INTERNATIONAL STANDARD

ISO 80369-1

Second edition
2018-11

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

Part 1: General requirements

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

Partie 1: Exigences générales

Reference number
ISO 80369-1:2018(E)

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Published in Switzerland

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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*, in collaboration with IEC/TC 62, *Electrical equipment in medical practice,* Subcommittee SC D, *Electromedical equipment* and CEN/CENELEC TC 3/WG 2, *Small-bore connectors*.

This second edition cancels and replaces the first edition (ISO 80369-1:2010), which has been technically revised.

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

The main changes compared to the previous edition are as follows:

— the normative references have been updated;

— the requirement for Alternative SMALL-BORE CONNECTORS, including disclosure and marking requirements have been updated;

— in Annex B, the TEST METHODS for demonstrating NON-INTERCONNECTABLE CHARACTERISTICS to reflect the testing used in the development of ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 have been updated;

— Annex D has been created with the Assessment PROCEDURES SMALL-BORE CONNECTORS which replaces Clause 7 of the previous edition and contains a description of the computer aided design (CAD) analysis that was used in the evaluation of the NON-INTERCONNECTABLE characteristics.

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

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

Introduction

In the 1990s, concern grew regarding the proliferation of MEDICAL DEVICES fitted with Luer CONNECTORS as specified in ISO 80369-7 and the reports of PATIENT death or injury arising from misconnections that resulted in the inappropriate delivery of enteral solutions, intrathecal medication or compressed gases.

Concerns regarding the use of Luer CONNECTORS with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN/BT and the European Commission. In November 1997, the newly created CHeF steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report, CR 13825[12], in which they concluded that there is a problem arising from the use of a single CONNECTOR design to a number of incompatible APPLICATIONS. In a coronary care unit, there are as many as 40 Luer CONNECTORS on the MEDICAL DEVICES used with a single PATIENT. Therefore, it is not surprising that misconnections are made.

MEDICAL DEVICES have, for many years, followed the established principle of "safety under single fault conditions". Simply stated, this means that a single fault should not result in an unacceptable RISK. This principle is embodied in the requirements of numerous MEDICAL DEVICE standards[10]. Extending this principle to the use of Luer CONNECTORS, i.e. that misconnection should not result in an unacceptable RISK to a PATIENT, the FTG recommended that the Luer CONNECTOR should be restricted to MEDICAL DEVICES intended to be connected to the vascular system or a hypodermic syringe. In addition, new designs of SMALL-BORE CONNECTORS should be developed for other APPLICATIONS, and these should be NON-INTERCONNECTABLE with Luer CONNECTORS and each other.

ISO 16142-1 addresses this type of problem in Essential Principle B.1.2 (see Annex F):

— 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 is understood that SMALL-BORE 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 80369 series has, wherever practicable, restricted the number of CONNECTORS for each APPLICATION to one, unless there is sufficient clinical or technical evidence to have more.

It is expected that particular MEDICAL DEVICE standards will reference the interface requirements from the appropriate parts of the ISO 80369 series.

This document contains the general requirements to ensure the prevention of misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS as well as defining those APPLICATIONS.

It specifies the general requirements and TEST METHODS for assessing the NON-INTERCONNECTABLE characteristics of SMALL-BORE CONNECTORS within the ISO 80369 series.

ISO 80369-20 specifies the TEST METHODS for assessing the basic performance requirements specified in ISO 80369-2 to ISO 80369-7 for SMALL-BORE CONNECTORS.

ISO 80369-2 to ISO 80369-7 specify the dimensional requirements for the interfaces of the CONNECTORS and the basic performance requirements for assessing the CONNECTION interconnectability of the CONNECTOR-mating halves.

The designs and dimensions of SMALL-BORE CONNECTORS specified in ISO 80369-2 to ISO 80369-7 have been successfully assessed according to the requirements of this document (i.e. have been proven to be acceptable with regard to the RISK of misconnection with the other CONNECTORS of this series).

Subsequent parts of this series are expected to include requirements with regard to the CONNECTORS used in different APPLICATION categories.

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, and normative text of tables: in smaller type;

— terms defined in Clause 3 of this document or as noted: SMALL CAPITALS TYPE.

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.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

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

Part 1: General requirements

1 *Scope

This document specifies general requirements for SMALL-BORE CONNECTORS, which convey liquids or gases in healthcare APPLICATIONS. These SMALL-BORE CONNECTORS are used in MEDICAL DEVICES or ACCESSORIES intended for use with a PATIENT.

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

These healthcare fields include, but are not limited to:

— BREATHING SYSTEMS and driving gases;

— enteral;

— limb cuff inflation;

— neuraxial;

— intravascular or hypodermic.

This document provides the methodology to assess NON-INTERCONNECTABLE characteristics of SMALL-BORE 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 as specified in this document as well as those that will be developed under future parts of the ISO 80369 series.

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

NOTE 1 Clause 7 allows for additional designs of SMALL-BORE CONNECTORS for new APPLICATIONS for inclusion in the ISO 80369 series.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in the ISO 80369 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, the risks associated with changing to the new SMALL-BORE CONNECTORS as specified in the ISO 80369 series of standards will be considered.

NOTE 3 The CONNECTORS specified in the ISO 80369 series are intended for use only in their specified APPLICATION. Use of these CONNECTORS for other APPLICATIONS increases RISK that a hazardous misconnection could occur.

NOTE 4 MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in the ISO 80369 series to the Secretariat of ISO/TC 210 so that this feedback can be considered during the revision of the relevant part of the ISO 80369 series.

2 *Normative references

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

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

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

IEC 80369-5, *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*

ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

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 and 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 https://www.electropedia.org/

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, 3.3, modified — replaced "equipment" with "MEDICAL DEVICE".]

3.2
APPLICATION
specific healthcare field in which a SMALL-BORE CONNECTOR is intended to be used

Note 1 to entry: Annex E lists APPLICATIONS of SMALL-BORE CONNECTORS.

3.3
CONNECTION
union or joining of mating halves of a CONNECTOR (3.4)

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

3.5
CONTACTABLE SURFACE
any surface on a CONNECTOR that has an interaction potential in which physical contact occurs with any other surface on a specific opposing CONNECTOR

Note 1 to entry: CONTACTABLE SURFACES may include, but are not limited to, sealing surfaces as intended by design, crest geometry of external or internal threads, faces, shrouds, grips, etc. These are surfaces on a CONNECTOR that can possibly interact with another CONNECTOR.

3.6
LEAST MATERIAL CONDITION
LMC
condition in which a feature contains the least amount of material within the stated tolerance

EXAMPLE Maximum hole diameter, minimum shaft diameter.

3.7
MAXIMUM MATERIAL CONDITION
MMC
condition in which a feature contains the maximum amount of material within the stated tolerance

EXAMPLE Minimum hole diameter, maximum shaft diameter.

3.8
NOMINAL (value)
value quoted for reference purposes that is subject to agreed tolerances

[SOURCE: IEC 60601-1:2005, 3.69]

3.9
NON-CONTACTABLE SURFACE
any surface on a CONNECTOR that is unable to come into contact, during an interaction, with any other surface on an opposing CONNECTOR

Note 1 to entry: NON-CONTACTABLE SURFACES may 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 is intended to be covered by tubing or shrouds and grips, etc.

3.10
NON-INTERCONNECTABLE
having characteristics which incorporate geometries or other characteristics that prevent different CONNECTORS from making a CONNECTION

3.11
PATIENT
person undergoing a medical, surgical or dental PROCEDURE

[SOURCE: IEC 60601-1:2005+A1:2012, 3.76, modified — replaced "living being (person or animal)" with "person" and deleted the note.]

3.12
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a MEDICAL DEVICE

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, USER and RESPONSIBLE ORGANIZATION can be one and the same person.

Note 2 to entry: Education and training is included in "use".

[SOURCE: IEC 60601-1:2005, 3.101, modified — replaced "an ME EQUIPMENT or an ME SYSTEM" with "MEDICAL DEVICE".]

3.13
SMALL-BORE
inner-fluid pathway of a CONNECTION with a diameter less than 8,5 mm

Note 1 to entry: For the purposes of this document, the 8,5 mm cone and socket of ISO 5356-1 is not considered a SMALL-BORE CONNECTOR

3.14
TARGET INTERFERENCE CONNECTOR OR FEATURE
component that physically represents a SMALL-BORE CONNECTOR or CONNECTOR feature that is used to evaluate whether a CONTACTABLE SURFACE (3.5) can misconnect with the SMALL-BORE CONNECTOR being evaluated

Note 1 to entry: CONTACTABLE SURFACES are identified during the dimensional analysis per B.2.

3.15
TEST METHOD
definitive PROCEDURE for evaluating CONNECTORS that produces a test result

4 *Materials

The surfaces of SMALL-BORE CONNECTORS necessary to ensure NON-INTERCONNECTABLE characteristics shall be made of materials with a NOMINAL modulus of elasticity either in flexure or in tension greater than 700 MPa, unless specified otherwise in the ISO 80369 series. Surfaces, other than those necessary to ensure NON-INTERCONNECTABLE characteristics, need not comply with this requirement.

Check compliance by applying the tests of ASTM D638-14[13], ISO 527, ASTM D790-17[14] or ISO 178 or for metallic materials, the tests of ISO 6892-1.

NOTE A correlation between the ISO and ASTM TEST METHODS is found in Reference [15].

5 SMALL-BORE CONNECTOR incompatibility

SMALL-BORE CONNECTORS of each APPLICATION category specified in this document shall be NON-INTERCONNECTABLE with any of the SMALL-BORE CONNECTORS of every other APPLICATION category, unless otherwise indicated in this document or within the ISO 80369 series.

Check compliance by confirming that OBJECTIVE EVIDENCE demonstrates 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. Confirm that the SMALL-BORE CONNECTOR is NON-INTERCONNECTABLE.

NOTE 1 For the purpose of this document, dimensional compliance and modulus of elasticity compliance with the requirements of the various APPLICATION parts of the ISO 80369 series is considered sufficient OBJECTIVE EVIDENCE of NON-INTERCONNECTABLE characteristics.

NOTE 2 Annex E lists examples of the sort of MEDICAL DEVICES or ACCESSORIES for which the SMALL-BORE CONNECTORS within each APPLICATION are intended.

6 *CLINICAL applications

6.1 *Additional SMALL-BORE CONNECTOR designs

Designs of SMALL-BORE CONNECTORS other than those specified in 6.2 to 6.5, for inclusion in the ISO 80369 series, and used in MEDICAL DEVICES or ACCESSORIES intended for use with a PATIENT, shall meet the requirements of Clause 4, Clause 7 and Annex D.

When an additional SMALL-BORE CONNECTOR is created or proposed for a new APPLICATION, Annex D requires a new part of the ISO 80369 series to be created.

Check compliance by application of Clause 4, Clause 7 and Annex D.

6.2 Enteral APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in the enteral APPLICATION shall comply with ISO 80369-3, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or ACCESSORY, or shall comply with Clause 7.

Check compliance by inspection of the documentation demonstrating that the SMALL-BORE CONNECTOR conforms to the requirements of ISO 80369-3 or, in case of alternative connectors as per Clause 7, by applying the tests of ISO 80369-3. See also Clause 7 for alternative methods of compliance.

6.3 Limb cuff inflation APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in limb cuff inflation APPLICATION shall comply with IEC 80369-5, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or ACCESSORY, or shall comply with Clause 7.

Check compliance by inspection of the documentation demonstrating that the SMALL-BORE CONNECTOR conforms to the requirements of IEC 80369-5 or, in case of alternative connectors as per Clause 7, by applying the tests of IEC 80369-5. See also Clause 7 for alternative methods of compliance.

6.4 Neuraxial APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in neuraxial APPLICATION shall comply with ISO 80369-6, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or ACCESSORY, or shall comply with Clause 7.

Check compliance by inspection of the documentation demonstrating that the SMALL-BORE CONNECTOR conforms to the requirements of ISO 80369-6 or, in case of alternative connectors as per Clause 7, by applying the tests of ISO 80369-6. See also Clause 7 for alternative methods of compliance.

6.5 Intravascular or hypodermic APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in intravascular or hypodermic APPLICATION shall comply with ISO 80369-7, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or ACCESSORY, or shall comply with Clause 7.

Check compliance by inspection of the documentation demonstrating that the SMALL-BORE CONNECTOR conforms to the requirements of ISO 80369-7 or, in case of alternative connectors as per Clause 7, by applying the tests of ISO 80369-7. See also Clause 7 for alternative methods of compliance.

7 *Alternative SMALL-BORE CONNECTORS

Alternative designs of SMALL-BORE CONNECTORS to those specified in Clause 6 may be used in a MEDICAL DEVICE or ACCESSORY, and if used, they shall:

a) be evaluated according to Clause 5 for NON-INTERCONNECTABLE characteristics, with the exception of a CONNECTOR within the same APPLICATION to which it is intended to connect;

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

c) be evaluated according to the engineering analysis of D.3;

d) comply with the materials characteristics of Clause 4.

The MEDICAL DEVICE or ACCESSORY, which incorporates an alternative design SMALL-BORE CONNECTOR, shall:

e) be marked with either

   — the symbol ISO 15223-1:2016, 5.4.3 (see Table C.1, symbol "consult the instructions for use"), or

   — the safety sign ISO 7010-M002 (see Table C.1, safety sign "consult the accompanying documents is a mandatory action");

f) include in its accompanying documents a warning to the effect that "WARNING: As this medical device uses an alternative small-bore connector design different from those specified in the ISO 80369 series, there is a possibility that a misconnection can occur between this medical device and a medical device using a different alternative small-bore connector, which can result in a HAZARDOUS SITUATION causing HARM to the patient. Special measures need be taken by the user to mitigate these reasonable foreseeable RISKS."

An alternative design SMALL-BORE CONNECTOR that complies with this subclause may claim compliance or conformance with this document, but shall not claim compliance or conformance with the other parts of the ISO 80369 series. Generic claims of compliance or conformance to the ISO 80369 series shall not be made.

Check compliance by confirming that OBJECTIVE EVIDENCE demonstrates that RISKS have been reduced to meet the acceptability criteria specified in Annex B and other acceptability criteria established by the MANUFACTURER for NON-INTERCONNECTABLE characteristics for the MEDICAL DEVICE or ACCESSORY. Confirm compliance with Clause 4, Clause 5 and the specified portions of Annex D.

Annex A
(informative)

Rationale

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.

The clauses in this annex have been so numbered to correspond to the clauses in 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 fluid delivery, enteral feeding, respiratory gas sampling, non-invasive blood pressure measurement and injection of intrathecal medication. Despite the varied nature of the functions performed, many of these MEDICAL DEVICES use a universal system of SMALL-BORE CONNECTORS based on the 6 % Luer tapered CONNECTOR as formerly specified in ISO 594 series. ISO 594 series is now withdrawn and replaced by ISO 80369-7 with the important difference that the latter applies to intravascular or hypodermic applications only.

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[16][17][18][19][20].

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

Introducing a series of NON-INTERCONNECTABLE, SMALL-BORE CONNECTORS for MEDICAL DEVICES will help reduce the likelihood of misconnections and lead to a direct improvement in PATIENT safety. It was important that any series also included the 6 % Luer, although this is now restricted to intravascular or hypodermic APPLICATIONS.

CEN BT TF 123 carried out an extensive RISK ANALYSIS of possible misconnections that might result when the same CONNECTOR is used in different APPLICATIONS. Reducing the identified unacceptable RISKS is the basis of the ISO 80369 series.

Originally, it was hoped that the SMALL-BORE CONNECTORS included in the ISO 80369 series could be designed so that they did not misconnect with other CONNECTORS commonly used within similar environments and covered by ISO/EN standards. (e.g. the nipples in EN 13544-2[11],the conical CONNECTORS in ISO 5356-1 and the temperature sensor ports specified in ISO 80601-2-74).

During the CAD (computer-assisted design) analysis, it became evident that the dimensions contained within these International Standards were not specified in a manner that allows for evaluation of NON-INTERCONNECTABLE characteristics between these CONNECTORS and the CONNECTORS specified in the ISO 80369 series. These CONNECTORS were, therefore, not part of the CAD VERIFICATION/validation

or the NON-INTERCONNECTABLE characteristics testing and might misconnect with the SMALL-BORE CONNECTORS described in the ISO 80369 series.

Clause 2 Normative references

For various reasons the respiratory part of the series of standards (intended to be published as ISO 80369-2) was not available to be referenced at the point in time the voting of this standard was performed. However, it is the clear and confirmed intention of ISO/TC 210/JWG 4 that the respiratory part of the series of standards become part of the ISO 80369 series and that ISO 80369-2 will be added as a normative reference to this standard as soon as this document becomes available so that the content of ISO 80369-2 will — in whole or in part — constitute requirements of this document.

Clause 4 Materials

To prevent misconnection between MEDICAL DEVICES that should not connect, the rigidity of the materials from which SMALL-BORE CONNECTORS are made has been specified to eliminate the possibility of forcing a fit between incompatible SMALL-BORE CONNECTORS made from flexible materials. To achieve this, the committee determined that the previous semi-rigid requirement had to be increased to a more rigid (greater than 700 MPa) material.

NOTE ISO 80369-6 requires the NOMINAL modulus of elasticity to be greater than 950 MPa.

It is understood that SMALL-BORE CONNECTOR systems cannot be designed to overcome all chances of misconnection or to eliminate deliberate misuse. For example, the possibility of the misconnection of a SMALL-BORE CONNECTOR to a specialized PATIENT-access port can still exist. Specialized PATIENT-access ports often require the use of flexible materials which are intended to permit access by a range of MEDICAL DEVICES or ACCESSORIES, such as, endoscopes, bronchoscopes, and surgical instruments. These access ports can permit interconnection with some SMALL-BORE CONNECTORS. The RISKS associated with the use of these specialized PATIENT-access ports are not addressed by this document. MANUFACTURERS of MEDICAL DEVICES or ACCESSORIES and the committees responsible for the development of standards for MEDICAL DEVICES or ACCESSORIES that incorporate these specialized PATIENT-access ports will need to assess these RISKS.

Clause 6 Clinical APPLICATIONS

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

CEN Report, CR 13825[12], identifies possible misconnections between MEDICAL DEVICES involving the conveyance of a gas or liquid for the different APPLICATION categories and classifies each according to the SEVERITY of the HARM that can occur. The report confirms that the APPLICATION categories specified in this document are incompatible, i.e. misconnections among these APPLICATION categories can cause serious injury or death.

The committee reviewed this report and agreed that these APPLICATION categories were the highest areas of RISK to public health from MEDICAL DEVICE misconnection if a misconnection were to occur. This determination comes from years of adverse event reports, literature reviews and research on MEDICAL DEVICE misconnection. It is noted that the identified APPLICATION categories do not encompass all medical areas to which MEDICAL DEVICES are intended to be used and therefore, all potential areas of misconnection might not be addressed by this document. It is intended that the APPLICATION categories in this clause represent a majority of MEDICAL DEVICES containing SMALL-BORE CONNECTORS and therefore, the use of these SMALL-BORE CONNECTORS will bring the RISK of misconnection to an acceptable level.

This clause specifies the APPLICATIONS for each of the standard series parts. The purpose of including these APPLICATIONS is to reduce the RISK of misconnection between these categories to a minimum. For new designs of SMALL-BORE CONNECTOR, by providing OBJECTIVE EVIDENCE that the SMALL-BORE

CONNECTOR meets the requirements set forth in Clause 4, Clause 5, Annex B and Annex D, the RISK of misconnection between APPLICATIONS has been shown to have been minimized.

For various reasons the respiratory part of the series of standards (intended to be published as ISO 80369-2) was not available to be referenced at the point in time the voting of this standard was performed. However, it is the clear and the confirmed intention of ISO/TC 210 to amend this document once ISO 80369-2 becomes available. It is intended to include the future ISO 80369-2 into Clause 6 to the following effect: that "Small-bore connectors intended to be used for connections in the respiratory application shall comply with ISO 80369 2, unless the use of these connectors create an unacceptable risk for a specific medical device or accessory and further that compliance to be checked by inspection of the documentation demonstrating that the small-bore connector conforms to the requirements of the future ISO 80369-2 or, in case of alternative connectors as per by Clause 7, by applying the tests of the future ISO 80369-2."

In some cases, the RISK of misconnection cannot be fully assessed until the SMALL-BORE CONNECTOR is part of a MEDICAL DEVICE or ACCESSORY. It is also recognized that not all possible means of preventing misconnection can be part of the design of the SMALL-BORE CONNECTOR interfaces. The ultimate responsibility to assess the RISKS of misconnection lies with the MANUFACTURER of the MEDICAL DEVICE or ACCESSORY.

Sublause 6.1 Additional SMALL-BORE CONNECTOR designs

The purpose of this subclause is to allow other APPLICATIONS not already identified to be included in the ISO 80369 series. It provides the requirements to ensure that new SMALL-BORE CONNECTORS for inclusion into the ISO 80369 series are adequately tested and validated.

Clause 7 Alternative SMALL-BORE CONNECTORS

Despite the intention to restrict the number of SMALL-BORE CONNECTORS to one for each APPLICATION, unless there are clinical or technical reasons for more, it is not the intent of this document to prevent the use of alternative designs (proprietary SMALL-BORE CONNECTORS) within an identified APPLICATION or a new APPLICATION, should a MANUFACTURER deem it necessary. Clause 7 has therefore been included, allowing alternative designs of SMALL-BORE CONNECTORS as long as they are subjected to the same requirements as the SMALL-BORE CONNECTORS specified in this series.

As MANUFACTURERS of alternative designs of SMALL-BORE CONNECTORS cannot protect against possible misconnections with other alternative SMALL-BORE CONNECTORS of differing APPLICATIONS, it was agreed that MANUFACTURERS are required to make the USERS aware that the RISKS of misconnections and HARM to the PATIENT were still possible. This document does not protect against misconnections between these independently-developed alternative CONNECTORS.

Sublause D.2 Design proposal

The proposal serves two interrelated purposes. One provides justification for a new APPLICATION category and the other introduces a design for a new SMALL-BORE CONNECTOR for that category. ISO/TC 210 evaluates the proposal to determine if a new APPLICATION category is needed and that necessary requirements for the new SMALL-BORE CONNECTOR for that category have been identified.

The need for a new APPLICATION category can arise by the introduction of a MEDICAL DEVICE for a new medical APPLICATION or changing conveyance requirements for MEDICAL DEVICES within an existing APPLICATION category. However, safety is always an important consideration in justifying that need. Thus, justification for a new medical APPLICATION involving conveyance of a gas or liquid is based on analytical results establishing the need to prevent CONNECTIONS with the other APPLICATION categories. Those safety concerns are based in large part on the SEVERITY of the HARM that can occur with misconnections. Thus, the justification involving changing requirements is based upon RISK ANALYSIS, adverse events, reported complaints, and other relevant safety issues.

Safety requirements are also important for a new SMALL-BORE CONNECTOR. The RISK of misconnection for a proposed new SMALL-BORE CONNECTOR is required to be acceptable. New SMALL-BORE CONNECTORS are designed to be NON-INTERCONNECTABLE between MEDICAL DEVICES or between ACCESSORIES for the different APPLICATION categories. However, since NON-INTERCONNECTABLE characteristics alone cannot

eliminate misconnections, the use of identified HAZARDS and HAZARDOUS SITUATIONS to establish safety-related USABILITY goals is also needed to reduce RISKS for the new SMALL-BORE CONNECTOR to an acceptable level. Thus, OBJECTIVE EVIDENCE is required, demonstrating that acceptability criteria are met and validation is required to assess the acceptability of NON-INTERCONNECTABLE characteristics under clinical or simulated use conditions.

NON-INTERCONNECTABLE CONNECTORS are expected to easily fall apart after a USER attempts to assemble them to prevent the perception that a secure CONNECTION has been made. The very low force of separation of 0,02 N (2 g) was chosen as the lowest haptic detection threshold of secure CONNECTION that can be easily measured. In some cases, the SMALL-BORE CONNECTORS are heavier than 2 g (0,02 N), thus it is practical to set the acceptance criteria for separation forces at the greater of either the SMALL-BORE CONNECTOR under test component weight or 0,02 N. Additional leak testing is proposed, because a leaking CONNECTION that appears to be a secure CONNECTION is considered by the committee an acceptable RISK as administration of the wrong medium would not occur.

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 SMALL-BORE CONNECTOR being evaluated and the other SMALL-BORE CONNECTORS specified in the ISO 80369 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 SMALL-BORE CONNECTOR being evaluated, when attempted to be assembled with the TARGET INTERFERENCE CONNECTOR OR FEATURE under a specified force and torque, does not separate when using the specified minimal force or leaks profusely.

B.2 Dimensional analysis TEST METHOD

B.2.1 General

The purpose of the dimensional analysis TEST METHOD is to evaluate if the surfaces of the SMALL-BORE CONNECTOR under evaluation can have a potential CONTACTABLE SURFACE, and as such, have the potential to interact in a manner that can form a misconnection with the other SMALL-BORE CONNECTORS of the ISO 80369 series.

B.2.2 Requirements

The CONTACTABLE SURFACES of the SMALL-BORE CONNECTOR under evaluation shall not engage with the surfaces of any other SMALL-BORE CONNECTORS of the ISO 80369 series 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 CONTACTABLE SURFACE diameters and features

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

Identify the diameters and features on the SMALL-BORE CONNECTORS of the ISO 80369 series that have the potential to be a CONTACTABLE SURFACE. Such critical diameters, threads, and ribs shall include, but need not be limited to, the LMC, MMC and NOMINAL material condition of the diameters and of features.

Supplementary features can assist (or can help lead) misconnection 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.

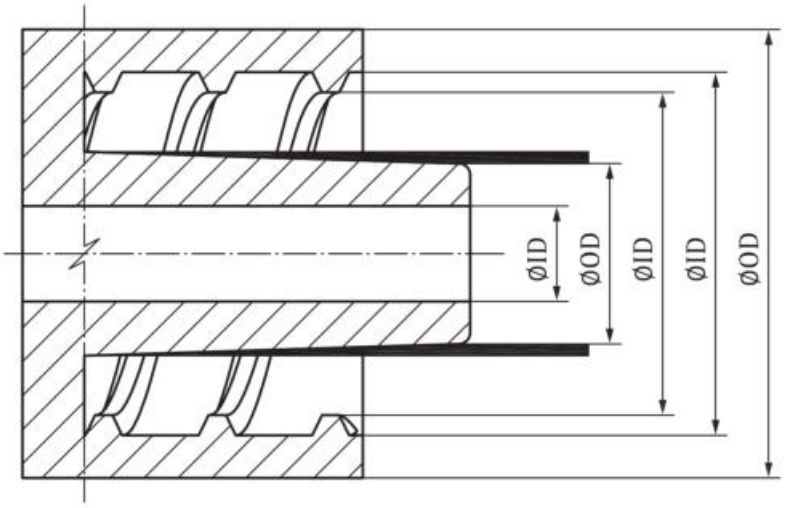
An example of a typical fixed collar male CONNECTOR'S diameters to be evaluated is shown in Figure B.1. Features that shall be evaluated include, but not limited to:

— 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.

— the minor and major thread diameters;

— the fluid pathway ID.



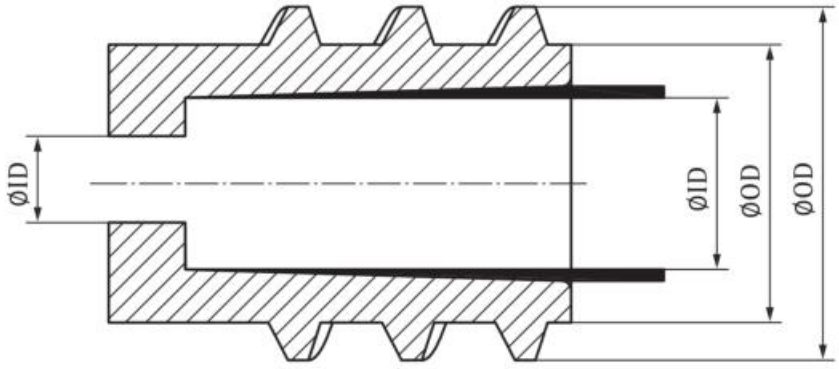
Key

ID inside diameter of the feature

OD 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).



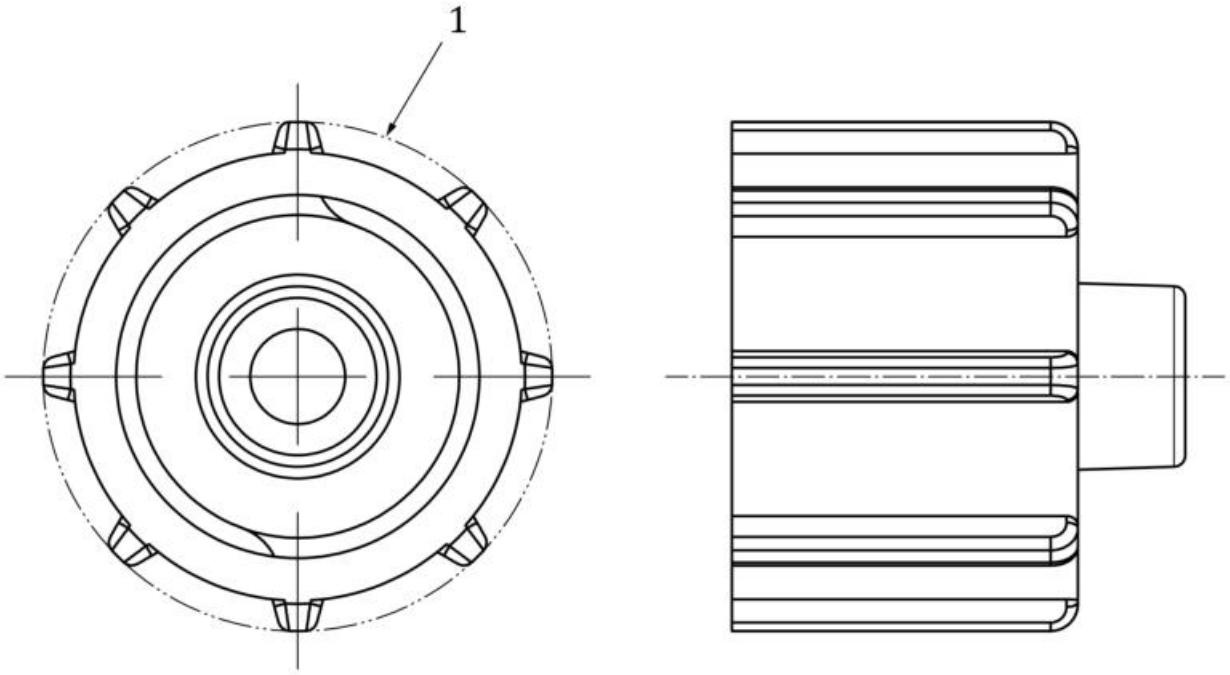
Key

ID inside diameter of the feature

OD 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.

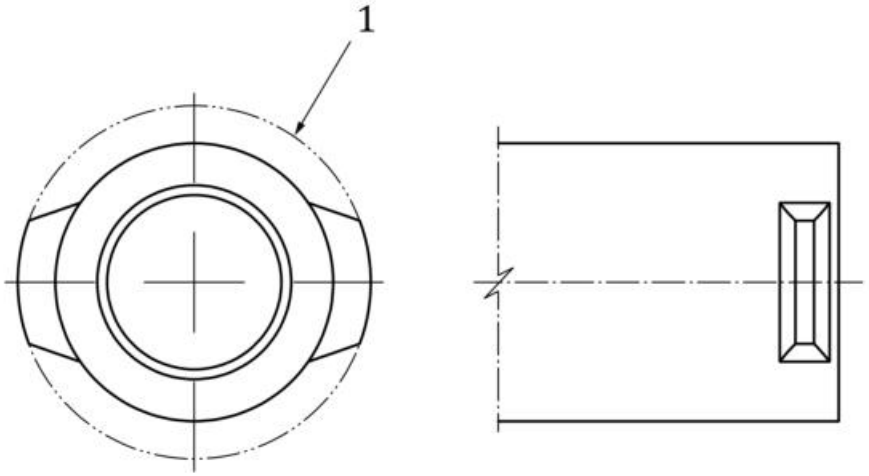


Key

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. They are

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.

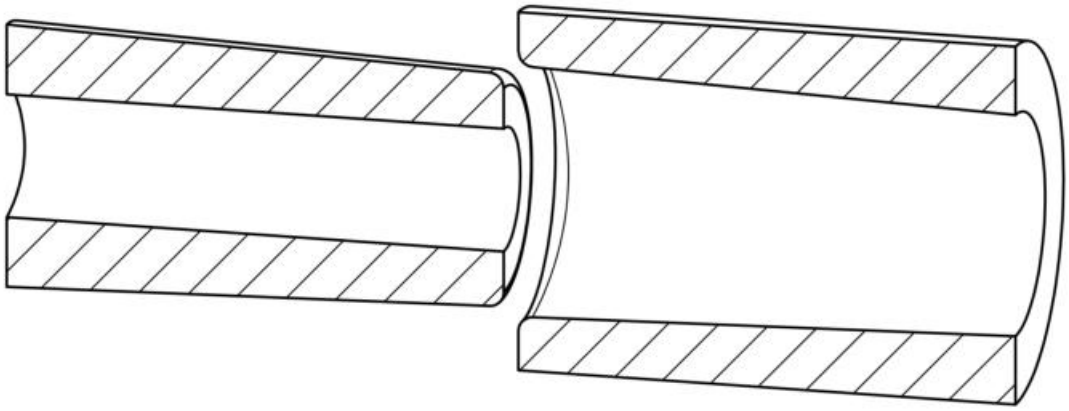


Figure B.5 — Example of a typical cylinder-to-cylinder interface to be evaluated

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

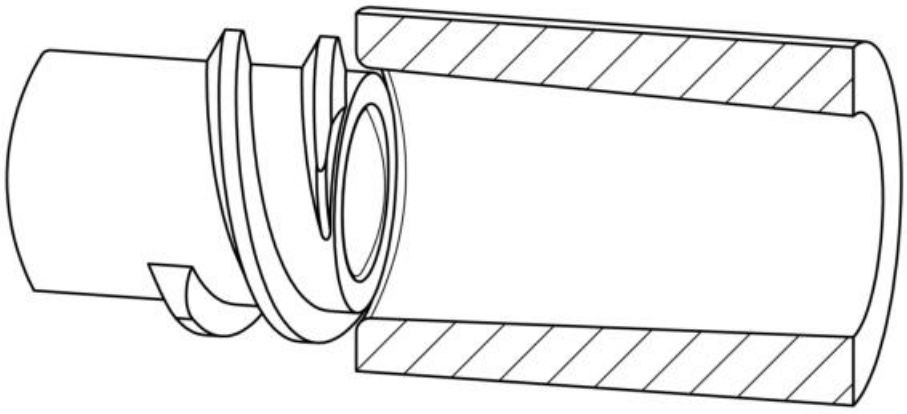


Figure B.6 — Example of a typical cylinder to full thread interface to be evaluated

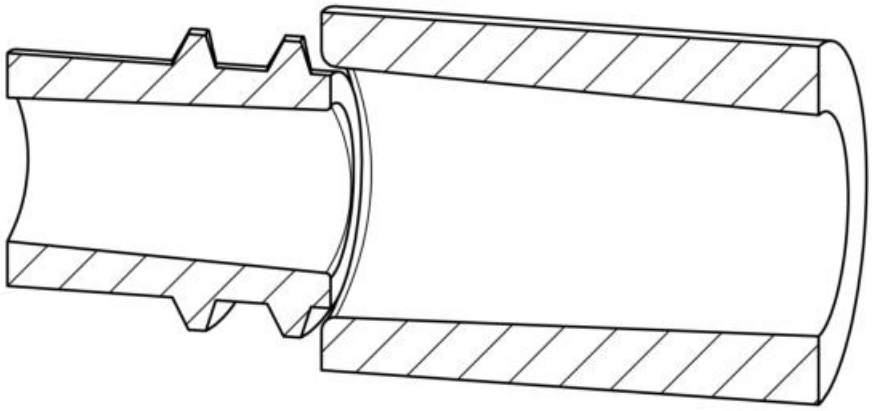


Figure B.7 — Example of a typical cylinder to full thread interface to be evaluated (cross-section view)

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 CONTACTABLE SURFACE with another CONNECTOR'S ID.

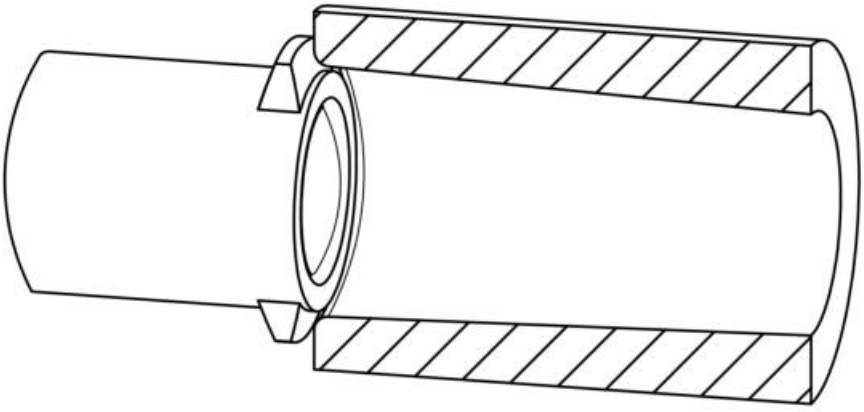


Figure B.8 — Example of a typical cylinder to external lug interface to be evaluated

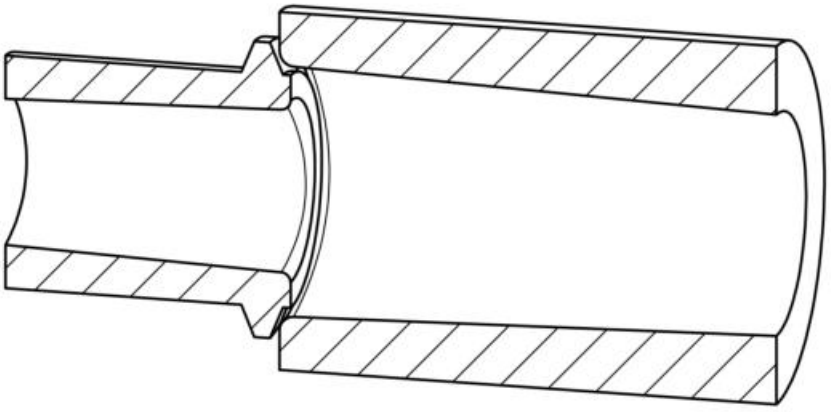


Figure B.9 — Example of a typical cylinder to external lug interface to be evaluated (cross-section view)

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 CONTACTABLE 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 CONTACTABLE 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.

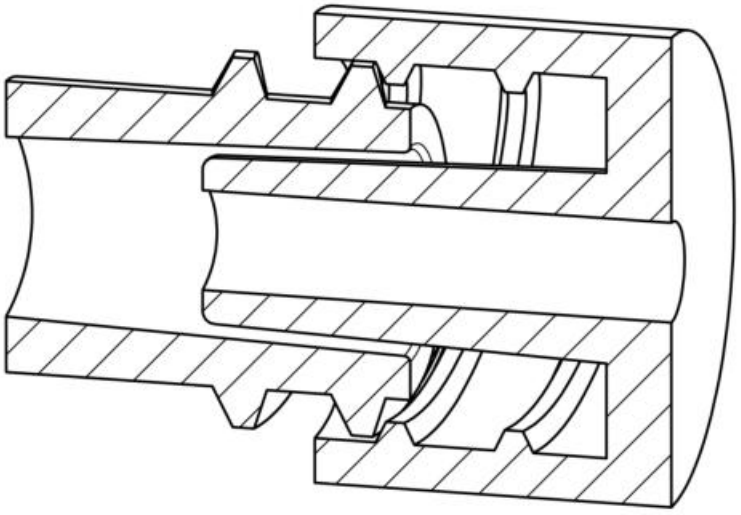


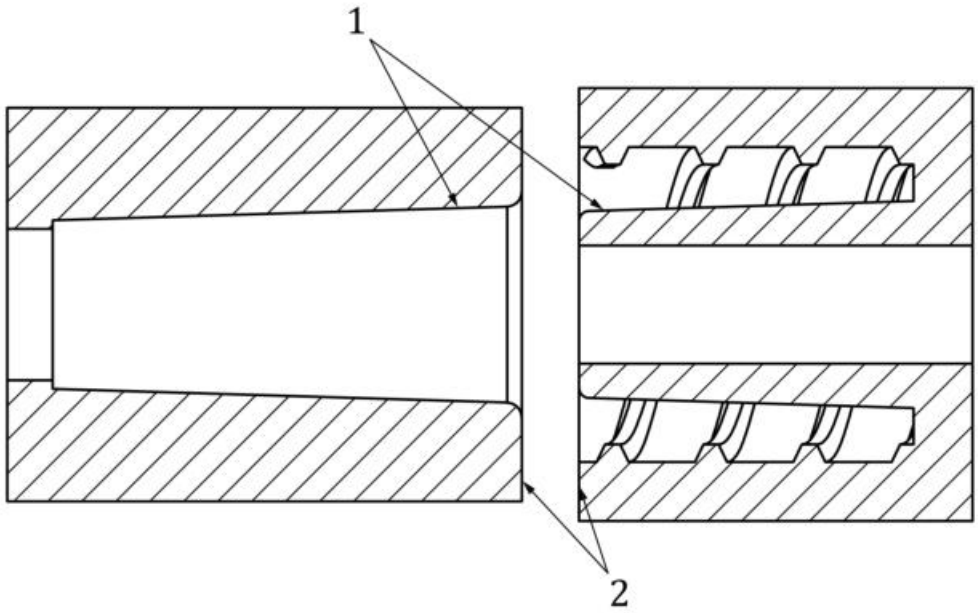
Figure B.10 — Example of a typical thread-to-thread interface to be evaluated (cross-section view)

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 misconnecting.

Figure B.11 shows two CONNECTORS that are evaluated in the analysis. Figure B.11 key item 1 identifies the potential CONTACTABLE SURFACES. However, a feature or geometry inhibits the CONNECTORS from misconnecting. In this case, key item 2 indicates that feature or geometry.

A two-dimensional or three-dimensional 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 contactable surface

2 misconnection prevention feature

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.

$$A = ID_{\min} - OD_{\max} \tag{B.1}$$

$$B = ID_{\max} - OD_{\min} \tag{B.2}$$

where

$ID_{\min}$ is the minimum inside diameter at MMC;

$ID_{\max}$ is the maximum inside diameter at LMC;

$OD_{\min}$ is the minimum outside diameter at LMC;

$OD_{\max}$ is the maximum outside diameter at MMC.

NOTE Be sure to include the entire diametrical range of the surface. 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 both formulae 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.

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 absolute 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) testing is then required to determine if a misconnection is possible.

Table B.1 — Dimensional analysis from the equation results

Result of relationship *A*	Result of relationship *B*	Outcome
Positive value	Positive value	For values less than 0,05 mm, misconnection possible, perform physical test methods. For values greater than 0,05 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* absolute value 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 SMALL-BORE CONNECTOR under evaluation shall disengage from the TARGET INTERFERENCE CONNECTOR OR FEATURE under its own weight or 0,02 N, whichever is greater, when tested according the mechanical TEST METHOD in B.3.5 or the misconnection is classified as an unintended CONNECTION.

The SMALL-BORE 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 SMALL-BORE CONNECTOR under evaluation

The SMALL-BORE CONNECTOR under evaluation shall be made:

a) of a material with a modulus of elasticity in tensile or flexure no more than 100 MPa greater than the minimum modulus as specified for the SMALL-BORE CONNECTOR, and

b) to (as far as it is practicable) dimensions within, but biased to the worst case extents of, the tolerance range of the SMALL-BORE CONNECTOR .

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 SMALL BORE CONNECTOR 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 shall 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.

   EXAMPLE Such features can include outside diameters, inside diameters, threads, ribs, flanges, etc. 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 SMALL-BORE 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

Utilize the following apparatus.

B.3.5.1.1 **SMALL-BORE CONNECTOR** under evaluation.

B.3.5.1.2 **TARGET INTERFERENCE CONNECTOR OR FEATURE**.

B.3.5.1.3 **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 SMALL-BORE 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

Check compliance with the following.

a) Attempt to assemble the SMALL-BORE CONNECTOR under evaluation (B.3.5.1.1) to the TARGET INTERFERENCE CONNECTOR OR FEATURE (B.3.5.1.2) 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 1 The maximum torque might not be achieved due to the lubricious nature or geometry of the CONNECTORS in the test.

NOTE 2 This assembly force of 70 N is intended to simulate the haptic force applied by a typical USER and represents the fiftieth percentile force of NOMINAL human adult[21].

The assembly method may need to be revised depending on design of the SMALL-BORE CONNECTOR under evaluation (i.e. the presence of features to prevent rotation, floating or rotatable collars, latching mechanisms, etc.) 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 SMALL-BORE CONNECTOR under evaluation below, confirm that the assembled SMALL-BORE CONNECTOR disengages from the simulated mating CONNECTOR under its own mass.

e) If the SMALL-BORE CONNECTOR under evaluation does not disengage and the mass of the SMALL-BORE 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 SMALL-BORE CONNECTOR under evaluation disengages from the TARGET INTERFERENCE CONNECTOR OR FEATURE.

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

g) If applicable (i.e. for a threaded SMALL-BORE 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

Utilize the following apparatus.

B.3.6.1.1 SMALL-BORE CONNECTOR under evaluation.

B.3.6.1.2 Appropriate TARGET INTERFERENCE CONNECTOR OR FEATURE, with provision for attachment of the pressure source.

B.3.6.1.3 Means to simultaneously apply an axial force of 70 N and a torque of 0,12 N·m.

B.3.6.1.4 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 SMALL-BORE 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 SMALL-BORE 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.

B.3.6.1.5 Syringe, with a minimum volume capacity of 10 ml.

EXAMPLE A syringe complying with ISO 7886-1.

B.3.6.1.6 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.

B.3.6.1.7 Pinch clamp sized for the tubing.

B.3.6.1.8 Weigh pan.

B.3.6.1.9 Gram scale.

B.3.6.2 Test sample preconditioning

Prior to testing, precondition the SMALL-BORE 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

Check for compliance with the following test.

a) Assemble the SMALL-BORE CONNECTOR (B.3.6.1.1) to the TARGET INTERFERENCE CONNECTOR OR FEATURE (B.3.6.1.2) 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 SMALL-BORE CONNECTOR under evaluation (i.e. the presence of features to prevent rotation, floating or rotatable collars, latching mechanisms, etc.) 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 SMALL-BORE 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 SMALL-BORE CONNECTOR under evaluation and TARGET INTERFERENCE CONNECTOR OR FEATURE and the outlet of the orifice/tubing (B.3.6.1.6) on a level plane.

e) Prime the SMALL-BORE CONNECTOR under evaluation, TARGET INTERFERENCE CONNECTOR OR FEATURE, tubing and the simulated orifice with water (B.3.6.1.4) 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 (B.3.6.1.5) on the scale (B.3.6.1.9) and zero the scale by pressing the tare button.

g) Fill the syringe with water.

h) Weigh the filled syringe on the scale 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 (B.3.6.1.7).

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 (B.3.6.1.8) onto the scale 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):

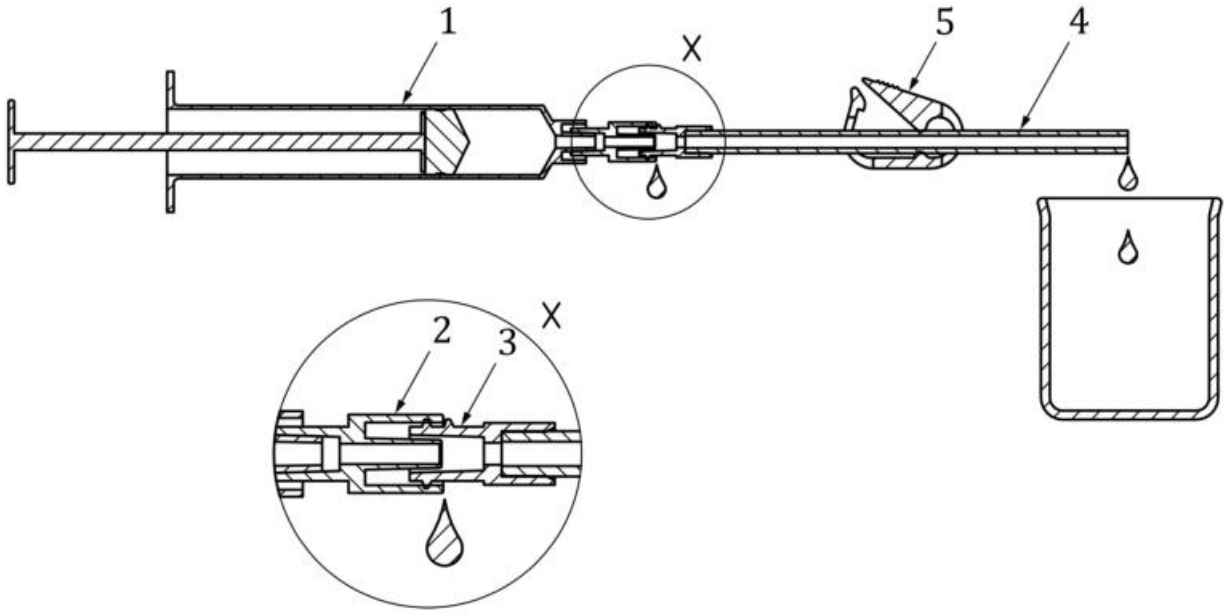
$$L_w = \frac{m_1 - m_2}{m_1} \times 100 \quad \text{(B.3)}$$

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 SMALL-BORE CONNECTOR under evaluation
4 tubing
5 pinch clamp

Figure B.12 — Leak TEST METHOD set up

Annex C
(informative)

Symbols and safety signs

The symbol or mandatory action safety sign of Table C.1 is required by this document. In Table C.1, the graphic and title are provided for information.

Table C.1 — Safety sign

No.	Symbol or safety sign	Reference	Title
1		ISO 15223-1:2016, 5.4.3 ISO 7000-1641	Consult instruction for use
2		ISO 7010-M002	Refer to instruction manual/ booklet

Annex D
(normative)

Assessment PROCEDURES SMALL-BORE CONNECTORS

D.1 General

D.1.1 Request to include a new design

Working groups or individuals, including MANUFACTURERS, wishing to include a new design of a SMALL-BORE CONNECTOR into this family of International Standards, should make this request to ISO/TC 210 according to the PROCEDURE set out in this annex.

D.1.2 Intellectual Property Rights

Those submitting a design are responsible for identifying any patent rights covering the design and for informing ISO/TC 210 accordingly. In case such patents rights are identified, the owners shall formally agree to comply with the Common Patent Policy for ITU-T/ITU-R/ISO/IEC.

D.2 * Design proposal

Groups or individuals submitting a new SMALL-BORE CONNECTOR design shall submit to ISO/TC 210 a concept proposal identifying the targeted application.

The design proposal shall include:

a) a justification for the proposal that includes a description of any CONNECTIONS of concern, which need to become NON-INTERCONNECTABLE, literature reviews, adverse event information and/or complaint analysis;

b) design requirements that include USER PROFILES, according to IEC 62366-1, USE ENVIRONMENTS, functional requirements suitable to maintain clinical performance necessary to achieve freedom from unacceptable RISK, requirements suitable to maintain NON-INTERCONNECTABLE characteristics, RISK ANALYSIS and results, according to ISO 14971, if any, from previous similar designs;

c) design specifications, including a USER INTERFACE SPECIFICATION, according to IEC 62366-1, which satisfy all aspects of design requirements; it shall include OBJECTIVE EVIDENCE that RISKS have been reduced to acceptable levels, according to ISO 14971, for the acceptability criteria specified in Annex B;

d) consideration given to misuse, ageing and the effects of cleaning and disinfection or cleaning and sterilization;

e) a completed summary of SMALL-BORE CONNECTOR criteria and requirements for the proposed SMALL-BORE CONNECTOR design.

D.3 Engineering analysis

D.3.1 Design

The submitter shall conduct an engineering analysis of the design of the proposed SMALL-BORE CONNECTOR against the design details in the ISO 80369 series for NON-INTERCONNECTABLE

characteristics. The submitter shall conduct an engineering analysis of the design of the SMALL-BORE CONNECTOR to ensure that the design meets the necessary performance requirements. These evaluations can include, but are not limited to, minimum and maximum tolerance stack up assessments that compare the proposed design with other existing or proposed designs of SMALL-BORE CONNECTORS in the ISO 80369 series. Computer-assisted design (CAD) drawing evaluations or other appropriate design feasibility assessment tools may be utilized.

D.3.2 Design realization

The submitter shall produce test samples and carry out testing, as described in D.3.3 and D.3.4, to demonstrate that design requirements and design specifications are met.

D.3.3 Design VERIFICATION

The submitter shall verify the design as follows.

a) Design review and VERIFICATION testing shall be performed.

b) The submitter shall conduct dimensional analyses, physical testing and MEDICAL DEVICE category-specific performance testing on sample sizes sufficient to allow statistical analysis of test results. The tests shall demonstrate that the design meets the specifications and NON-INTERCONNECTABLE characteristics with the other SMALL-BORE CONNECTORS in this series, and that physical performance properties and MEDICAL DEVICE performance requirements are met. The design VERIFICATION shall include OBJECTIVE EVIDENCE that RISKS have been reduced to acceptable levels, according to ISO 14971, for the acceptability criteria specified in Annex B and other acceptability criteria established for NON-INTERCONNECTABLE characteristics.

c) Evidence of design acceptance by clinical USERS of a potential target MEDICAL DEVICE shall be confirmed.

d) VERIFICATION reports summarizing the above testing shall be prepared and submitted. These reports shall include VERIFICATION results for each identified design requirement and each element of the design specification.

D.3.4 Design validation

After design VERIFICATION, the submitter shall conduct a design validation assessment. This validation shall assess the acceptability of production quality of the SMALL-BORE CONNECTOR in the intended APPLICATION and MEDICAL DEVICE with a population of intended USERS in the clinical or simulated environment. The validation shall assess the NON-INTERCONNECTABLE characteristics of the SMALL-BORE CONNECTORS with the SMALL-BORE CONNECTORS of the other APPLICATIONS as specified in Clause 5. Conclusions shall be statistically based and demonstrate that performance objectives have been met.

The design validation shall include a SUMMATIVE EVALUATION of HAZARD-RELATED USE SCENARIOS related to the intended CONNECTIONS according to IEC 62366-1.

D.4 Design review

ISO/TC 210 will review the submitted design and decide on the suitability of the proposed SMALL-BORE CONNECTOR for inclusion in the ISO 80369 series for the intended APPLICATION.

A summary of the data and reports (see D.3) shall be prepared as an informative annex to be included as a rationale in the preparation of the subsequent standard.

Annex E
(informative)

APPLICATIONS of SMALL-BORE CONNECTORS

Table E.1 summarizes the categories of APPLICATION of SMALL-BORE CONNECTORS.

Table E.1 — APPLICATIONS of SMALL-BORE CONNECTORS

APPLICATION category	Specific use	Examples of MEDICAL DEVICES	SMALL BORE CONNECTOR specification
Limb cuff inflation	CONNECTIONS for inflation of sphygmomanometer cuffs	tubing CONNECTORS for neonatal sphygmomanometers	IEC 80369-5
		tubing CONNECTORS for 1-hose paediatric/ adult sphygmomanometers	IEC 80369-5
		tubing CONNECTORS for 2-hose paediatric/ adult sphygmomanometers	IEC 80369-5
	CONNECTIONS for inflation of tourniquets	tubing connectors for tourniquets	IEC 80369-5

Table E.1 *(continued)*

APPLICATION category	Specific use	Examples of MEDICAL DEVICES	SMALL BORE CONNECTOR specification
Enteral	CONNECTIONS for access to the stomach or intestine.	enteral feeding sets (nutrition) gravity plus pumped feed connecting sets medication ports (Y-ports, T-sets) enteral tubes nasal, gastric, duodenal, jejunal percutaneous endoscopic gastrostomy (PEG) and percutaneous endoscopic jejunostomy (PEJ) syringes for feeding and enteral medication administration	ISO 80369-3
Neuraxial	CONNECTIONS for access to nerves or the nervous system	epi(peri)dural and intrathecal (spinal) needles, catheters and administration sets caudal needles (adult and paediatric) introducer needles, drawing up needles, other needles (e.g. other nerve blocks) epidural/spinal catheters inline filters syringes (2 ml to 100 ml) neuraxial extension sets neuraxial infusion pump sets loss of resistance syringes continuous nerve block	ISO 80369-6
Intravascular or hypodermic	CONNECTIONS for access to arterial and venous vascular systems CONNECTIONS for subcutaneous, intramuscular and intraperitoneal injections and infiltrations MEDICAL DEVICES intended to connect to syringes	venous access port central venous catheter arterial pressure lines diagnostic catheter extracorporeal devices syringes hypodermic needles peripheral intravenous catheters intravenous administration sets	ISO 80369-7

Annex F
(informative)

Reference to the Essential Principles

This document has been prepared to support the essential principles of safety and performance of SMALL-BORE CONNECTORS as components of MEDICAL DEVICES as listed in ISO 16142-1:2016, Table B.1 and Table B.2. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO 16142-1. Other means are possible. Table F.1 shows the correspondence between the clauses and subclauses of this document and the essential principles of safety and performance of MEDICAL DEVICES as listed in ISO 16142-1:2016, Annex B.

Table F.1 — Correspondence between this document and the essential principles

Essential principles listed in ISO 16142-1:2016, Annex B	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
12.1	Clause 4, Clause 5, Clause 6, Clause 7	Only the part relating to design is addressed.
17.4	Clause 4, Clause 5, Clause 6, Clause 7	Only the part relating to design is addressed.
17.5	Clause 4, Clause 5, Clause 6, Clause 7	Only the part relating to design is addressed.

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[1] ISO 178, *Plastics — Determination of flexural properties*

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

[3] ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

[4] ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

[5] ISO 7010:2011, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

[6] ISO 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

[7] ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

[8] ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

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

[10] IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

[11] EN 13544-2:2002+A1:2009, *Respiratory therapy equipment. Tubing and connectors*

[12] CEN/CR 13825, *Luer connectors — A report to CEN CHeF from the CEN forum task group "Luer fittings"*

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[14] ASTM D790-17, *Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

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ICS 11.040.20; 11.040.10

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