FINAL DRAFT
International Standard

ISO/FDIS 80369-6

Small bore connectors for liquids and gases in healthcare applications —

Part 6: Connectors for neural applications

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

Partie 6: Raccords pour applications neurales

ISO/TC **210**

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 document 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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 80369-6:2016), which has been technically revised.

The main changes are as follows:

— The materials requirements of Clause 5 were updated to include all applicable parts of the ISO 527 series.

— All performance requirements of the first edition of this document utilized ISO 80369-20:2015. This second edition references ISO 80369-20:2024. To retain the backward compatibility with the first edition of this document, two of the ISO 80369-20:2015 *test methods* were migrated into this document as Annex F and Annex G. Several informative passages related to these methods were similarly migrated into Annex A. Performance requirements 7.1.2 and 7.2 now reference the *test methods* of Annex F and Annex G, respectively. All other performance requirements reference the *test methods* of ISO 80369-20:2024.

— Tolerances of several *connector* dimensions in Annex B were modified. All changes are deemed backwards compatible, except for the pitch "*p*" which is now a dimensional requirement only and radius "*r*2" of Figure B.1, which is now normative. The figures were updated for clarity.

— Annex C reference *connector* figures and dimensions were reviewed and modified to increase tolerances. All reference *connectors* manufactured to the requirements of the first edition of this document also conform to the modified figures of this document. The figures were updated for clarity.

— Annexes E and F of the first edition of this document were removed as the *small-bore connectors* defined in this document have been verified against usability and design requirements.

— Annex G of the first edition of this document and all Clause 4 references to non-interconnectability, including all residual misconnections / misconnection analysis, were moved to ISO 80369-1:—,[1] Annex E.

— Annex H of the first edition of this document was removed as this content is included in ISO 80369-1:—, Annex B.

— Annex J of the first edition of this document is now Annex H.

— Remaining Annexes were renumbered accordingly.

— To ensure inclusive wording, the word “male” was replaced by “cone” and “female” replaced by “socket” throughout the document.

— Compared to the first edition of this document, the word “neuraxial” has been replaced with “neural” throughout the document.

— The bibliography was revised to cite only documents and standards that are referenced informatively in this document.

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

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

Introduction

The *small-bore connectors* specified in this document conform with the *non-interconnectability* requirements of ISO 80369-1:—.

This document includes design and performance requirements for *small-bore connectors* for neural *applications*. Neural *applications* involve the use of *medical devices* intended to administer medications to neural sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.

NOTE 1 Sites for the neural *application* include the spine, intrathecal or subarachnoid space, ventricles of the brain, and the epidural, extradural, or peridural space. Neural *application* anaesthetics can be administered regionally affecting a large part of the body, such as a limb, and include plexus blocks, such as the brachial plexus blocks or single nerve blocks. Neural *application* procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 2 For the purposes of this document, local anaesthesia injected hypodermically is not considered a neural *application*.

EXAMPLES Intended administration includes intrathecal chemotherapy, local anaesthetics, radiological contrast agents, antibiotics, analgesics.

It is possible that the *small-bore connectors* specified in this document are not suitable for some *medical devices* within this application.

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” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

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

Annex A contains guidance and rationale for specific clauses and subclauses in this document.

Small bore connectors for liquids and gases in healthcare applications —

Part 6:
Connectors for neural applications

1 Scope

NOTE Clause A.2 contains guidance or rationale for this clause.

This document specifies requirements for *small-bore connector*s intended to be used for *connection*s in neural *applications*.

This document does not specify requirements for the *medical devices* or *accessories* that use these *connector*s. Such requirements are given in particular standards for specific *medical devices* or *accessories*.

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 178, *Plastics — Determination of flexural properties*

ISO 527-1:2019, *Plastics — Determination of tensile properties — Part 1: General principles*

ISO 527-2:2012, *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics*

ISO 527-5:2021, *Plastics — Determination of tensile properties — Part 5: Test conditions for unidirectional fibre-reinforced plastic composites*

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

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

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

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

ISO 80369-20:2024, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-14, *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*

1) Third edition under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2024. The previous edition is ISO 80369-1:2018.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971:2019, ISO 80369-1:2018, ISO 80369-7:2021, and the following apply.

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

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

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

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

[SOURCE: ISO 10209:2022, 3.3.2]

3.2
lock connector
connector with a locking mechanism

3.3
slip connector
connector without a locking mechanism

4 Non-interconnectability requirements

*Small-bore connector*s of *medical devices* or *accessories* intended for use in neural *applications* made in conformance with this document shall be in accordance with ISO 80369-1:—.

NOTE 1 An assessment of *medical devices* and their attributes with *connection*s within this *application* is given in informative Annex D.

NOTE 2 A summary of the assessment of the design of *connector*s for this *application* is given in ISO 80369-1:—, Annex E.

NOTE 3 This document has been prepared to support the essential principles for medical device or accessories incorporating neural application small-bore *connectors* according to the International Medical Device Regulators Forum (IMDRF). A summary is included in informative Annex E.

5 Materials requirements

NOTE Clause A.2 contains rationale for this requirement.

The design features of neural *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 950 MPa. Design features, other than those necessary to ensure *non-interconnectable* characteristics, may be excluded from this requirement.

Check conformity by applying the tests of ASTM D638-14, ISO 527-1:2019, ISO 527-2:2012, ISO 527-5:2021, ASTM D790-17, ISO 178, or, for metallic materials, the tests of ISO 6892-1.

6 Dimensions and tolerances

Neural *small-bore connector*s shall be in accordance with the dimensions and tolerances given in:

— Figure B.1 and Table B.1 for an N1 cone *slip connector*;

— Figure B.2 and Table B.2 for an N2 cone *lock connector*;

— Figure B.3 and Table B.3 for an N2 cone *lock connector* with rotatable collar;

— Figure B.4 and Table B.4 for an N2 socket *lock connector*;

— Figure B.5 and Table B.5 for an N2 socket *lock connector* with lugs.

Check conformity by confirming the relevant dimensions specified in Annex B, for the appropriate Figure and Table.

7 Performance requirements

7.1 Positive pressure leakage

7.1.1 General

Neural *small-bore connector*s shall be evaluated for leakage using either the leakage by pressure decay *test method* or the positive pressure liquid leakage *test method*.

7.1.2 Leakage by pressure decay

Neural *small-bore connector*s evaluated for fluid leakage performance with the leakage by pressure decay *test method* shall not exceed a leakage rate of 0,005 Pa·m^3/s while being subjected to an applied pressure of between 300 kPa and 330 kPa over a hold period between 15 s and 20 s using air as the medium.

Check conformance by applying the tests of Annex F, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.2 and C.4, as appropriate). A greater applied pressure may be used.

7.1.3 Falling drop positive pressure liquid leakage

Neural *small-bore connector*s evaluated for fluid leakage performance with the positive pressure liquid leakage *test method* shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 300 kPa and 330 kPa.

Check conformance by applying the tests of ISO 80369-20:2024, Annex C, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.2 and C.4, as appropriate). A greater applied pressure may be used.

7.2 Sub-atmospheric pressure air leakage

Neural *small-bore connector*s shall not exceed a leakage rate of 0,005 Pa·m^3/s while being subjected to an applied sub-atmospheric pressure of between 80,0 kPa and 88,0 kPa over a hold period of between 15 s and 20 s.

Check conformance by applying the tests of Annex G, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.2 and C.4, as appropriate). A greater applied sub-atmospheric pressure may be used.

7.3 Stress cracking

Neural *small-bore connector*s shall meet the requirements of 7.1 after being subjected to the stresses specified in ISO 80369-20:2024, Annex E.

Check conformance by applying the tests of ISO 80369-20:2024, Annex E, while using the stress cracking reference *connector* specified in Annex C (Figures C.1, C.2 and C.4, as appropriate).

7.4 Resistance to separation from axial load

Neural *small-bore connector*s 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:

a) 23 N and 25 N for a *slip connector*;

b) 32 N and 35 N for a *lock connector*.

Check conformance by applying the tests of ISO 80369-20:2024, Annex F, while using the resistance to separation from axial load reference *connector* specified in Annex C (Figures C.2, C.3 and C.5, as appropriate). A greater disconnection applied axial force or a longer hold period may be used.

7.5 Resistance to separation from unscrewing

Neural *lock 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 conformance by applying the tests of ISO 80369-20:2024, Annex G, while using the resistance to separation from unscrewing reference *connector* specified in Annex C (Figures C.1 and C.4, as appropriate). A greater applied unscrewing torque or a longer hold period may be used.

7.6 Resistance to overriding

Neural *small-bore connector*s shall not override the threads or lugs of the reference *connector* while being subjected to an applied torque of between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s.

Check conformance by applying the tests of ISO 80369-20:2024, Annex H, while using the resistance to overriding reference *connector* specified in Annex C (Figures C.3 and C.5, as appropriate). A greater applied torque or a longer hold period may be used.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This Annex provides 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 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

A.2.1 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 using a series of *non-interconnectable connector*s, differentiated by design, for use in different medical *applications*. The strategy reserves the use of *Luer connector*s solely for use in *medical devices* used to access the vascular system or for hypodermic syringes so that they can achieve their intended function. The *connector*s of this document are reserved for neural *applications*.

*Manufacturer*s and *responsible organizations* are encouraged to report their experience with the *small-bore connector*s specified in this document to the user's national standards body, so that it can consider this feedback during the revision of the relevant part of the ISO and IEC 80369 series. A complete listing of these bodies can be found at www.iso.org/members.html.

A.2.2 Clause 5: Materials requirements

The minimum value of the nominal flexural or tensile modulus of 950 MPa was chosen for neural *applications* predominantly due to current use of polypropylenes for syringe manufacturing. Usability testing, in several cases, demonstrated misconnections with other *small-bore connector*s of the ISO and IEC 80369 series when using low modulus materials. *Manufacturer*s should choose the highest modulus material possible for those parts of their *medical device* forming the *small-bore connector*, with preference to be 1 500 MPa or higher wherever possible.

A.2.3 Annex F: Leakage by pressure decay *test method*

This pressure decay *test method* is identical to the normative Leakage by pressure decay *test method* of the withdrawn ISO 80369-20:2015, Annex B.

A.2.4 Clause F.2: Test conditions

Temperature and humidity preconditioning requirements have been added for hygroscopic materials, as these materials are known to absorb moisture from surrounding gases and liquids, which can alter physical characteristics, dimensions, and performance of *connectors*.

The temperature range specified for testing is identical to that specified in the withdrawn ISO 80369-20:2015.