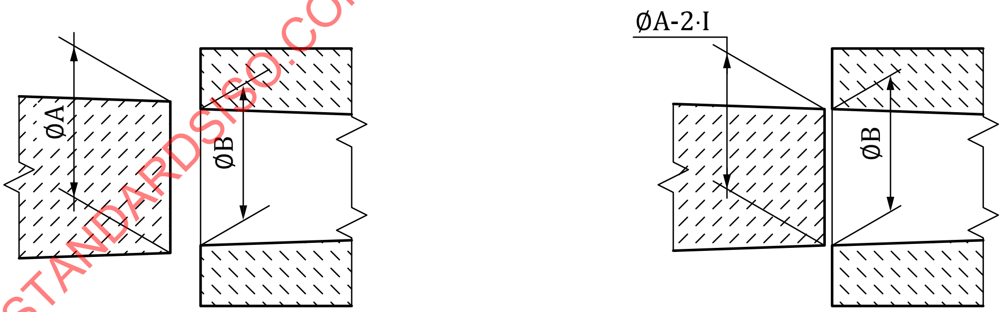
Misconnections of this kind should be avoided in principle by changing the connectors' dimensions where possible when the overall risk, considering probability of inadvertent occurrence and potential consequences, is manifestly unacceptable. Intentional tampering or misuse are outside the scope of this document and cannot in principle be managed.

Subclause B.2.5 Calculation of clearances (gaps), overlaps and interferences

Interference may also be defined in the following operational way.

When attempting a misconnection between a male connector bigger than the compared female connector, the insertion of the male connector in the female port is not possible. The interference between profiles may also be defined as the hypothetical reduction in male component transverse dimension that may allow the male component to be inserted into the female one. The interference is measured referring to the radius of the circle that circumscribes the male profile or the one that inscribes the female port.

In Figure A.1, the interference is defined as: I = (ØA - ØB)/2.



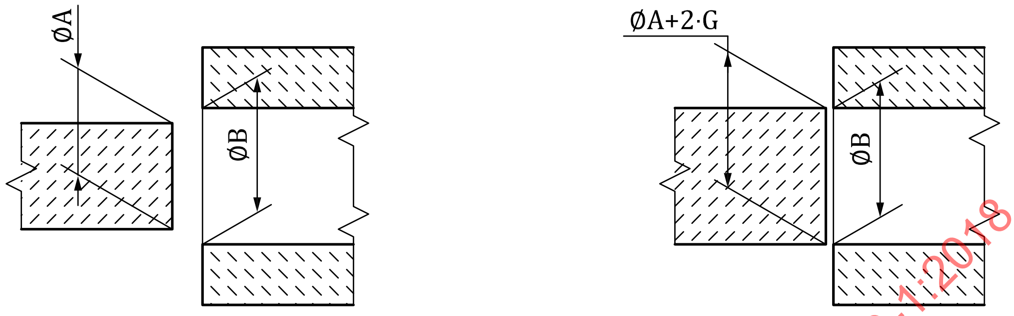
a) misconnection prevented by interference **b) If ØA is reduced by 2·I, it equals ØB and the misconnection is possible**

Figure A.1 — Prevention of misconnection by interference

Clearance (gap) may also be defined in the following operational way.

When attempting a misconnection between a male connector smaller than the compared female connector, the contact of the male connector surface with the female port surface is not possible because the male feature is slack into the female port. The gap between profiles may also be defined as the hypothetical increase in male component transverse dimension that may allow the male component surface to come in contact with the female one. The gap is measured referring to the radius of the circle that circumscribes the male profile.

In Figure A.2, the gap is defined as: G = (ØB - ØA)/2.



a) MISCONNECTION prevented by gap: male component is slack in female port

b) If ØA is increased by 2·G, it equals ØB and the MISCONNECTION is possible

Figure A.2 — Prevention of MISCONNECTION by gap

Subclause B.2.6 Analysis of the mathematical results of clearances (gaps), overlaps and interferences

In case of small interference values, i.e. when the value of relationship B as derived from the dimensional analysis is less than the values listed in Table B.2, a MISCONNECTION may still be possible depending on the level of interference and the material properties of the two CONNECTORS. Such very close profiles are therefore readdressed to physical TEST METHODS in order to assess NON-INTERCONNECTABLE characteristics because there may occur some extraordinary situations like the following examples:

— either or both CONNECTORS are intended to deliver heavy fluids that may leave dried incrustations able to fill a small gap, or lubricant fluids able to ease the insertion for small interferences;

— two CONNECTORS intended for different purposes show interference but very strong and unskilled USERS may not detect it and try to force the CONNECTION attempt beyond the reasonable force threshold assumed herein for physical testing.

Subclause B.3.5.3 PROCEDURE

The assembly force of 70 N is intended to simulate the haptic force applied by a typical USER and represents the fiftieth percentile force of a nominal human adult according to Reference [32].

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

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 TYPE TEST METHODS for hygroscopic materials, as these materials are known to absorb moisture from surrounding 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 C 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 Sub atmospheric-pressure air leakage TEST METHOD

This sub atmospheric-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 sub atmospheric-pressure (5.3 of both ISO 594-1 and ISO 594-2) creates an unspecified sub atmospheric test pressure and asks the observer to look for continued formation of bubbles of an unspecified size. The TEST METHOD included in this document was implemented in ISO 80369-20:2015.

Subclause D.4 **PROCEDURE** [Formula (*D.1)]

Formula (*D.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 (*D.1) includes a term ($1/p_t$) which normalizes the results, making all results comparable to the requirement regardless of different initial applied pressures.

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

Formula (*D.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 and of the experimental measuring errors.

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

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 performance leak test after the stress cracking test sequence 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 in the ISO 594 series.

Annex I **Disconnection by unscrewing TEST METHOD for floating or rotating screw-thread locking CONNECTORS and locking CONNECTORS with fixed threads**

This disconnection by unscrewing TEST METHOD supplements the TEST METHOD described in the ISO 594 series. It is intended to ensure that CONNECTORS, which can be connected and disconnected multiple times per day, can be successfully disconnected by the USER.

Suclause I.1 **Principle**

This disconnection by unscrewing TEST METHOD cannot be applied to TWIST-LOCK CONNECTORS that are locking and sealing systems in which the locking position is reached when a bump is elastically forced into a corresponding recess and therefore the locking mechanism is not comparable with what occurs on screwed CONNECTIONS where the friction between thread profiles provides the resistance to unscrewing.

Annex J Modification of the 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 CONNECTOR 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)

TEST METHODS for demonstrating NON-INTERCONNECTABLE characteristics

B.1 Principle

This annex specifies the criteria and TEST METHODS to be used to obtain OBJECTIVE EVIDENCE to demonstrate NON-INTERCONNECTABLE characteristics between a RESERVOIR CONNECTOR being evaluated and the CONNECTORS from the other parts of this series. Either dimensional analysis or physical testing is used to demonstrate the NON-INTERCONNECTABLE characteristics.

The physical TEST METHODS are intended to demonstrate that the RESERVOIR CONNECTOR being evaluated, when attempted to be assembled with the target reference CONNECTOR or feature under a specified force and torque does not remain connected when separated using the specified minimal force or leaks profusely.

There can and will be other CONNECTOR-specific acceptability criteria necessary for NON-INTERCONNECTABLE characteristics such as specific dimensional or rigidity requirements. They are not addressed in this annex. However, VERIFICATION that such other acceptability criteria are met is required for all such criteria. The TEST METHODS used should be appropriate for those acceptability criteria.

B.2 Dimensional analysis TEST METHOD

B.2.1 General

The present method is intended to obtain OBJECTIVE EVIDENCE to demonstrate NON-INTERCONNECTABLE characteristics. A comprehensive evaluation of the full range of all CONNECTOR dimensions is performed to determine if any surfaces of the CONNECTORS have the potential to interact in a manner that may form a CONNECTION.

The purpose of the dimensional analysis TEST METHOD is to evaluate if the surfaces of the RESERVOIR CONNECTOR under evaluation can have a potential connectable surface and as such have the potential to interact in a manner that can form a MISCONNECTION with the other RESERVOIR CONNECTORS specified in the ISO 18250 series.

Dimensional specifications that represent the least material condition (LMC), nominal material condition (NMC), and maximum material condition (MMC) are assembled graphically using two-dimensional (2D) or three-dimensional (3D) drawing tools using the tables of dimensions in the specifications for the CONNECTORS under assessment. These shall represent all critical dimensions and tolerances of dimensions required by the design to ensure performance, USABILITY, and physical performance properties necessary to maintain clinical performance, as well as all critical dimensions necessary for NON-INTERCONNECTABLE characteristics.

These critical dimensions include, but may not be limited to, the least, nominal and maximum dimensions of all surfaces and radii (lengths and angles) that may create a potential for an interconnectable surface or radii with each of the critical surfaces or radii on the other CONNECTOR under test.

— Least material condition (LMC) is the condition in which the size of the feature contains the least amount of material within the stated tolerance limits. For example, this condition would indicate that a male cone outside diameter would be at a minimum value and a female socket internal diameter would be at a maximum value.

— Maximum material condition (MMC) is the condition in which the size of the feature contains the maximum amount of material within the stated tolerance limits. For example, this condition would indicate that a male cone outside diameter would be at a maximum value and a female socket inside diameter would be at a minimum value.

— Nominal material condition (NMC) is the condition in which all dimensions are set to their nominal values, or average values if specified by minimum and maximum values only.

Some dimensions may not have any impact on the definition of least, most and nominal material conditions. Their choice shall be demonstrated to be the worst case for every analysed MISCONNECTION scenario.

B.2.2 Requirements

The connectable surfaces of the RESERVOIR CONNECTOR under evaluation shall not engage with CONNECTORS and surfaces as specified in Clause 5 in a manner that can form a MISCONNECTION.

If the dimensional analysis cannot ensure the NON-INTERCONNECTABLE characteristics of the two CONNECTORS, then physical TEST METHODS (see B.3) shall be utilized for evaluation.

B.2.3 *Identification of potential connectable or contactable surface diameters and features

Connectable or contactable surface is defined as any surface on a CONNECTOR that has an interaction potential in which physical contact occurs with any other surface on an opposing CONNECTOR. Connectable surfaces may include (but are not limited to): sealing surfaces as intended by design, crest geometry of external or internal threads, faces, shrouds or grips. These are surfaces on a CONNECTOR that can possibly interact with another CONNECTOR.

Identify the diameters and features on the RESERVOIR CONNECTOR under evaluation that have the potential to be a connectable surface. Such diameters may include any internal diameters (IDs) or any outside diameters (ODs) of the RESERVOIR CONNECTOR. Also, consider features such as threads and ribs (and other connectable geometries).

NOTE Non-connectable surfaces are surfaces that will not come in contact during an interaction with another component. These can include (but are not limited to): root geometry of external or internal threads, internal bore geometry that cannot be accessed by other CONNECTORS, geometry that will be covered by tubing or snap-on shrouds and grips.

Identify the diameters and features on the RESERVOIR CONNECTOR of the ISO 18250 series that have the potential to be a connectable surface. Such critical diameters, threads, and ribs shall include, but need not be limited to, the LMC, MMC and NMC of the diameters and or features.

Supplementary features can assist MISCONNECTION (or can help lead) with another CONNECTOR and therefore shall be considered in the analysis.

EXAMPLES Radii (internal and external), fillets, chamfers, edges of cylinders, or any surface edge.

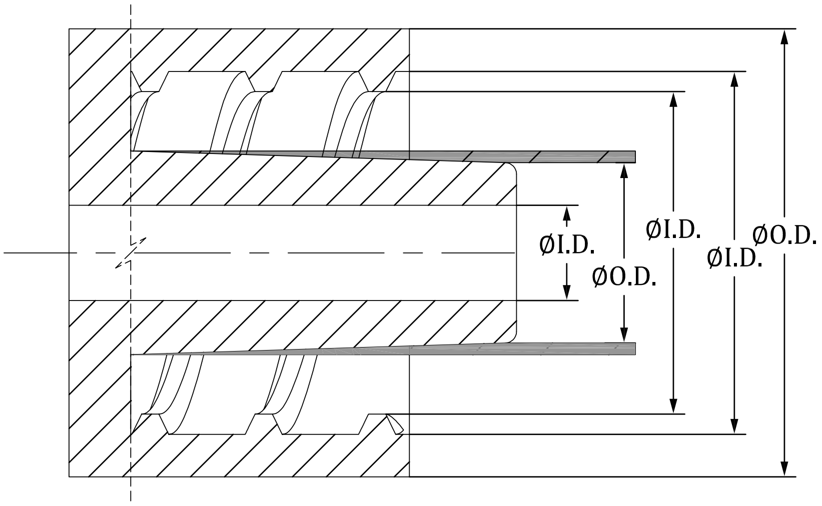
An example of a typical fixed collar male CONNECTOR's diameters to be evaluated are shown in Figure B.1. Features that shall be evaluated include, but are not limited to:

a) where a cone taper or angled surface exists, the full dimensional range of the surface;

EXAMPLE The cone taper tip OD and the cone taper base OD, as they describe the full surface (indicated by the grey band) shown in Figure B.1.

b) the minor and major thread diameters; and

c) the fluid pathway ID.



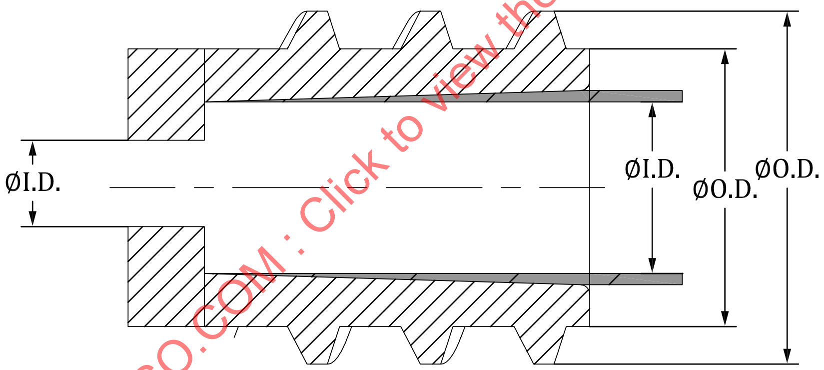
Key

ØI.D. inside diameter of the feature

ØO.D. outside diameter of the feature

Figure B.1 — Example of typical fixed collar male CONNECTOR diameters to be evaluated

A similar example for a full threaded female CONNECTOR is shown in Figure B.2. Again, both ends of a cone taper shall be considered, along with the surface between the two (indicated by the grey band).



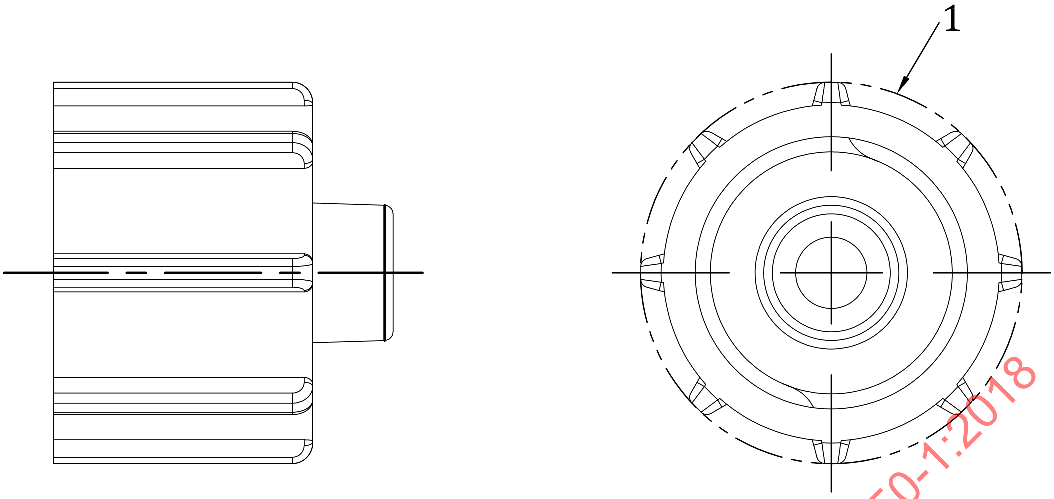
Key

ØI.D. inside diameter of the feature

ØO.D. outside diameter of the feature

Figure B.2 — Example of typical full threaded female CONNECTOR diameters to be evaluated

An example of a rib diameter is shown in Figure B.3. The effective diameter or the rib's largest diameter shall be evaluated. Additionally, the base diameter of the rib shall be evaluated, along with the gap between the ribs.

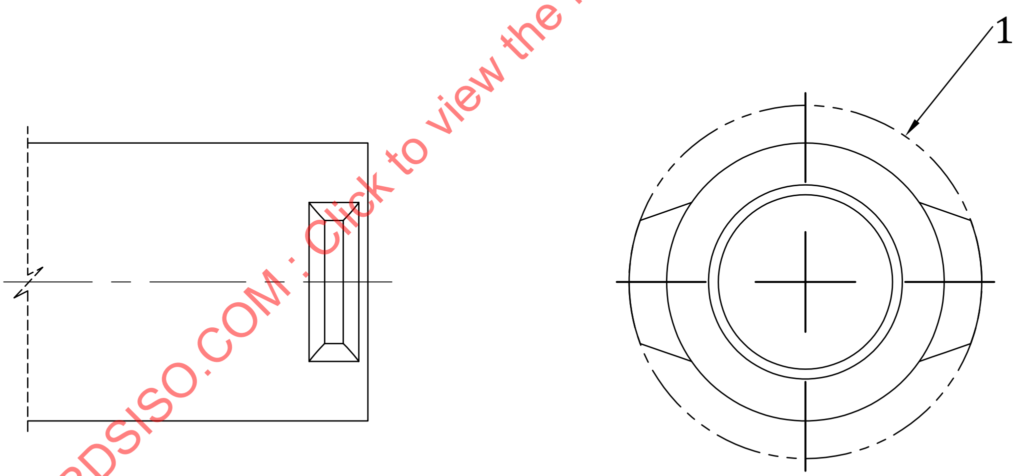


Key

1 effective diameter

Figure B.3 — Example of a typical rib diameter to be evaluated

The same concept is displayed for a CONNECTOR with a lug, as in Figure B.4. The effective diameter of the lug shall be evaluated. Additionally, the base diameter of the lug shall be evaluated, along with the gap between the lugs.



Key

1 effective diameter

Figure B.4 — Example of a typical connector with a lug to be evaluated

There are four general types of interfaces that shall be evaluated for the analysis:

a) cylinder-to-cylinder,

b) cylinder to full thread,

c) cylinder to lug thread, and

d) thread-to-thread.

Figure B.5 displays the cylinder-to-cylinder interface, where one cylinder interacts with another.

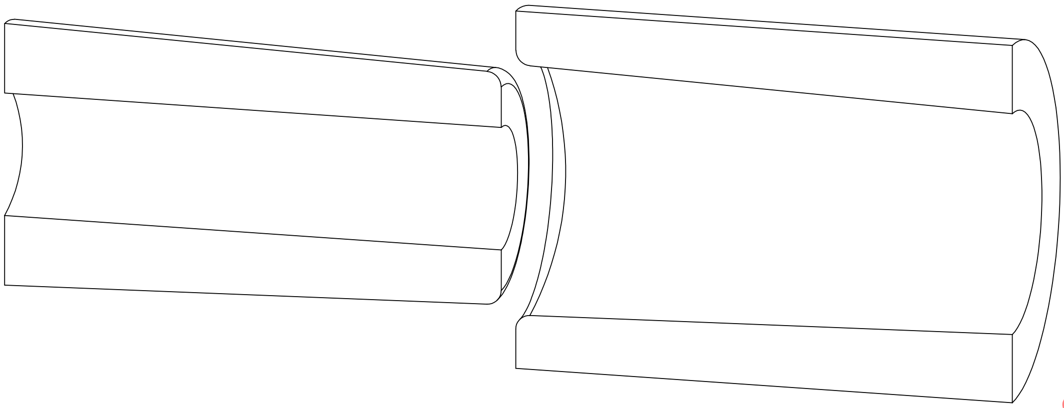


Figure B.5 — Example of a typical cylinder-to-cylinder interface to be evaluated

Figure B.6 displays the cylinder to full thread interface, where the thread of one of the CONNECTORS creates a potential connectable surface with another CONNECTOR's ID. This example is further detailed in the cross- section view of Figure B.7.

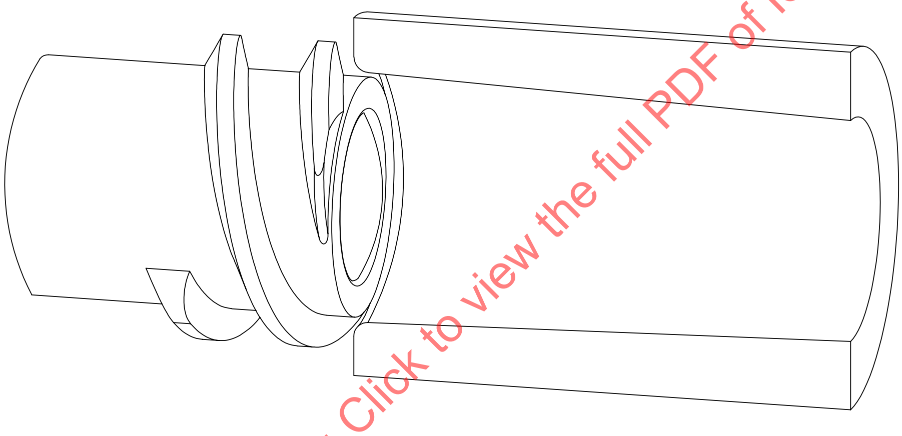


Figure B.6 — Example of a typical cylinder to full thread interface to be evaluated

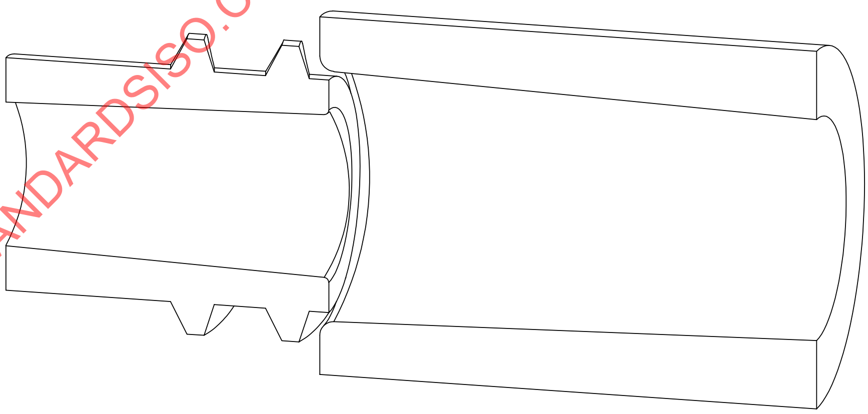


Figure B.7 — Example of a typical cylinder to full thread interface to be evaluated (cross-section view)

Similar to the full thread example, the cylinder to lug thread interface is shown in Figure B.8 and Figure B.9, where the external lug of one of the CONNECTORS creates a potential connectable surface with another CONNECTOR's ID.

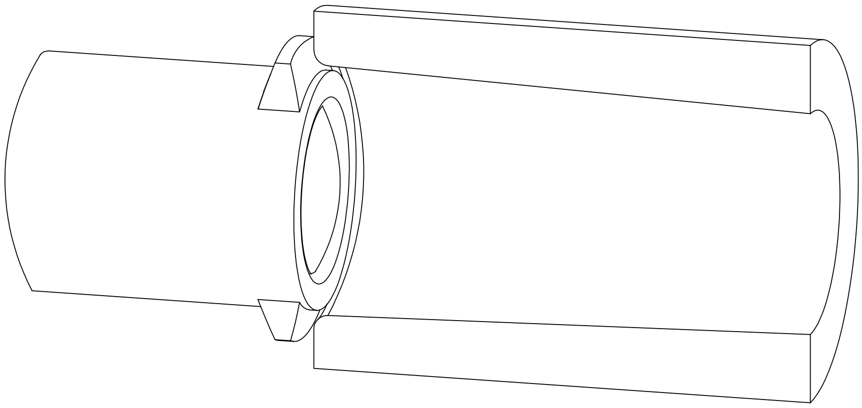


Figure B.8 — Example of a typical cylinder to external lug interface to be evaluated

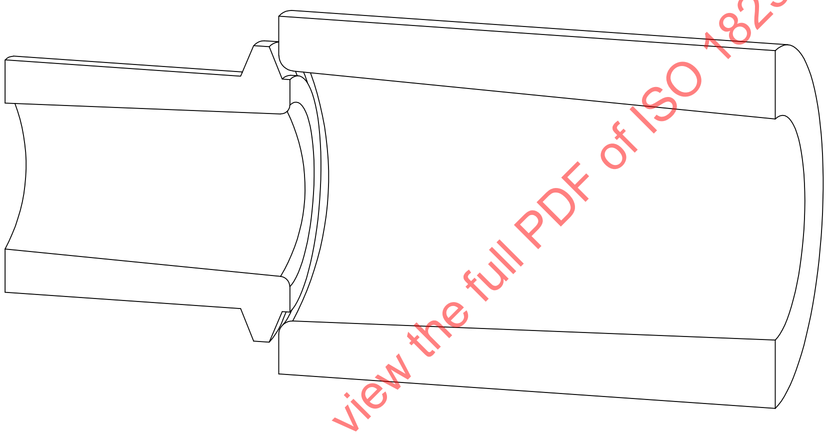


Figure B.9 — Example of a typical cylinder to external lug interface to be evaluated (cross-section view)

The last example is the thread-to-thread interface in Figure B.10, whereby the exterior thread of a CONNECTOR is shown to be evaluated against the possible CONNECTABLE SURFACE of an interior thread.

In a very specific condition where the diameters of the thread forms overlap, the interface between the root and crest of the opposing thread form needs to be considered as a connectable surface. In this situation, the thread forms could inadvertently engage. The inadvertent engagement can occur between lug type, full thread type or a combination of the two.

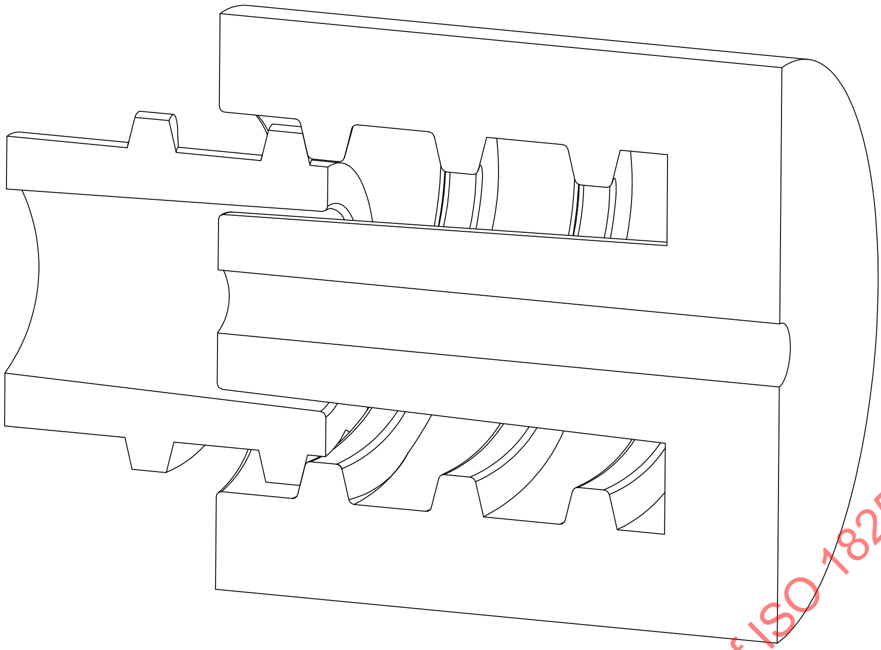


Figure B.10 — Example of a typical thread-to-thread interface to be evaluated (cross-section view)

B.2.4 Identification of the insertion and interaction potential of contactable surfaces

The potential for insertion and interaction shall be evaluated by checking for features that would prevent contactable surfaces from MISCONNECTION.

The potential for insertion is defined as the possibility of one component inserting into the other. The following is a non-exhaustive list of criteria that would indicate insertion potential of one CONNECTOR to another. Insertion potential may in principle exists if:

— a "fillet-to-fillet," "chamfer-to-chamfer," "chamfer-to-fillet," or any other similar contact occurs between the edges of two cylindrical or conical features,

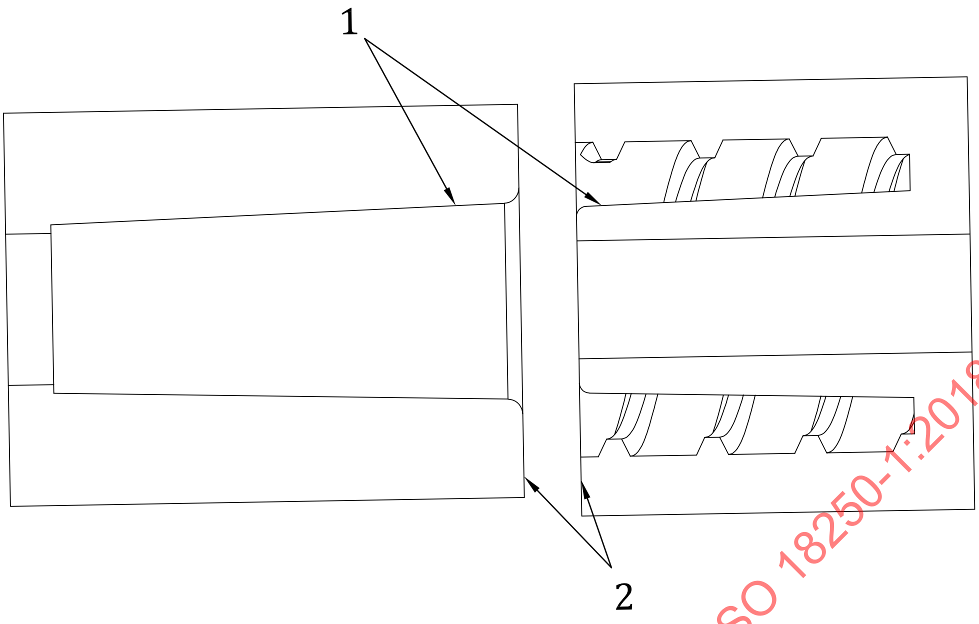
— the outer diameter of a conical or cylindrical feature is equal to or less than the inner diameter of a socket or bore of another component,

— the external dimensions of a feature (not necessarily conical or cylindrical) are such that the feature could fit within an internal geometry on another component,

EXAMPLE A grip with external protruding ribs having an overall edge-to-edge distance less than or equal to that of the interior dimensions of a socket of any shape.

Figure B.11 shows two CONNECTORS that are evaluated in the analysis. Figure B.11 identifies the potential misconnecting surfaces. However, a MISCONNECTION prevention feature or geometry inhibits the CONNECTORS from misconnecting.

A 2D or 3D graphical depiction of the CONNECTORS can be an efficient way to visualize the effect of a MISCONNECTION prevention feature. However, other methods may be used.



Key

1 potential misconnecting surfaces

2 MISCONNECTION prevention features

Figure B.11 — Example of a feature or geometry inhibiting a MISCONNECTION

B.2.5 *Calculation of clearances (gaps), overlaps and interferences

The dimensions of a potential interacting contactable surface ID and OD pairs are evaluated at LMC and MMC in order to determine if a clearance (gap), overlap or interference exists.

To determine the type and level of interaction between two contactable surfaces (such as an OD and ID pair), calculate their relationship when both are at MMC and LMC using the Formula (B.1) for relationship A at MMC conditions and Formula (B.2) for relationship B at LMC conditions:

$$A = \mathrm{ID}_{\mathrm{min}} - \mathrm{OD}_{\mathrm{max}} \quad \text{(B.1)}$$

$$B = \mathrm{ID}_{\mathrm{max}} - \mathrm{OD}_{\mathrm{min}} \quad \text{(B.2)}$$

where

$\mathrm{ID}_{\mathrm{min}}$ is the minimum inside diameter at MMC;

$\mathrm{ID}_{\mathrm{max}}$ is the maximum inside diameter at LMC;

$\mathrm{OD}_{\mathrm{min}}$ is the minimum outside diameter at LMC;

$\mathrm{OD}_{\mathrm{max}}$ is the maximum outside diameter at MMC.

The entire diametrical range of the surface needs to be included. The LMC value of a male cone is the minimum diameter at the small end of the cone. The MMC value of the same male cone is the maximum diameter of the large end of the cone.

B.2.6 *Analysis of the mathematical results of clearances (gaps), overlaps and interferences

If Formulae (B.1) and (B.2) both result in positive values (greater than 0 mm), then a clearance exists at all material conditions and no MISCONNECTION is possible. For very small clearance values, such as ones below 0,05 mm, the CONNECTORS need not readily fall apart due to interface friction, out of roundness, or entrapped air.

If the resulting value of the MMC Formula (B.1) (relationship A) is zero or negative (less than 0 mm) and the resulting values of the LMC Formula (B.2) (relationship B) is zero or positive (greater than 0 mm), then an overlap between the two diameters exist within the range of possible material conditions and a CONNECTION is possible.

For the case of 0 mm values, where by a line to line interface is determined, this is considered a special case of an interference fit and NON-INTERCONNECTABLE testing (physical testing) is then required to determine if a MISCONNECTION is possible.

If both Formula (B.1) and Formula (B.2) result in negative values (less than 0 mm), then interference exists at all material conditions.

See summary in Table B.1.

A MISCONNECTION may still be possible depending on the level of interference and the material properties of the two CONNECTORS. For this case, the resulting values of the LMC Formula (B.2) (relationship B) is compared to the values in Table B.2 for the type of interface (for the effective diameters) in order to determine if a MISCONNECTION is possible.

If the value of relationship B as derived from the dimensional analysis is greater than the values listed in Table B.2 then no MISCONNECTION is possible. If the value of relationship B as derived from the dimensional analysis is less than the values listed in Table B.2 then the interference may not be sufficient to prevent a MISCONNECTION. NON-INTERCONNECTABLE (physical) testing is then required to determine if a MISCONNECTION is possible.

Table B.1 — Dimensional analysis from the formula results

Result of relationship A	Result of relationship B	Outcome
Positive value	Positive value	For values less than 0,5 mm, MISCONNECTION possible: Perform physical TEST METHODS. For values greater than 0,5 mm, clearance, no CONNECTION possible for all material conditions.
Zero or negative value	Zero or positive value	Size of the ID and OD overlap within the tolerance range. CONNECTION ensured within the range of material conditions (neglecting features preventing MISCONNECTION): Perform physical TEST METHODS.
Negative value	Negative value	Interference. CONNECTION possible depending on the level of minimum interference and the stiffness of the materials. See Table B.2.

Table B.2 — MISCONNECTION interference limits

Dimensions in millimetres

Type of interface	No MISCONNECTION is possible[a] when the B values is equal to or greater than:
Cylinder-to-cylinder	0,284
Cylinder to full thread	0,400
Cylinder to lug thread	0,820
Thread-to-thread	0,400

[a] Assuming a material modulus in flexural or tension of 700 MPa or greater.

B.3 Physical TEST METHODS

B.3.1 General

The purpose of the physical TEST METHODS is to further evaluate those potential MISCONNECTIONS that display a very close condition as determined by the dimensional analysis TEST METHOD. Other CONNECTIONS as identified for analysis by the MANUFACTURER may also be evaluated using these physical TEST METHODS. The mechanical TEST METHOD and the leak TEST METHOD comprise the physical TEST METHODS.

The mechanical TEST METHOD evaluates these potential MISCONNECTIONS to determine if a CONNECTION is made.

The leak TEST METHOD determines whether a MISCONNECTION creates a seal adequate to inadvertently administer fluid.

B.3.2 *Requirements

The RESERVOIR CONNECTOR under evaluation shall disengage from the target interference CONNECTOR or feature under its own weight or 0,02 N (about 2 g), whichever is greater, when tested according the mechanical TEST METHOD in B.3.5, or the MISCONNECTION is classified as an unintended CONNECTION.

The RESERVOIR CONNECTOR and simulated mating CONNECTOR, which is classified as having an unintended CONNECTION, shall leak more than 75 % of the total fluid when tested per the TEST METHOD in B.3.6, or the CONNECTION is classified as an unacceptable MISCONNECTION.

B.3.3 RESERVOIR CONNECTOR under evaluation

The RESERVOIR CONNECTOR under evaluation shall be made:

a) of a material with a nominal modulus of elasticity in tensile or flexure within the range of:

   — the minimum modulus as specified for the RESERVOIR CONNECTOR, and

   — the minimum modulus plus 100 MPa; and

b) to (as far as is practicable) dimensions within, but biased to the worst case extents of, the tolerance range of the RESERVOIR CONNECTOR design being evaluated.

B.3.4 Target interference CONNECTOR or feature

The target interference CONNECTOR or feature shall:

a) be produced (e.g. moulded or machined) from a material with a nominal modulus of elasticity in tensile or flexure no greater than the minimum nominal modulus as specified for the target interference CONNECTOR or feature plus 100 MPa;

b) be produced (e.g. moulded or machined) with a feature that has the dimensions sized and appropriately modified to reflect the interference as calculated during the dimensional analysis; and

   The actual samples of the RESERVOIR CONNECTORS under evaluation will most likely not reflect the dimensions causing the potential MISCONNECTION, but should be within the tolerance range as specified. For this reason, the corresponding dimensions of the target interference CONNECTOR or feature are intended to be adjusted accordingly to obtain the interference as calculated during the dimensional analysis.

c) include the features of the target interference CONNECTOR or feature not directly involved with the interference under evaluation that mimic the target interference CONNECTOR or feature.

   EXAMPLES Such features can include outside diameters, inside diameters, threads, ribs and flanges that exist in the vicinity of the potentially misconnecting feature.

NOTE The target interference CONNECTOR or feature is intended to be customized to the as-built metrology of the RESERVOIR CONNECTOR under evaluation. Therefore, the target interference CONNECTOR or feature is intended to be expendable during the test.

B.3.5 Mechanical TEST METHOD

B.3.5.1 Apparatus

a) The RESERVOIR CONNECTOR under evaluation.

b) The target interference CONNECTOR or feature.

c) A means to simultaneously apply an axial force of 70 N and a torque of 0,12 N·m.

B.3.5.2 Test sample preconditioning

Prior to testing, precondition the RESERVOIR CONNECTOR under evaluation and the target interference CONNECTOR or feature at 20 °C ± 5 °C and a relative humidity of 50 % ± 10 % for not less than 1 h.

B.3.5.3 *PROCEDURE

a) Attempt to assemble the RESERVOIR CONNECTOR under evaluation to the target interference CONNECTOR or feature by applying an axial force at a rate of 10 N/s ± 1 N/s up to an applied force of 70 N ± 1 N and a simultaneous torque of 0,12 N·m ± 0,02 N·m to a limit of no more than 90° of rotation. Apply the torque in a clockwise direction.

b) Hold the assembly force, torque and rotation angle for 10 s ± 1 s.

NOTE The maximum torque might not be achieved due to the lubricious nature or geometry of the CONNECTORS in the test.

The assembly method may need to be revised depending on design of the RESERVOIR CONNECTOR under evaluation (e.g. the presence of features to prevent rotation, floating or rotatable collars, or latching mechanisms) maintaining the force and torque requirements.

c) Without activation of any latch or disengagement mechanism, release the applied force and torque.

d) While holding the target interference CONNECTOR or feature with the RESERVOIR CONNECTOR under evaluation below, confirm that the assembled RESERVOIR CONNECTOR disengages from the simulated mating CONNECTOR under its own weight.

e) If the RESERVOIR CONNECTOR under evaluation does not disengage and the mass of the RESERVOIR CONNECTOR under evaluation is less than 2 g, clamp one end and then apply a force of 0,02 N normal to the CONNECTION axis at the opposite end of the unclamped end. Confirm that the assembled RESERVOIR CONNECTOR under evaluation disengages from the target interference CONNECTOR or feature.

f) If the RESERVOIR CONNECTOR under evaluation does not disengage, perform the leak TEST METHOD given in B.3.6.

g) If applicable (i.e. for a threaded RESERVOIR CONNECTOR under evaluation or target interference CONNECTOR or feature with left-handed threads), perform a) to f) by assembling the CONNECTORS in a counter-clockwise direction in step a).

h) Repeat a) to g) for every potentially misconnecting feature.

B.3.6 Leak TEST METHOD

B.3.6.1 Apparatus

a) The RESERVOIR CONNECTOR under evaluation.

b) The appropriate target interference CONNECTOR or feature with provision for attachment of the pressure source.

c) A means to simultaneously apply an axial force of 70 N and a torque of 0,12 N·m.

d) Distilled or potable water. The water may be dyed with methylene blue or other chemicals at a dose that does not noticeably change the rheological behaviour of water.

The MANUFACTURER should evaluate the clinical relevance of the medium used for this leak TEST METHOD as there can be instances where water does not adequately represent the clinical use. The clinical use of both the RESERVOIR CONNECTOR under evaluation as well as the APPLICATION represented by the target interference CONNECTOR or feature should be considered. For example, there can be circumstances where under actual clinical use, the fluid that flows through the MISCONNECTION between the RESERVOIR CONNECTOR being evaluated and the target interference CONNECTOR or feature could be of higher viscosity. A higher viscosity fluid can result in less leakage and more fluid flowing through the fluid path.

e) A syringe with a minimum volume capacity of 10 ml.

EXAMPLE A syringe complying with ISO 7886-1.

f) A length of tubing not exceeding 15 cm in length with an inner diameter not less than the maximum inner diameter of the bore of the target interference connector or feature.

g) A pinch clamp sized for the tubing.

h) A weigh pan.

i) Gram scales.

B.3.6.2 Test sample preconditioning

Prior to testing, precondition the RESERVOIR CONNECTOR under evaluation and the target interference CONNECTOR or feature at 20 °C ± 5 °C and a relative humidity of 50 % ± 10 % for not less than 1 h.

B.3.6.3 PROCEDURE

a) Assemble the RESERVOIR CONNECTOR to the target interference CONNECTOR or feature by applying an axial force at a rate of 10 N/s ± 1 N/s up to an applied force of 70 N ± 1 N and a simultaneous torque of 0,12 N·m ± 0,02 N·m to a limit of no more than 90° of rotation. Apply the torque in a clockwise direction.

b) Hold the assembly force and torque or rotation angle for 10 s ± 1 s.

The assembly method may need to be revised depending on design of the RESERVOIR CONNECTOR under evaluation (e.g. the presence of features to prevent rotation, floating or rotatable collars, or latching mechanisms) maintaining the force and torque requirements.

NOTE The maximum torque might not be achieved due to the lubricious nature or geometry of the CONNECTORS in the test.

If the RESERVOIR CONNECTOR under evaluation and target interference CONNECTOR or feature are pre-attached per the fit test described in B.3.5, they need not be reassembled.

c) Without activation of any latch or disengagement mechanism, release applied force and torque.

d) Assemble the apparatus as shown in Figure B.12 with the fluid path of the RESERVOIR CONNECTOR under evaluation and target interference CONNECTOR or feature and the outlet of the orifice/tubing on a level plane.

e) Prime the RESERVOIR CONNECTOR under evaluation and target interference CONNECTOR or feature, tubing and the simulated orifice with water by filling the circuit until water drips from the end of the orifice or tubing. Pinch the tubing to prevent leakage.

f) Place the syringe on the scales and zero the scales by pressing the tare button.

g) Fill the syringe with water.

h) Weigh the filled syringe on the scales and RECORD this mass as m_1 (syringe water only).

i) Press the filled syringe into the simulated mating CONNECTOR and open the pinch clamp.

j) Confirm that the CONNECTION between the syringe and the simulated mating CONNECTOR does not leak water during the test.

k) Place the weigh pan onto the scales and zero the scale by pressing the tare button.

l) Place the weigh pan under the orifice or tubing such that water that emerges from the tubing is collected in the weigh pan.

m) Slowly depress the syringe plunger such that the water is fully expelled in 7 s to 15 s.

n) Weigh the pan with water collected from the end of the tubing. RECORD this mass as m_2. This represents the water that did not leak from the assembly.

o) Calculate the percentage of water leaking (L_w) from the MISCONNECTION using Formula (B.3).

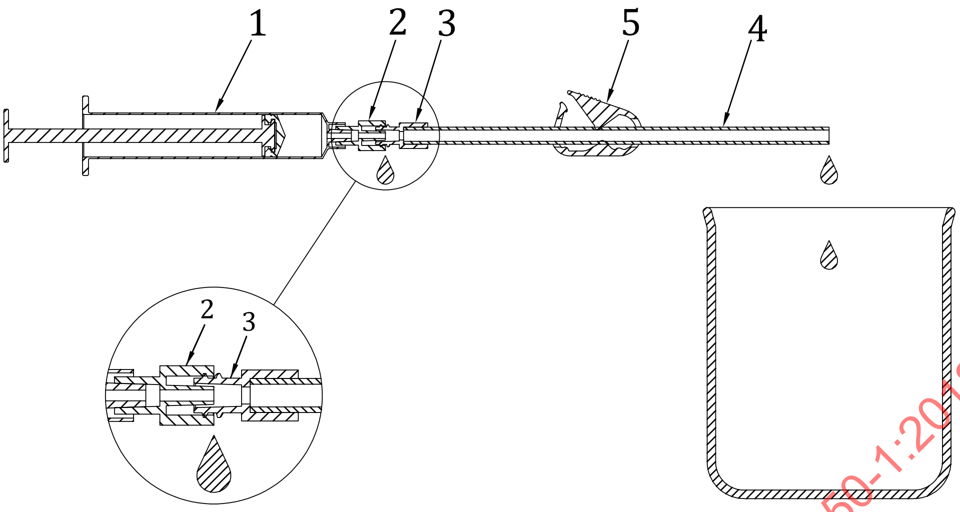
$$L_w = \frac{m_1 - m_2}{m_1} \times 100 \tag{B.3}$$

where

m_1 is the mass measured in step h);

m_2 is the mass measured in step n).

p) Confirm that $L_w > 75$.



Key

1 pressure source (e.g. syringe)

2 target interference CONNECTOR or feature

3 RESERVOIR CONNECTOR under evaluation

4 tubing

5 pinch clamp

Figure B.12 — Leak TEST METHOD setup

Annex C
(normative)

*Positive pressure liquid leakage TEST METHOD

C.1 Principle

A CONNECTOR is assembled to a reference CONNECTOR. Water is introduced into the CONNECTION and pressurized for the hold period.

C.2 *Test conditions

C.2.1 Test sample preconditioning

Prior to testing, precondition the CONNECTORS under test at 20 °C ± 5 °C and 50 % ± 10 % relative humidity for not less than 24 h. Preconditioning does not need to 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 relative humidity between 25 % and 65 %, unless other ranges are specified in the relevant APPLICATION part of the ISO 18250 series.

C.3 Apparatus

a) The male or female CONNECTOR under test.

b) The appropriate reference CONNECTOR, as specified in the relevant APPLICATION part of the ISO 18250 series 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 the ISO 18250 series.

d) A means to contain and pressurize water to the specified test pressure. Rigid fixtures and apparatus materials (such as metal or very stiff plastics) should be used to avoid inaccurate test results.

e) A pressure gauge capable of measuring the applied positive liquid pressure with a minimum accuracy of 1 % of the reading.

f) A device capable of measuring and displaying the elapsed time with an accuracy of ± 1 s.

g) Distilled or potable water. The water may be dyed with methylene blue or other chemicals at a dose that do not noticeably change the rheological behaviour of water.

C.4 PROCEDURE

a) For a TWIST-LOCK CONNECTOR

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

2) Take care not to make the locking lugs interfere with each other, place the CONNECTOR under test by applying axial force not less than 27,5 N, or different if specified in the relevant APPLICATION part of the ISO 18250 series, so that CONNECTORS fully contact mating surfaces.

3) Assemble by applying an axial force not less than 27,5 N for a minimum of 5 s, or different if specified in the relevant APPLICATION part of the ISO 18250 series, while rotating the CONNECTOR under test to a torque not less than 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, until fully assembled.

b) For floating or rotating screw-thread locking CONNECTORS

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

2) Insert the male geometric feature into the female port and then screw the revolving lock until the thread is securely engaged. During insertion the force can vary dependent on the presence of a sealing membrane in different locations and on physical properties. After engagement settle the CONNECTION by applying a 0,25 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque to the revolving lock for a time between 5 s and 10 s.

c) For a locking CONNECTOR with fixed threads

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

2) Assemble by applying an axial force of between 26,5 N and 27,5 N for 5 s to 6 s while rotating the CONNECTOR under test to a torque of between 0,08 N·m and 0,12 N·m, or different if specified in the relevant APPLICATION part of this series of standards. After engagement settle the CONNECTION by applying a 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque for a time between 5 s and 10 s.

d) Introduce water into the assembly to expel the air. If the RESERVOIR system is vented, sealing the vent might be required to prevent leakage.

e) Ensure that the outside of the CONNECTOR assembly is dry.

f) With the axis of the assembled CONNECTOR horizontal, seal the assembly outlet and increase the internal water pressure to 50^{+5}_{-0} kPa, or different if specified in the relevant APPLICATION part of the ISO 18250 series.

g) Maintain the pressure for the hold period of 30 s, or different if specified in the relevant APPLICATION part of the ISO 18250 series, while maintaining the assembled CONNECTORS in the horizontal orientation.

h) Visually inspect for a falling drop of water from the CONNECTION during the specified hold period.

C.5 Test report

The test report shall include at least the following elements:

— a statement specifying that testing was performed according to ISO 18250-1:2018, Annex C, Positive pressure liquid leakage test method;

— the description/identification of the CONNECTORS under test;

— the number of CONNECTORS tested;

— the applied pressure used;

— the acceptance criterion used;

— the measured test pressure;

— the hold period of the test; and

— the presence or absence of a falling drop of water within the test period of 30 s, or different if specified in the relevant APPLICATION part of the ISO 18250 series.

Annex D
(normative)

*Sub-atmospheric-pressure air leakage TEST METHOD

D.1 Principle

Air leakage during aspiration in a CONNECTOR assembly is tested by measuring the change in sub-atmospheric pressure over time after the vacuum source is shut off.

D.2 *Test conditions

D.2.1 Test sample preconditioning

Prior to testing, precondition the CONNECTORS under test at 20 °C ± 5 °C and 50 % ± 10 % relative humidity for not less than 24 h. Preconditioning does not need to 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 relative humidity between 25 % and 65 %, unless other ranges are specified in the relevant APPLICATION part of the ISO 18250 series.

D.3 Apparatus

a) The male or female CONNECTOR under test.

b) The appropriate reference CONNECTOR, as specified in the relevant APPLICATION part of the ISO 18250 series 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 the ISO 18250 series.

d) A vacuum source.

EXAMPLE A syringe in accordance with ISO 7886-1.

e) A device capable of measuring and displaying the elapsed time with an accuracy of ± 1 s.

f) A pressure gauge capable of measuring the applied sub-atmospheric pressure.

g) A stop valve.

h) A leak proof plug.

An automated pressure decay leak test system may be substituted for items d), f), g) and h).

If a digital pressure gauge is used with manual recording of data, the gauge should incorporate some form of a data stabilization algorithm to facilitate easy reading of the digital display.

D.4 Procedure

a) For a TWIST-LOCK CONNECTOR

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

   2) Taking care not to make the locking lugs interfere with each other, place the CONNECTOR under test by applying axial force not less than 27,5 N, or different if specified in the relevant APPLICATION part of the ISO 18250 series, so that CONNECTORS fully contact mating surfaces.

   3) Assemble by applying an axial force not less than 27,5 N for a minimum of 5 s, or different if specified in the relevant APPLICATION part of the ISO 18250 series, while rotating the CONNECTOR under test to a torque not less than 0,12 N·m or different if specified in the relevant APPLICATION part of the ISO 18250 series, until fully assembled.

b) For floating or rotating screw-thread locking CONNECTORS

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

   2) Insert the male geometric feature into the female port and then screw the revolving lock until the thread is securely engaged. During insertion the force can vary dependent on the presence of a sealing membrane in different locations and on physical properties. After engagement settle the CONNECTION by applying a 0,25 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque to the revolving lock for a time between 5 s and 10 s.

c) For a locking CONNECTOR with fixed threads

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

   2) Assemble by applying an axial force of between 26,5 N and 27,5 N for 5 s to 6 s while rotating the CONNECTOR under test to a torque of between 0,08 N·m and 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series. After engagement settle the CONNECTION by applying a 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque for a time between 5 s and 10 s.

d) Assemble the sub-atmospheric-pressure air leak test apparatus (see example in Figure D.1).

e) If the RESERVOIR system is vented, sealing the vent might be required to prevent leakage.

f) The internal volume of the leak test apparatus on the test sample side of the stop valve (opposite the vacuum source) shall not exceed 25 ml.

g) Seal the outlet bore of the CONNECTOR under test so that it is airtight.

h) Apply the sub-atmospheric pressure specified in the relevant APPLICATION part for the CONNECTOR system under test and close the valve.

i) RECORD the pressure and start the stopwatch.

j) Wait the hold period specified in the relevant APPLICATION part for the CONNECTOR system under test and record the pressure and time.

k) Calculate the change in pressure.

l) Calculate the leakage index L on the basis of the following Formula (*D.1).

$$L = \frac{p_s}{p_t} \times v \times \frac{\Delta p}{\Delta t} \quad (*D.1)$$

where

L is the leak age index;

p_s is the specified nominal sub-atmospheric test pressure;

p_t is the actual sub-atmospheric test pressure at the start of the test;

v is the volume between the valve and the test specimen;

Δp is the pressure change during the test period;

Δt is the test period.

EXAMPLE At a specified sub-atmospheric pressure of 40 kPa (gauge), a test sub-atmospheric pressure of 39 kPa (gauge) and a total volume of 10 ml, a pressure change of 10 kPa (gauge) is established within a period of 25 s, or

$$L = \frac{-4 \times 10^4}{-3{,}9 \times 10^4} \times 10 \times 10^{-6} \times \frac{1 \times 10^4}{25}$$

$$L = 0{,}004\,1 \text{ Pa} \cdot \text{m}^3 / \text{s}$$

m) Verify that the leakage index does not exceed the value specified in the relevant APPLICATION part for the CONNECTOR system under test.

D.5 Test report

The test report shall include at least the following elements:

— a statement specifying that testing was performed according to ISO 18250-1:2018, Annex D, Sub-atmospheric-pressure air leakage test method;

— the description/identification of the CONNECTORS under test;

— the number of CONNECTORS tested;

— the applied pressure used;

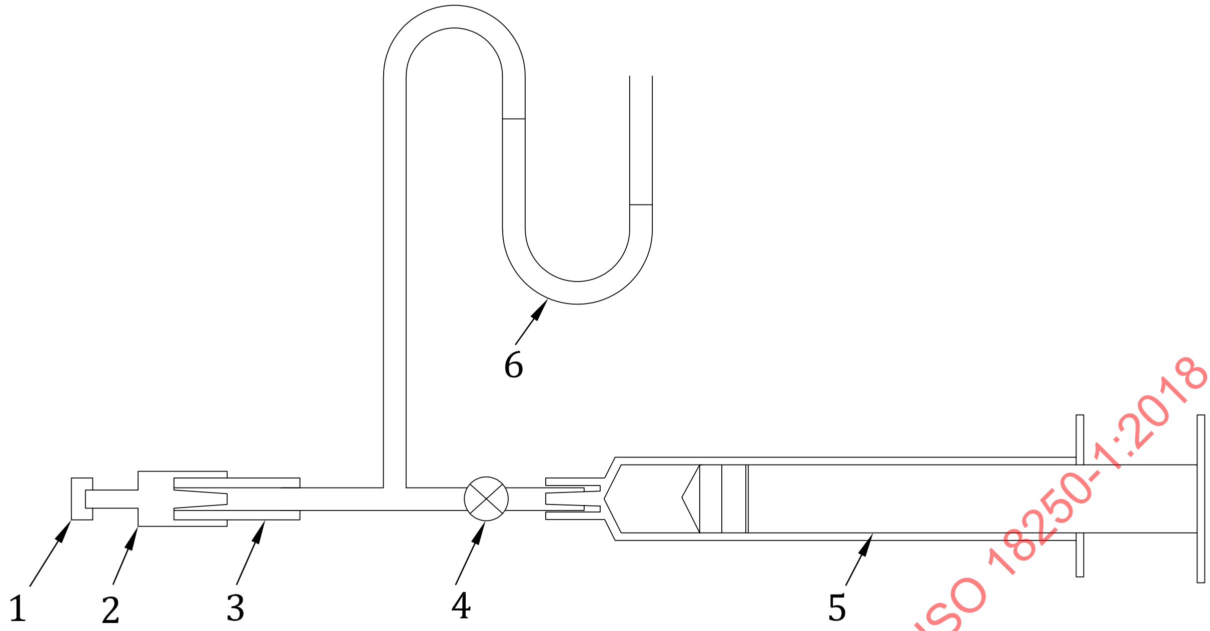
— the acceptance criterion used;

— the volume of the test apparatus;

— the hold period of the test;

— the pressure at the start and end of the test; and

— the calculated leak index.



Key

1 leak-proof plug

2 CONNECTOR under test

3 reference CONNECTOR

4 stop-valve

5 vacuum source, e.g. a syringe

6 pressure-measuring device, e.g. a manometer

Figure D.1 — Example sub-atmospheric-pressure air leakage test apparatus

Annex E
(normative)

*Stress cracking TEST METHOD

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 the leak test.

E.2 *Test conditions

E.2.1 Test sample preconditioning

Prior to testing, precondition the CONNECTORS under test at 20 °C ± 5 °C and 50 % ± 1 % relative humidity for not less than 24 h. Preconditioning does not need to 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 relative humidity between 25 % and 65 %, unless other ranges are specified in the relevant APPLICATION part of the ISO 18250 series.

E.3 Apparatus

a) The male or female CONNECTOR under test.

b) The appropriate reference CONNECTOR, as specified in the relevant APPLICATION part of the ISO 18250 series for the stress cracking 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 the ISO 18250 series.

d) A device capable of measuring and displaying the elapsed time with an accuracy of ± 10 min for at least 48 h.

E.4 PROCEDURE

a) For a TWIST-LOCK CONNECTOR

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

   2) Taking care not to make the locking lugs interfere with each other, place the CONNECTOR under test by applying axial force not less than 27,5 N, or different if specified in the relevant APPLICATION part of the ISO 18250 series, so that CONNECTORS fully contact mating surfaces.

   3) Assemble by applying and axial force not less than 27,5 N for a minimum of 5 s, or different if specified in the relevant APPLICATION part of the ISO 18250 series, while rotating the

CONNECTOR under test to a torque not less than 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, until fully assembled.

b) For floating or rotating screw-thread locking CONNECTORS

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

   2) Insert the male geometric feature into the female port and then screw the revolving lock until the thread is securely engaged. During insertion the force can vary dependent on the presence of a sealing membrane in different locations and on physical properties. After engagement settle the CONNECTION by applying a 0,25 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque to the revolving lock for a time between 5 s and 10 s.

c) For a locking CONNECTOR with fixed threads

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

   2) Assemble by applying an axial force of between 26,5 N and 27,5 N for 5 s to 6 s while rotating the CONNECTOR under test to a torque of between 0,08 N·m and 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series. After engagement settle the CONNECTION by applying a 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque for a time between 5 s and 10 s.

d) 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 18250 series.

e) Verify that the CONNECTOR under test properly seals by performing a leakage test as specified in the relevant APPLICATION part of the ISO 18250 series. The preconditioning PROCESS of the leakage test need not be performed.

E.5 Test report

The test report shall include at least the following elements:

— a statement specifying that testing was performed according to ISO 18250-1:2018, Annex E, Stress cracking test method;

— the description/identification of the CONNECTORS under test;

— the number of CONNECTORS tested;

— the duration of the test; and

— the results of the leakage test performed.

Annex F
(normative)

*Resistance to separation from axial load TEST METHOD

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 CONNECTORS under test at 20 °C ± 5 °C and 50 % ± 10 % relative humidity for not less than 24 h. Preconditioning does not need to 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 relative humidity between 25 % and 65 %, unless other ranges are specified in the relevant APPLICATION part of the ISO 18250 series.

F.3 Apparatus

a) The male or female CONNECTOR under test.

b) The appropriate reference CONNECTOR, as specified in the relevant APPLICATION part of the ISO 18250 series for the resistance to separation TEST METHOD, to be assembled to the CONNECTOR under test.

c) 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 18250 series.

d) A device capable of measuring and displaying the elapsed time.

e) A means of measuring the applied axial separation force.

F.4 PROCEDURE

a) For a TWIST-LOCK CONNECTOR

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

2) Taking care not to make the locking lugs interfere with each other, place the CONNECTOR under test by applying axial force not less than 27,5 N, or different if specified in the relevant APPLICATION part of the ISO 18250 series, so that CONNECTORS fully contact mating surfaces.

3) Assemble by applying an axial force not less than 27,5 N for a minimum of 5 s, or different if specified in the relevant APPLICATION part of the ISO 18250 series, while rotating the

CONNECTOR under test to a torque not less than 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, until fully assembled.

b) For floating or rotating screw-thread locking CONNECTORS

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

2) Insert the male geometric feature into the female port and then screw the revolving lock until the thread is securely engaged. During insertion the force can vary dependent on the presence of a sealing membrane in different locations and on physical properties. After engagement settle the CONNECTION by applying a 0,25 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque to the revolving lock for a time between 5 s and 10 s.

c) For a locking CONNECTOR with fixed threads

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

2) Assemble by applying an axial force of between 26,5 N and 27,5 N for 5 s to 6 s while rotating the CONNECTOR under test to a torque of between 0,08 N·m and 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series. After engagement settle the CONNECTION by applying a 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque for a time between 5 s and 10 s.

d) Apply minimum axial force of 35 N, or different if specified in the relevant APPLICATION part of the ISO 18250 series, in a direction away from the test fixture at a rate of approximately 10 N/s until the minimum specified force is reached. For CONNECTORS with floating collar apply the axial force to the body that includes the mating surfaces.

e) Hold the axial force for the hold period of 15 s, or different if specified in the relevant APPLICATION part of the ISO 18250 series. Do not apply any force in other directions.

f) Verify that the CONNECTORS have not completely detached.

F.5 Test report

The test report shall include at least the following elements:

— a statement specifying that testing was performed according to ISO 18250-1:2018, Annex F, Resistance to separation from axial load test method;

— the CONNECTORS under test;

— the number of CONNECTORS tested;

— the applied axial force;

— the duration of the test; and

— the presence or absence of the separation of the CONNECTORS.

Annex G
(normative)

*Resistance to separation from unscrewing TEST METHOD

G.1 Principle

The security of CONNECTION to a twist of male and female 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 CONNECTORS under test at 20 °C ± 5 °C and 50 % ± 10 % relative humidity for not less than 24 h. Preconditioning does not need to 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 relative humidity between 25 % and 65 %, unless other ranges are specified in the relevant APPLICATION part of the ISO 18250 series.

G.3 Apparatus

a) The male or female CONNECTOR under test.

b) The appropriate reference CONNECTOR, as specified in the relevant APPLICATION part of the ISO 18250 series for the resistance to separation 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 the ISO 18250 series.

d) A device capable of measuring and displaying the elapsed time.

e) A means of measuring the applied unscrewing torque.

G.4 PROCEDURE

a) For a TWIST-LOCK CONNECTOR

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

2) Taking care not to make the locking lugs interfere with each other, place the CONNECTOR under test by applying axial force not less than 27,5 N, or different if specified in the relevant APPLICATION part of the ISO 18250 series, so that CONNECTORS fully contact mating surfaces.

3) Assemble by applying and axial force not less than 27,5 N for a minimum of 5 s, or different if specified in the relevant APPLICATION part of the ISO 18250 series, while rotating the

CONNECTOR under test to a torque not less than 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, until fully assembled.

b) For floating or rotating screw-thread locking CONNECTORS

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

2) Insert the male geometric feature into the female port and then screw the revolving lock until the thread is securely engaged. During insertion the force can vary dependent on the presence of a sealing membrane in different locations and on physical properties. After engagement settle the CONNECTION by applying a 0,25 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque to the revolving lock for a time between 5 s and 10 s.

c) For a locking CONNECTOR with fixed threads

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

2) Assemble by applying an axial force of between 26,5 N and 27,5 N for 5 s to 6 s while rotating the CONNECTOR under test to a torque of between 0,08 N·m and 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series. After engagement settle the CONNECTION by applying a 0,12 N·m, or different if specified in the relevant APPLICATION part in the ISO 18250 series, torque for a time between 5 s and 10 s.

d) Apply an unscrewing or disassembly torque as specified in the relevant APPLICATION part in the ISO 18250 series for the CONNECTOR system under test to the assembly. For CONNECTORS with floating or rotating collar, apply the unscrewing torque to the collar.

e) Hold the torque at this value for the hold period specified in the relevant APPLICATION part in the ISO 18250 series for the CONNECTOR system under test. Do not apply any supplementary force in other directions.

f) Verify that the CONNECTORS have not completely separated.

G.5 Test report

The test report shall include at least the following elements:

— a statement specifying that testing was performed according to ISO 18250-1:2018, Annex G, Resistance to separation from unscrewing test method;

— the description/identification of the CONNECTORS under test;

— the number of CONNECTORS tested;

— the applied unscrewing torque;

— the duration of the test; and

— the presence or absence of the separation of the CONNECTORS.

Annex H
(normative)

*Resistance to overriding TEST METHOD

H.1 Principle

The resistance to overriding of male and female 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 °C ± 5 °C and 50 % ± 10 % relative humidity for not less than 24 h. Preconditioning does not need to 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 relative humidity between 25 % and 65 %, unless other ranges are specified in the relevant APPLICATION part of the ISO 18250 series.

H.3 Apparatus

a) The male or female CONNECTOR under test.

b) The appropriate reference CONNECTOR, as specified in the relevant APPLICATION part of the ISO 18250 series for the resistance to overriding 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 the ISO 18250 series.

d) A device capable of measuring and displaying the elapsed time.

e) A means of measuring the applied overriding torque.

H.4 PROCEDURE

a) For a TWIST-LOCK CONNECTOR

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

2) Taking care not to make the locking lugs interfere with each other, place the CONNECTOR under test by applying axial force not less than 27,5 N, or different if specified in the relevant APPLICATION part of the ISO 18250 series, so that CONNECTORS fully contact mating surfaces.

3) Assemble by applying and axial force not less than 27,5 N for a minimum of 5 s, or different if specified in the relevant APPLICATION part of ISO 18250 series, while rotating the CONNECTOR

under test to a torque not less than 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, until fully assembled.

b) For floating or rotating screw-thread locking CONNECTORS

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

2) Insert the male geometric feature into the female port and then screw the revolving lock until the thread is securely engaged. During insertion the force can vary dependent on the presence of a sealing membrane in different locations and on physical properties. After engagement settle the CONNECTION by applying a 0,25 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque to the revolving lock for a time between 5 s and 10 s.

c) For a locking CONNECTOR with fixed threads

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

2) Assemble by applying an axial force of between 26,5 N and 27,5 N for 5 s to 6 s while rotating the CONNECTOR under test to a torque of between 0,08 N·m and 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series. After engagement settle the CONNECTION by applying a 0,12 N·m, or different if specified in the relevant APPLICATION part of the ISO 18250 series, torque for a time between 5 s and 10 s.

d) Apply the torque specified in the relevant APPLICATION part for the CONNECTOR system under test to the assembly. For CONNECTORS with floating or rotating collar, apply the overriding torque to the collar.

e) Hold the torque at this value for the hold period specified in the relevant APPLICATION part for the CONNECTOR system under test. Do not apply any supplementary force or torque in other directions.

f) Verify that the threads, lock lugs or guide grooves of the reference CONNECTOR have not completely extended or over-ridden past the threads or lock lugs or guide grooves of the CONNECTOR under test.

H.5 Test report

The test report shall include at least the following elements:

— a statement specifying that testing was performed according to ISO 18250-1:2018, Annex H, Resistance to overriding test method;

— the description/identification of the CONNECTORS under test;

— the number of CONNECTORS tested;

— the applied torque;

— the hold period of the test; and

— the presence or absence of the threads, lugs, lock lugs or guide grooves of the reference CONNECTOR overriding the threads, lugs, lock lugs or guide grooves of the CONNECTOR under test.