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2024-09

Small-bore connectors for liquids and gases in healthcare applications

Part 2: Connectors for respiratory applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé — Partie 2: Raccords destinés à des applications respiratoires

Partie 2: Raccords destinés à des applications respiratoires

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Foreword

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

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

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.htmlwww.iso.org/members.html.

This corrected version of ISO 80369-2:2024 incorporates the following corrections:

— In Tables B.1 to B.5, commas have been added in the values.

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Introduction

The *small-bore connectors* specified in this document conform with the requirements for *non-interconnectable* characteristics of ISO 80369-1.

This document includes design and performance requirements for *small-bore connectors* for the respiratory *application*.

It is recognised that the *small-bore connectors* specified in this document might not be suitable for some *medical devices* or *accessories* within this *application*.

Annex AAnnex A contains guidance or rationale on the requirements in this document.

This document has been prepared to support the essential principles for *medical device* or *accessories* incorporating respiratory *application small-bore connectors* according to the International Medical Device Regulators Forum (IMDRF). See Annex H.See Annex H.

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

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or capability; and

— "must" is used to express an external constraint.

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

Small-bore connectors for liquids and gases in healthcare applications

Part 2: Connectors for respiratory applications

1 Scope

This document specifies the design and dimensions for two *small-bore connectors* intended to be used for *connections* in respiratory *applications* of *medical devices* and *accessories*. One *connector* (R1) is intended for use on *medical devices* and *accessories* subjected to pressures up to 15 kPa (e.g. a *breathing system*). The other *connector* (R2) is intended for use on *medical devices* and *accessories* subjected to higher pressures between 15 kPa and 600 kPa (e.g. oxygen therapy tubing).

NOTE 1 The pressure is related to pressure available at the source to which the *medical device* is connected.

NOTE 2 The intended *application* does not preclude the use of other *connectors* on *medical devices* or *accessories* within this *application*.

NOTE 3 Requirements for alternative connectors for this intended application are specified in ISO 80369-1.

This document does not specify requirements for the *medical devices* or *accessories* that use these *connectors*. Such requirements are given in device-specific standards.

NOTE 4 If a device-specific standard does not exist, the performance and material requirements specified in ISO 80369-1 can be used as guidance.

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.

~~<std>ISO 178, *Plastics — Determination of flexural properties*</std>~~

~~<std>ISO 527 (all parts), *Determination of tensile properties*</std>~~

~~<std>ISO 6892-1:2019, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*</std>~~

~~<std>ISO 14971:2019, *Medical devices — Application of risk management to medical devices*</std>~~

~~<std>ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*</std>~~

~~<std>~~ISO 178, *Plastics — Determination of flexural properties*

ISO 527 (all parts), *Determination of tensile properties*

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

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications</std>

<std>ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*</std>

<std>ASTM D638-22, *Standard Test Method for Tensile Properties of Plastics*</std>

<std>ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-22, *Standard Test Method for Tensile Properties of Plastics*

ASTM D790-17, Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials</std>

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971, ISO 80369-1, ISO 80369-7, ISO 80369-20 and the following apply.

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

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

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

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

3.1
auxiliary dimension
dimensions derived from other dimensions given for information purposes only

[SOURCE: ISO 10209:2022, 3.3.2]

3.2
breathing system
pathways through which gas flows to or from the *patient* at *respiratory pressures* and continuously or intermittently in fluid communication with the *patient's* respiratory tract during any form of artificial ventilation or respiratory therapy

[SOURCE: ISO 4135:2022, 3.6.1.1, modified — Notes 1 to 5 to entry have been removed.]

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3.3
cone
<*connector*> with external sealing surface

Note 1 to entry: The sealing surface need not be conical.

Note 2 to entry: This type of *connector* was previously referred to as male.

3.4
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2016, 3.36]

3.5
normal use
operation, including routine inspection and adjustments by any *user*, and stand-by, according to the instructions for use

Note 1 to entry: *Normal use* should not be confused with *intended use*. While both include the concept of use as intended by the *manufacturer*, *intended use* focuses on the medical purpose while *normal use* incorporates not only the medical purpose, but maintenance, service, transport, etc. as well

[SOURCE: IEC 60601-1:2005, 3.71, modified — replaced '*operator*' with '*user*'.]

3.6
socket
<*connector*> with internal sealing surface

Note 1 to entry: This type of *connector* was previously referred to as female.

3.7
user
person interacting with (i.e. operating or handling) the *medical device*

Note 1 to entry: There can be more than one *user* of a *medical device*.

Note 2 to entry: Common *users* include clinicians, *patients*, cleaners, maintenance and service personnel.

[SOURCE: IEC 62366-1:2015, 3.24]

4 Non-interconnectability requirements

Small-bore connectors made in conformance with this document conform with the requirements of ISO 80369-1.

NOTE 1 The reference *connectors* for evaluation of the *non-interconnectable* characteristics are described in ~~Annex C.~~Annex C.

NOTE 2 The summary of *medical devices* and their attributes with *connections* within this *application* is provided in informative ~~Annex D.~~Annex D.

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NOTE 3 The summary of the usability requirements for *connectors* for this *application* is provided in informative Annex E.

NOTE 4 The summary of criteria and requirements for *connectors* for this *application* is provided in informative Annex F.

NOTE 5 The summary of assessment of the design of *connectors* for this *application* according to ISO 80369-1:2018, 6.1, is contained in informative Annex G.

NOTE 6 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[8].

5 Material requirements

NOTE There is rationale for the option to apply either the ISO or the ASTM standards to confirm the modulus of elasticity contained in Annex A.

a) R1 and R2 *small-bore connectors* shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 700 MPa.

b) Surfaces, other than those necessary to ensure *non-interconnectable* characteristics, need not comply with the modulus of elasticity requirement.

Check conformity by applying the tests of ASTM D638-22, the ISO 527 series, ASTM D790-17 or ISO 178 or for metallic materials, the tests of ISO 6892-1.

6 Dimensions and tolerances

6.1 R1 *small-bore connectors*

Small-bore connectors intended for use on respiratory *medical devices* and *accessories* at pressures less than 150 hPa (15 kPa) above ambient shall conform with the dimensions and tolerances as given in

a) Figure B.1 and Table B.1 for a R1 *cone connector*, and

b) Figure B.2 and Table B.2 for a R1 *socket connector*.

Check conformity by confirming the relevant dimensions and tolerances specified in Annex B.

6.2 R2 *small-bore connectors*

Small-bore connectors intended to be used on respiratory *medical devices* and *accessories* at pressures between 15 kPa and 600 kPa above ambient shall conform with the dimensions and tolerances given in

a) Figure B.3 and Table B.3 for a R2 *cone connector*, and

b) Figure B.4 and Table B.4 for a R2 *socket connector*.

Check conformity by confirming the relevant dimensions and tolerances specified in Annex B.

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7 Performance requirements

7.1 Leakage by pressure decay

NOTE Annex AAnnex A contains guidance or rationale for this subclause.

a) a) R1 and R2 *small-bore connectors* shall be evaluated for fluid leakage using the leakage by pressure decay *test method*.

b) b) When tested over a hold period between 30 s and 35 s using air as the medium,

1) 1) a R1 *small-bore connector* shall not exceed a leakage rate of 0,000 25 Pa·m³/s while being subjected to an applied pressure of between 12,5 kPa and 15,0 kPa, and

2) 2) a R2 *small-bore connector* shall not exceed 0,005 Pa·m³/s while being subjected to an applied pressure of between 600 kPa and 640 kPa.

Check conformity by applying the tests of ISO 80369--20:2015, Annex B, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.3, C.8,Annex C (Figures C.1, C.3, C.8, and C.10,C.10, as appropriate). A greater applied pressure or a longer hold period may be used.

7.2 Sub-atmospheric pressure air leakage

a) a) A R1 *connector* shall not exceed a leakage flowrate of 0,000 05 Pa·m³/s while being subjected to an applied sub atmospheric pressure of between 3,0 kPa and 5,0 kPa over a hold period of between 25 s and 35 s.

b) b) A R2 *connector* shall not exceed a leakage flowrate of 0,005 Pa·m³/s while being subjected to an applied sub atmospheric pressure of between 35,0 kPa and 45,0 kPa over a hold period of between 20 s and 30 s.

Check conformity by applying the tests of ISO 80369--20:2015, Annex D, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.3, C.8,Annex C (Figures C.1, C.3, C.8, and C.10,C.10, as appropriate). A greater applied sub-atmospheric pressure may be used.

7.3 Stress cracking

R1 and R2 *small-bore connectors* shall meet the requirements of 7.17.1 and 7.27.2 after being subjected to the stresses specified in ISO 80369--20:2015, Annex E.

Check conformity by applying the tests of ISO 80369--20:2015, Annex E, while using the stress cracking reference *connector* specified in Annex C (Figures C.1, C.3, C.8,Annex C (Figures C.1, C.3, C.8, and C.10,C.10, as appropriate).

7.4 Resistance to separation from axial load

R1 and R2 *small-bore connectors* shall not separate from the reference *connector* over a hold period between 10 s and 15 s while being subjected to a disconnection applied axial force between 32 N and 35 N.

Check conformity by applying the tests of ISO 80369--20:2015, Annex F, while using the separation from axial load reference *connector* specified in Annex C (Figures C.2, C.4, C.9,Annex C (Figures C.2, C.4, C.9, and C.11,C.11, as appropriate). A greater disconnection applied axial force or a longer hold period may be used.

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7.5 Resistance to separation from unscrewing

R1 and R2 *connectors* shall not separate from the reference *connector* for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,018 N·m to 0,020 N·m.

Check conformity by applying the tests of ISO 80369-20:2015, Annex G, while using the separation from unscrewing reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate). A greater applied unscrewing torque or a longer hold period may be used.

7.6 Resistance to overriding

R1 and R2 *small-bore connectors* shall not override the threads or lugs of the reference *connector* while being subjected to an applied torque of

a) between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s for a R1 *connector*, and

b) between 0,22 N·m to 0,25 N·m over a hold period between 5 s and 10 s for a R2 *connector*.

Check conformity by applying the tests of ISO 80369-20:2015, Annex H, while using the resistance to overriding reference *connector* specified in Annex C (Figures C.2, C.4, C.9, and C.11, as appropriate). A greater applied torque or a longer hold period may be used.

7.7 Disconnection by unscrewing

R1 and R2 *small-bore connectors* shall separate from the reference *connector* with an applied unscrewing torque of no greater than 0,35 N·m.

Check conformity by applying the tests of ISO 80369-20:2015, Annex I, while using the disconnection by unscrewing the reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate).

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Annex A
(informative)

Rationale and guidance

A.1 General guidance

This Annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document, but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

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

~~Clause 1~~Clause 1 Scope

In 2000, a Task Group of the European standards organization, CEN, proposed a strategy to reduce incidents of accidental misconnection of *patient* therapy lines by the use of a series of *non-interconnectable connectors*, differentiated by design, for use in different medical *applications*. The strategy reserves the use of *Luer connectors* solely for use in *medical devices* used to access the vascular system or for hypodermic syringes so that they can achieve their intended function.~~[7]~~ [7] The *connectors* specified in this document are intended to be used on respiratory *medical devices*.

Manufacturers and *responsible organizations* are encouraged to report their experience with the *small-bore connectors* specified in this document to their national standards body (see the last paragraph of the Foreword), so that it can consider this feedback during the revision of the relevant part of the ISO 80369 series.

~~Subclause 6.1~~Subclause 6.1 Leakage by pressure decay

The test pressures chosen are the worst-case pressures that can be generated under a *single fault condition* for a *breathing system* for the R1 *connector* and for a *medical gas pipeline system* for the R2 *connector*.

~~Clause 5~~Clause 5 Material requirements

It was determined although several fundamental differences exist between ASTM D 638 Standard Test Method of Tensile Properties of Plastics and ISO 527 Plastics - Determination of Tensile Properties, the actual test results can be quite similar. Test data for both test methods have been gathered by an interlaboratory testing provider and the summary statistics of the two groups were compared. The thermoplastic resins tested in this study included polycarbonate (PC), polybutylene terephthalate (PBT), acrylonitrilebutadiene-styrene (ABS) and high impact polystyrene (HIPS). All resins were unfilled, unreinforced, and uncoloured. The following properties were analysed: Tensile Stress at Yield, Tensile Stress at Break, Elongation at Yield, and Modulus of Elasticity. After removing outliers, the data from the remaining labs were analysed. The strength of agreement between ISO data and ASTM data varied depending on the property and material used. There were surprising similarities for modulus of elasticity since different speeds of testing and calculation methods were used.

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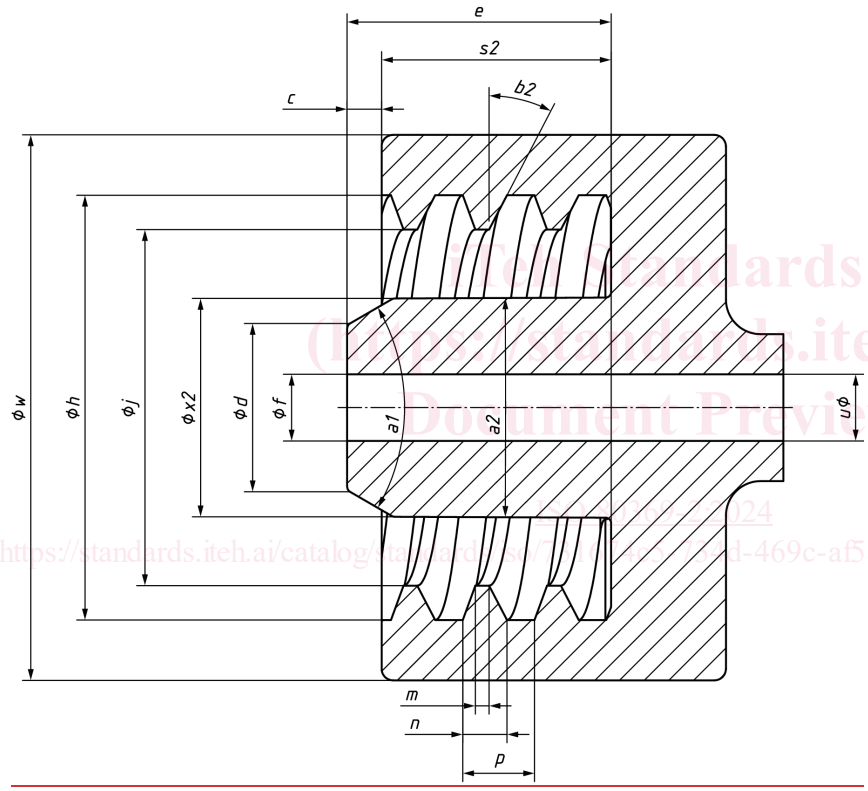
Annex B
(normative)

Small-bore connectors for *respiratory applications*

Table B.1Table B.1 contains the dimensions for Figure B.1.Figure B.1.

80369-2_ed1figB1.EPS



The *cone connector* shows a permanently connected internally threaded lock fitting. A rotatable internally threaded lock fitting may be used.

Figure B.1 — R1 *cone small-bore connector*

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