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**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 —*

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*Partie 1: Exigences générales*  
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ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Fax: +41 22 749 09 47  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

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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](http://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](http://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](http://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](http://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<sup>[12]</sup>, 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<sup>[10]</sup>. 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 80369-1:2018(E)

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.

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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] <https://standards.iteh.ai/catalog/standards/sist/6a693f73-91c8-4b37-b717-d9bd2bffc82/iso-80369-1-2018>

**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”.

## ISO 80369-1:2018(E)

[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 D 638-14 [13], ISO 527, ASTM D 790-17 [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](#).

## ISO 80369-1:2018(E)

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](#).

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